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Abstract

The aim of this work is to support DG Health and Food Safety with a baseline study on non-harmonised food contact materials (FCMs). The study aimed to analyse the existing regulatory frameworks at national or sectorial level to demonstrate compliance with the general safety requirements for materials not harmonised at EU level. It also examined the perceived barrier to trade and the burden of the current measures in place. Overall the entire sector of FCM suffers to a certain extent from the current situation, which exhibits a lack of harmonisation of materials listed under the framework regulation and is the object of issues in mutual recognition. There are multiple forms of legislation across Member States, but they are disparate for the different sectors. Measures are not always sufficiently detailed, in particular for requirements and quality assurance towards declaration of compliance and supporting documents, certification where applicable, basis for enforcement and sanctions. In the absence of agreed incentives and requirements, Member States can face hurdles in demonstrating the lack of safety and practical difficulties for enforcement and removal of products in their own markets. With regard to good manufacturing practices (GMP), generic guidance from Member States are also seldom very detailed from an implementation standpoint and rarely material specific. The HSFAA and BTSF actions clearly indicated that GMP was an endemic issue in the FCMs sector, although from the industry side, GMP is tackled by professional associations in the form of guidelines. It is however not clear whether these guidelines are used in practice by the members at national and local level all the way down to small and medium-sized enterprises. Further indicators not existing at this stage would be needed. In terms of material-specific aspects, the main hurdles are access to relevant legislation and disparities in both the nature of substances considered, the types of restrictions and the numerical values imposed. These factors constitute an impediment to mutual recognition. Practical implementation and enforcement is impeded by the lack of access to or availability of testing methods to test compliance with legislative limits. The study found a gap in quantitative indicators to evaluate efficiency (including burden and barriers to trade) and food safety in more depth, particularly in regard to effectiveness. This investigation was initiated to support DG Health and Food Safety in conducting an (*ex post*) evaluation and exploring options. The JRC extended the scope of the baseline to make it a base reference for anyone seeking information on requirements and tools on FCMs.

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Executive summary

Materials and articles intended to come in contact with food (food contact materials or FCMs) fall under a framework regulation ⁽¹⁾ that establishes the principles of safety assessment and management regarding the risk of transfer of chemicals from such materials into foods. While some materials are covered by EU-wide specific measures, others remain overseen by national rules and depend on mutual recognition, raising concerns that inconsistencies can impact safety and trade.

For these sectors, the EC-JRC conducted a review at national and sectorial level on measures and guidance related to risk assessment, risk management, controls and self-regulation by the value chain. It also reviewed the supply chains and their market, and examined the perceived barriers to trade and burden of the current situation.

Market and policy context

The market for FCMs represents approximately a EUR 100 billion annual turnover. Plastic, paper and board represent more than half, followed by glass, machinery and metal. Sectors of adhesives, inks, resins, waxes, ceramics, cork, wood, rubbers, silicone and coatings are smaller. Many sectors have a significant portion of SMEs even when their contribution to the turnover is limited.

The materials covered by Union legislation are active and intelligent materials, ceramics, plastics, and regenerated cellulose. The materials covered only by national measures are adhesives, printing inks, coatings, glass, ion exchange resins, waxes, metals, cork, wood, paper and board, silicones, rubber, textiles and combinations of materials.

Key conclusions

Four principal shortcomings to the current situation were identified:

- There is a lack of common guidelines and transparency in undertaking risk assessment (RA) work across Member States (MSs). Protocols for the authorisation of substances can differ between MSs and from that of the European Food Safety Agency (EFSA). The potential of RA tools developed in the EU is not fully exploited.
- National measures can be difficult to access and are not always consistently structured or sufficiently detailed. Specific standards on food safety requirements common to all FCMs and on Good Manufacturing Practice (GMP) are needed. In particular, the declaration of compliance (DoC) and supporting documents need specific quality criteria potentially linked to sanctions for the adequate quality and traceability of the information transfer along the chain.
- Measures are based on lists of authorised substances (with a total of close to 8 000), but show disparities among MSs in the nature of substances considered, the type of restrictions imposed and their numerical values. This leads to multiple testing requirements and further complicates mutual recognition.
- Testing methods are lacking for enforcement and compliance, making it more difficult to demonstrate that food safety is consistently ensured.

The study also found a gap in quantitative indicators on efficiency and effectiveness.

Main findings

The safety of FCMs relies on effective processes and criteria for risk assessment, risk management, enforceability and self-control by manufacturers.

National RA schemes and specific requirements for the authorisation of substances are not the same in all MSs and also often differ from that of EFSA. Their access is also very limited. The MS network created by EFSA to share data needs further follow-up activities comparing national protocols. Tools exist at EU, national or industry levels on hazard

¹ Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, and Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

characterisation or risk/exposure assessment that could be exploited further.

The transfer of safety-related information from one actor to the next in the manufacturing chains of FCMs presents flaws, often in the composition and toxicological characterisation of the substances used.

Measures on general requirements on chemical safety are not present or are different across MSs. In particular, the requirements on the DoC and supporting documents lack guidance and associated quality criteria enforced by sanctions. Requirements on GMP are mostly not material specific and lack practical guidance. Self-regulation on GMP often exists in the form of sectorial guidelines. It is not clear whether these are consistently applied equally by all members (from large enterprises to SMEs).

National measures on specific materials are mainly based on lists of authorised substances and corresponding restrictions. Close to 8 000 substances were found. Some materials are regulated by more than 10 MSs (metal, glass) and some only by a few (wood). National rules for ceramics, glass and metals/alloys cover about 15 heavy metals and ban substances such as barium and mercury. There are between 100 and over 5 000 substances authorised for each category of the other materials. Only 15-35 % of substances considered nationally are in the lists that EFSA reported as being adequately risk assessed.

A low proportion of substances (0.5-5 % for chemicals to 10-18 % for materials) are common to three or more MSs. Differences between Council of Europe (CoE) and MSs' lists suggest a limited transposition of CoE resolutions. For a given substance, the type of restriction (e.g. migration vs compositional limits or quantity in materials) or its numerical value can vary across MSs.

There is a lack of concerted strategies for the monitoring of various FCMs among MSs. This can be perceived as grey area for the systematic assurance of food safety. The level of non-compliance is not greater overall for non-harmonised materials, but it is prevalent for their imports. Enforcement also suffers from lack of standards or test methods.

The presence of multiple diverging rules, which may be difficult to access, have an unclear legal status and exist only in a single language are perceived as an added burden and barrier to trade for the non-harmonised sectors. It leads industries to seek external legal advice, which adds to costs and may result in lengthier authorisation processes and delayed market access. It can also result in a greater focus on certification and accreditation systems at industrial level.

Different requirements or restrictions also increase costs due to multiple (re)testing. The scarcity of analytical standards or methods can require industry to hire commercial laboratories. For official controls, the lack of methods leads to added efforts on development and validation for enforcement. The sectors increasingly tend to seek global food contact compliance in non-EU legislation to overcome the lack of coherent rules at EU level. The overall added burden may place SMEs at a disadvantage.

This multiple regulatory framework can lead to the incomplete or incorrect application of mutual recognition by some MSs. It can also be perceived as a lack of rules to adhere to by non-EU country operators importing into the EU. Industry self-regulation, if not under EU Guidelines (especially for RA), can limit the access to markets particularly for SMEs.

Outlook

This baseline study maps the industry supply chain and national frameworks in place for materials not covered by EU-wide measures, provides insight on possible safety and trade impacts of the current regulatory scheme and indicates where improvements are needed. This information will allow the European Commission to assess the efficiency and effectiveness of the current situation, including benefits and administrative burdens on businesses. It will support a Commission's evaluation to consider what, if any, possible steps need to be taken in the future concerning the regulation of FCMs in the EU.

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1. Introduction to the baseline study

1.1. Food contact materials and food safety in the EU

Food contact materials (FCMs) are all materials which are or are intended or likely to be in contact with food such as food packaging, kitchenware and tableware, as well as materials for food manufacturing, preparation, storage and distribution. They can thus influence food safety and quality throughout the whole of the food supply chain. FCMs cover a wide range of different materials such as plastic, paper, glass and metal, but also adhesives, printing inks and coatings used in the finishing of the final articles. Actors in the chain include manufacturers of raw materials, intermediate and final FCMs and food products, as well as importers and distributors.

Commission Regulation (EC) No 1935/2004 is the framework legislation for FCMs. Its purpose is to ensure the effective functioning of the internal market for materials and articles intended to come into contact with food and secure a high level of protection of human health, as well as the interests of consumers. It sets out general requirements that all FCMs must be manufactured in accordance with good manufacturing practice (GMP) so that they are safe and do not change the properties of food in unacceptable ways. As the general requirements for all FCMs set out under Article 3 are linked to the general obligations on GMP, separate rules on GMP are laid down in Commission Regulation (EC) No 2023/2006.

The framework legislation also sets out other rules, including those on labelling and on compliance documentation and traceability, and lays down the risk assessment process involving EFSA as part of the authorisation process for substances.

Specific measures for groups of materials and articles, including authorisation of substances, may also be introduced. Specific EU measures are in place for plastics, processes for recycling plastics, regenerated cellulose film, ceramics, and active and intelligent materials and articles.

In the absence of specific EU measures, MSs may maintain or adopt their own national provisions on FCMs provided they comply with the rules of the Treaty ⁽²⁾. Whilst the framework regulation dates from 2004, its basic provisions are essentially unchanged from the earliest Council Directive on FCMs, Directive 76/893/EEC from 1976 ⁽³⁾.

Over recent years, a number of issues linked to FCMs have raised concerns by Member States (MSs), industry, the European Parliament (EP) ⁽⁴⁾ and non-governmental organisations (NGOs) on the lack of specific EU legislation for certain materials. These relate both to the potential safety issues of FCMs and to the functioning of the internal market. National rules in place in MSs may differ from one another and may introduce inconsistencies in the approach to regulating FCMs, hindering the free movement of those materials and articles within the internal market.

In view of the national legislation in place in EU MSs, setting out individual rules on different materials and substances and of the size and complexity of the supply chain, the European Commission's Joint Research Centre (JRC) was tasked with carrying out a study on FCMs for which there are no specific measures at EU level to support DG Health and Food Safety in the evaluation of the of the current situation. This includes a market overview on the FCM supply chain, details of the current national measures in place and an analysis of the food safety aspects and burden of the current situation.

1.2. Aims and scope of the study

The objectives of the baseline study were to:

⁽²⁾ Treaty of the Functioning of the European Union (Art. 114), replacing the Treaty establishing the European Community

⁽³⁾ OJ L 340, 9.12.1976, p. 19-24.

⁽⁴⁾ Report 2015/2259(INI).

- collect information on the market situation for different material supply chains;
- collect and organise information on the current regulatory frameworks at national level or other recommendations/guidance for these materials, including requirements on substances, declarations of compliance, GMP and risk assessments (RAs);
- analyse the food safety aspects and burden of existing regulatory frameworks to demonstrate compliance with the general requirements for FCMs;
- collect data on costs and burden of current instruments and possible barriers to trade.

The scope of the study includes materials which are not yet subject to harmonised EU legislation ⁽⁵⁾, i.e. adhesives, ceramics (beyond its current EU measure), cork, glass, ion-exchange resins (IERS), metals and alloys, paper and board, printing inks, rubber, silicones, varnishes and coatings, waxes and wood. Plastics, including recycled plastics, active and intelligent materials and articles, and regenerated cellulose, do not fall under the scope of this study since they are already subject to EU harmonised legislation.

1.3 Methodological approach and structure of the report

The work was articulated into work packages.

One work package examines the organisation of the supply chains for the different sectors, including starting materials, intermediates and final materials and articles. It reviews market data (volumes, values) for different supply chains and distribution of micro, small and medium-sized enterprises (SMEs). It considers both packaging material articles such as kitchenware and food processing equipment or machinery.

A second work package focuses on the compilation of existing instruments at national level on risk management of substances from FCMs (national legislation, recommendations, guidance either existing or under preparation and reference documents or standards). The study covers principally documents from EU MSs and European Economic Area ⁽⁶⁾ countries. The desktop research encompasses a review of national regulatory frameworks both at an overarching level to all FCMs and with regard to material-specific measures. It includes supranational documents such as from the Council of Europe or Norden, standards such as CEN and ISO and measures from non-EU countries. It should be noted that, for the purpose of this report, Switzerland and Norway were examined in parallel, together with the 28 MSs (and generally listed in their protocol order unless specified otherwise). The report includes guidelines on GMP and other industry-produced self-regulation or guidance. It is based on what could be obtained publicly or from direct enquiries with stakeholders.

A third work package focuses on tabulating the data and providing an electronic repository. An IT tool was created to store all original documents and extracts from documents for both general and specific information (e.g. toolkits).

A fourth phase concentrates on the analysis of the information to generate key messages. It considers the general aspects of food safety for all FCMs (e.g. registration of food contact operators, details on GMP, declaration of compliance, supporting documents, sanctions, and enforcement and certification systems). It compares for each material the existence of lists of authorised (or banned) substances, limits or restrictions and the presence of methods for enforceability. With regard to safety indicators, reviews include inspections by the Health and Food Audit and Analysis (HFAA) office, notifications from the Rapid Alert System for Food and Feed (RASFF) and direct queries of national surveys and monitoring by MSs. Information on burden was requested from both MSs and stakeholders, with a focus on quantitative indicators where possible rather than the opinion polls which have previously been conducted ⁽⁷⁾.

⁽⁵⁾ Listed in Annex I to Regulation (EC) No 1935/2004.

⁽⁶⁾ Iceland, Liechtenstein and Norway, as part of the European Economic Area, also apply the Union legislation while keeping additional national legislation. Switzerland has adopted regulations corresponding to the Union legislation.

⁽⁷⁾ Report 2015/2259(INI).

2. FCMs, supply chains, markets, frameworks

2.1. Introduction

Actors in the chain include manufacturers of raw materials, intermediate and final FCMs and food businesses, as well as FCM importers and distributors. Many materials and articles in their finished state are also composed of several different materials.

2.2. Objectives

This work package aims to describe the current market situation for the relevant FCMs in the EU. The raw materials sector was also included, as was the plastics sector.

The chapter includes an overview of the organisation of the supply chains and the way they are structured and interact with the different actors involved both upstream and downstream of the supply chains. It describes the different European professional associations representing each sector and presents information on the values and volumes, as well as the distribution of SMEs vs large enterprises in the different sectors.

2.3. Materials and methods

Desk research was performed by seeking information from different sources, including from the European Commission, literature searches and internet searches. Technical documentation was sought from publicly available sources or requested from European professional associations. It was completed with sets of questionnaires to industry associations tailored more specifically for this report after review of previous questionnaires conducted by DG Health and Food Safety in 2012.

With regard to the **supply chain**, tasks included:

- a compilation of industry guidance documents;
- a compilation on the organisation of the supply chain for each sector, description, organisation and market representation of various sectorial professional associations;
- the generation of a flow chart to represent the different chains and the relations between the organisation of the supply chain of plastics and that of other materials/articles/products.

Feedback was requested from associations to: (1) trace any missing relevant industry document/scheme on the organisation of the supply chain; (2) verify the completeness and up-to-datedness of the information; and (3) organise the information in a harmonised way. This was done individually with the professional associations for the different materials' sectors. Three dedicated questionnaires were used. One questionnaire included the identification of the actors concerned upstream and downstream in a given material/product supply chain, information on the market position in volume and value of different supply chains, annual turnover, estimation of the distribution of SMEs in the different market positions/supply chains and information on volume of business operators in EU versus non-EU countries. Two additional questionnaires were on the existence of guidance documents used as self-regulations and information on sector-specific GMP guidelines (used in the other work package).

Trade data from several sources were also used for the purpose of this study. Data were sought from Eurostat and Prodcom and purchased from consultancies. Data such as those from Prodcom and Eurostat did not discriminate sufficiently for the purpose of this investigation between materials used specifically for FCMs and the same materials used in other products. Several commercial data sources were used or purchased for the purpose of this report, including Euromonitor, European, packaging and packaging waste statistics 1998-2011 and Smithers-Pira 2013.

Euromonitor data gave trade information for 20 MSs, along with Russia, Switzerland,

Turkey and Ukraine. Data were not available for Estonia, Croatia, Cyprus, Latvia, Lithuania, Luxembourg, Malta, Slovenia and Switzerland. The data were represented in **volumes expressed as millions of unit sales** featuring glass packaging, metal packaging, multimaterials, paper and board and plastic. No data on other materials were available from this source. The data were purchased for 1999-2013, with some forecasts for 2014-2018.

From this Euromonitor data, food packaging was grouped as follows:

- glass (glass bottles and glass jars);
- metal (aluminium foil, aluminium trays, collapsible metal tubes, kegs, metal aerosol cans, metal beverage cans, metal bottles, metal food cans, metal tins, other metals);
- multimaterials (aluminium/plastic pouches, bag in box, board tubes, brick cartons, composite containers, flexible aluminium/paper, flexible aluminium/plastic, flexible paper/plastic, gable top liquid cartons, paper based trays, shaped liquid cartons);
- paper and board, flexible paper, folding cartons;
- plastic (blister and strip packs, flexible plastic, HDPE bottles, PET bottles, other plastic bottles, ready meal trays, other plastic trays, PET jars, other plastic jars, plastic pouches, squeezable plastic tubes, stand-up pouches, thin wall plastic containers, other rigid containers).

Values and information on distribution of SMEs in different market sectors were available from Pira for 2013 for the then 27 MSs. Information was available on the percentage of small (1-49 employees), medium-sized (50-249 employees) and large (250 + employees) enterprises for paper and board, plastics, metal, glass, wood, cork, porcelain and ceramic kitchenware and general- and special-purpose machinery. Information from Eurostat was available on volumes in tonnes from 2011 for each of the then 27 EU MSs. For other types of material including adhesives, printing inks, varnishes/coatings and rubber, information was retrieved from professional associations.

Further searches were conducted on Eurostat (in the SME statistics section) and through the European Commission services that might own pertinent data, such as Enterprise Europe Network (EEN) ⁽⁸⁾ and some of their national associated bodies, the Executive Agency for Small and Medium-sized Enterprises (EASME), DG Internal Market, Industry, Entrepreneurship and SMEs, in particular units F1, F4, F5, COSME and ENTR-D1 Entrepreneurship and Social Economy. However, the level of information sought was not available or adequate for the purpose of this study.

2.4. Overview of the FCM supply chain

Article 17 of the framework regulation states that business operators must have in place systems and procedures to allow identification of the business from which and to which materials or articles are supplied and that the materials and articles must be identifiable to allow their traceability by labelling or via relevant documentation.

The 'Industrial guidelines on traceability of materials and articles for food contact' (2006) ⁽⁹⁾ define two levels of traceability, as follows.

- Level 1: within the operation of each stakeholder. This level covers the systems that each stakeholder has in place to link their products to the raw materials used to produce them.
- Level 2: between different stakeholders. This level is concerned with the transmission of information along the chain. It should be possible from any point downstream, and in particular from the retailing point, to go back up the chain to understand by whom the material or article has been manufactured. This also implies that, in the opposite direction, the material or article can be traced from any point up the chain down to

⁽⁸⁾ Commission staff working document - a fitness check of the food chain - state of play and next steps, SWD(2013) 516 final.

⁽⁹⁾ APEAL — Industrial guidelines on traceability, 2006.

the retailing point. Both levels must function to achieve full traceability.

The industrial guidelines give a simplified structure of the organisation of the FCM supply chain (Figure 1).

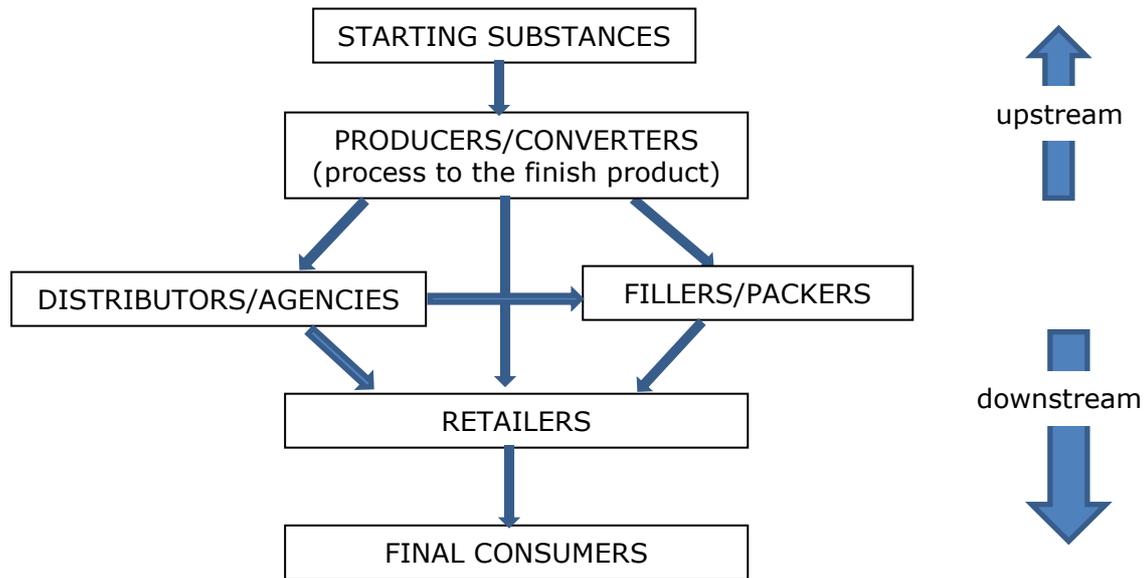


Figure 1: Simplified structure of the organisation of the FCM supply chain

The guideline states that 'using the above diagram, it is possible to identify a point where the FCM or article is manufactured, i.e. the converters and producers. At this point there is a separate identity, "upstream" and "downstream". Converters transform materials, which have been produced by "upstream" suppliers, into finished articles or semi-finished goods. Producers manufacture articles directly from starting materials, using processes involving chemical, as well as physical change.'

The scheme illustrated above assumes that the whole chain is within the EU. However, in some cases, part of the chain can be outside the EU; therefore another stakeholder should be included in the scheme, namely the importer. Imports may take place at different stages of the supply chain, such as:

- import of starting materials by the converters and producers;
- import of empty packaging by distributors or fillers;
- import of finished articles such as kitchenware/tableware by distributors or retailers;
- import of filled packaging by distributors or retailers.

In an ideal supply chain, e.g. a chain composed entirely by ISO 9000 certified companies, traceability will always be guaranteed, as every single step of the chain will have been documented. In practice, different identification rules may apply for upstream and downstream users. Upstream suppliers supplying a company operating under a certified quality system shall strictly guarantee traceability of their products. It is essential that companies operating under a certified quality system control their suppliers and ensure that the supplied products are appropriately identified.

Figure 2 is an attempt to visualise the supply chain across the various materials. Since importers can act in the whole supply chain, they have been omitted from the figure.

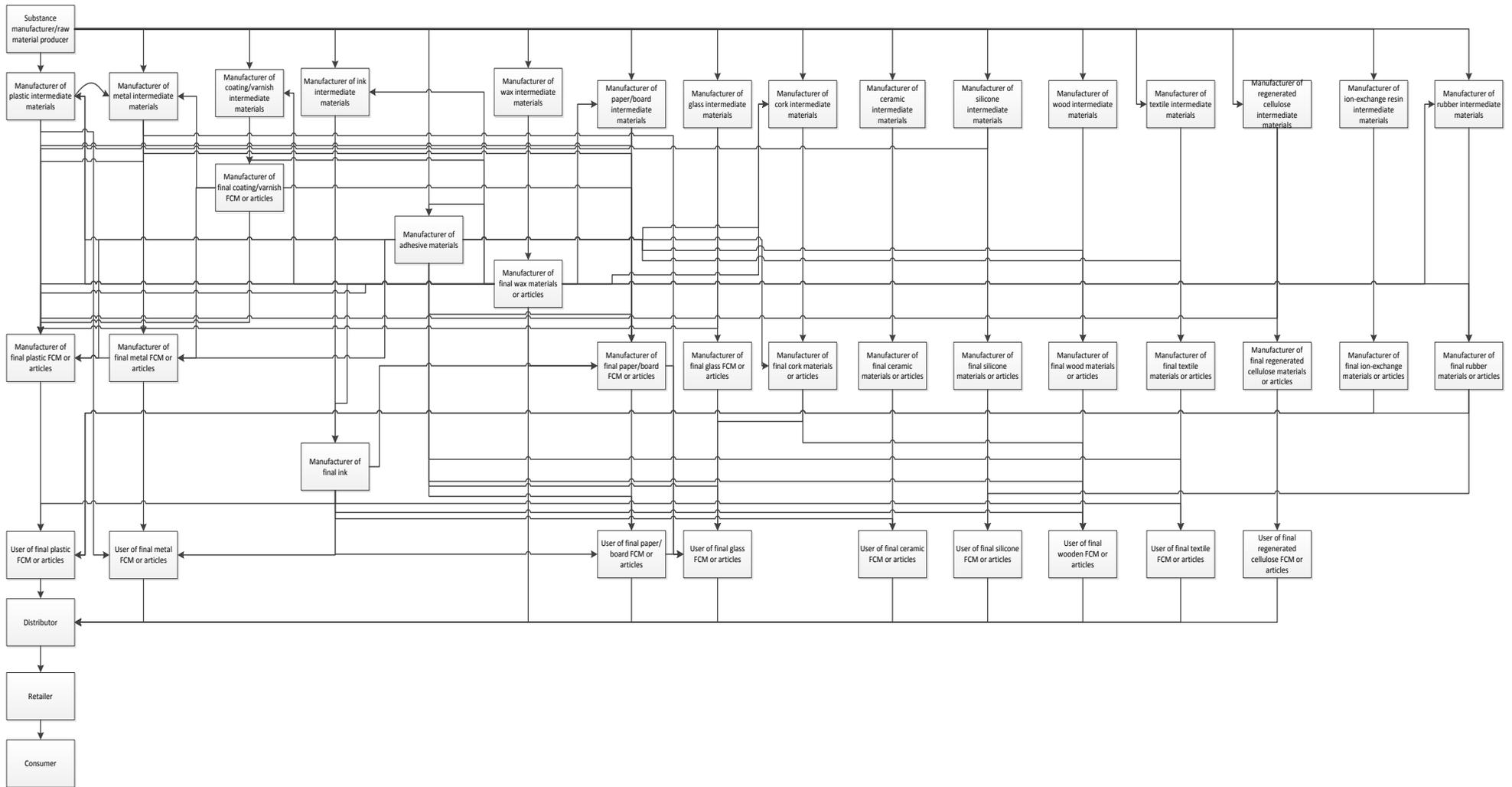


Figure 2: Flow chart representation of the different supply chains for various materials

2.5. Sectorial information on supply chains and markets

The information in the following sections describes each of the individual sectors, including volumes and values and distribution of the different types of businesses. The information should be interpreted with some caution as the diversity of the different information sources, lack of clarity or sensitivity or lack of information and different ways of quantifying and qualifying the information make it challenging to have a complete picture and to compare between the different sectors. For example, it was not always clear if the estimated annual turnover referred only to FCMs or to the total annual turnover of a material or article sector. Furthermore, the estimated coverage of the market and the distribution of the coverage of the annual turnover between large, medium-sized, small and micro enterprises within an EU professional organisation could be based either on the turnover or on the production volume. A focus was made on the turnover/sales and, wherever possible, with a distinction between this and the distribution in numbers of enterprises. A compilation of the available information collected on supply chains can be found in Annex 1. For the different sectors an overview is presented in the next sections.

2.5.1. Chemicals sectors and intermediate materials

This section describes the sectors that are engaged upstream of the supply chain and mostly provide for subsequent sectors in the supply chain towards semi-finished and finished products.

Starting substances

The overall **chemicals** industry in Europe is grouped under the umbrella organisation the European Chemical Industry Council (CEFIC), which represents 670 members and affiliates. The production of various FCMs requires technical additives in order to ensure the intended function and stability and to open up technical options for production.

The **professional association CEFIC-FCA** ⁽¹⁰⁾, i.e. the Food Contact Additives group, represents the majority of manufacturers that produce these additives, which according to the organisation are estimated at between 3 000 and 4 000 substances. CEFIC-FCA groups together 35 direct company members, including companies, and 15 associations covering different sectors from the FCM supply chain industry. Most if not all members are considered large enterprises and are listed on the organisation's website ⁽¹¹⁾.

CEFIC-FCA members **produce and supply** additives used in many different types of FCM applications, such as plastics, paper and board, printing inks and coatings, and therefore supply to a large number of sectors manufacturing FCMs.

The CEFIC website reports that the overall European chemical industry represents a value of EUR 673 billion industry and is the world's top exporter and importer of chemicals. CEFIC itself represents 29 000 large, medium-sized and small chemical companies in Europe, which directly provide 1.2 million jobs and account for 17 % of world chemical production. CEFIC states that in accordance with the EU competition law the sector was not in the position to collect either market volumes or values from its members. However, it can be seen from the CEFIC website that two of the biggest industrial users of chemicals are the plastics and rubber industry and the paper and pulp industry, sectors that are heavily involved in the manufacture of FCMs.

The use of **resins** in FCMs is sometimes considered separately. Resins are solid or highly viscous substances that are typically convertible into polymers and used as the basis for manufacturing plastics, adhesives, varnishes or other products. For plastics, resins are

⁽¹⁰⁾ www.cefic.org/FCA

⁽¹¹⁾ www.cefic.org/About-us/How-Cefic-is-organised/Fine-Speciality-and-Consumer-Chemicals/Food-Contact-Additives-FCA/

often produced in the form of pellets subjected to various processing steps.

The **European Resin Manufacturers Association (ERMA ⁽¹²⁾)** was formed to help the European resins industry meet the requirements of the European single market and represent the interests of resin manufacturers. ERMA entered into an affiliation with CEFIC to further promote European interests and ensure a uniform and concerted approach throughout Europe. No information on FCM trade was received from ERMA.

Adhesives

An adhesive can be described as a non-metallic substance capable of joining materials by surface bonding (adhesion), and the bond possessing adequate internal strength (cohesion). Adhesives are set by either evaporating a solvent or cooling, or they cure by chemical reactions that occur between two or more constituents. FCMs may be composed of different layers of packaging material (for example plastics, paper, etc.) held together by adhesives. The 2011 report of the EFSA scientific cooperation (ESCO) working group on non-plastic food contact materials, published by EFSA, describes adhesives as a complex group of chemical formulations widely used in different types of food packaging and in different applications such as in the manufacture of rigid packs and multilayers, attachment of labels or sealing flexible packaging.

The Association of the **European Adhesive and Sealant Industry (FEICA ⁽¹³⁾)** represents the adhesives sector, which broadly speaking covers building construction and civil engineering, paper and board products, assembly operations, consumer and do-it-yourself (DIY), transportation, and woodworking and joinery. The sector of adhesives for FCMs has about 600 enterprises. FEICA represents 90 % of the large enterprises involved in this sector in Europe. FEICA has 14 national association members ⁽¹⁴⁾ that represent 50-60 % of the SMEs. FEICA estimates that it covers about 85 % of the adhesives for the FCM market. FEICA also has 20 direct member companies and seven affiliate member companies.

Typical adhesive systems used in food contact applications are described in FEICA's guidance paper on migration testing of adhesives intended for food contact materials ⁽¹⁵⁾ and include reactive polyurethane adhesives used in the lamination of polymer films, metallised films or other materials such as paper, and adhesives based on natural polymers, acetate-based polymers or acrylic-based polymers, all of which are mainly used for paper and cardboard packaging of dry foodstuffs or for secondary and tertiary packaging, but also wet lamination of paper to foil.

Cold seals derived from natural or synthetic rubber, such as those used as a seam sealing application on film and paper for confectionary and ice cream, heat seals which are synthetic resins for film used for tray and cup lids and hot-melt adhesives based on high-levels of waxes and low levels of polyolefin copolymers applied to paper and cardboard packaging of dry foodstuffs, are also covered by FEICA's guidance.

With respect to the **supply chain**, whenever a material contains adhesives the adhesive is used at every step in the supply chain (intermediate down to final). The suppliers to the adhesive sector are manufacturers of substances and mixtures, as well as certain plastic intermediate materials (e.g. polymeric additives etc.). The adhesives sector supplies to manufacturers of final plastics, glass, paper and board materials and articles, manufacturers of cork, users of final plastics or paper and board materials and articles, manufacturers or users of intermediate or final wooden materials and articles, and retailers for labels. The sector also covers the paper tissue and towel sector.

As regards the **distribution of different sized enterprises**, 4 % of members are large companies, 7 % are medium-sized, 29 % are small and 60 % are micro enterprises

⁽¹²⁾ www.erma.org.uk

⁽¹³⁾ www.feica.eu

⁽¹⁴⁾ <http://www.feica.eu/about-feica/organigram.aspx>

⁽¹⁵⁾ www.feica.eu/cust/documentview.aspx?DocID=1775

(Figure 3). These account for 50 %, 15 %, 25 % and 10 %, respectively, of the annual turnover. The small to micro adhesive producers are mainly in the south of Europe.

Figures from FEICA from 2010-2012 indicate that the overall adhesives demand (**annual turnover**) in Europe was estimated at around EUR 8.6 billion (food and non-food). Of this, around EUR 2.4 billion was the demand for adhesives for paper and board and related products. Available statistics are not detailed enough to indicate the proportion of this relevant to FCMs. However, FEICA has estimated that adhesives for FCMs are about 50 % of those figures — meaning around EUR 1.2 billion for Europe — or around 15 % of the total adhesives market in Europe.

Using these figures, approximate values are therefore around EUR 600 million for large enterprises, around EUR 500 million for SMEs and around EUR 100 million for micro enterprises (Figure 4). The value of food contact adhesives covered by FEICA (large enterprises and approximately half of SMEs) is thus estimated at EUR 850 million, with the remaining SMEs and micro enterprises accounting for c. EUR 350 million.

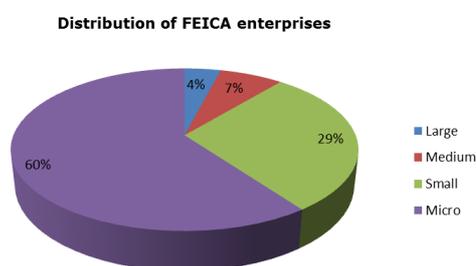


Figure 3: Approximate distribution of different types of enterprises represented by FEICA producing adhesives for FCM in Europe

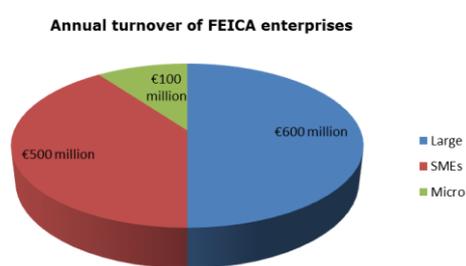


Figure 4: Approximate annual turnover of different types of enterprises represented by FEICA producing adhesives for FCM in Europe (total estimated at EUR 1.2 billion)

Printing inks

Printing inks are used primarily on food packaging to give information to the consumer about the food product or for marketing purposes. Different types of inks are used including low migration ultra-violet (UV) curing inks, low migration electron beam (EB) curing inks, conventional oleo-resinous inks and low migration water-based coatings. Food packaging inks consist of a combination of colourants, binders, solvents and additives, utilising in excess of 5 000 different chemical substances.

Printing inks are used in combination with many other different types of materials, including paper and board, plastics and multimaterial finished articles where the packaged goods are in prolonged direct contact with the non-printed side of the packaging material. Other types of packaging may involve an inner-wrap so that the printed material is not in direct contact with the contents. Most printing inks are therefore not intended to be in direct contact with the food, however physical or gas-phase migration of substances into the food can still occur.

The **European Printing Ink Association (EuPIA (¹⁶))** represents 13 national organisations comprising 117 member companies in the following countries:

- Austria (FCIÖ)
- Belgium (IVP)
- Denmark (DFL)
- Finland (PVY)
- France (AFEI)
- Germany (VdL)
- Greece (Hellenic Coatings Association)
- Italy (AVISA)
- Netherlands (VVVF)
- Spain (ASEFAPI)
- Sweden (SVEFF)
- Switzerland (VSLF)
- United Kingdom (BCF)

(¹⁶) www.eupia.org

Suppliers to the printing ink industry are mainly EU chemical industries, including substance manufacturers and raw material producers, for example pigment manufacturers, resin manufacturers, wax manufacturers and solvent manufacturers. Printing ink manufacturers themselves are 'manufacturers of non-plastic intermediate materials'. IP-Europe members supply the printing industry. The ink industry supplies its products to the manufacturers of final FCM materials and articles (printers and converters), for example manufacturers of plastic, metal or paperboard FCM or articles.

As regards the **distribution of different sized enterprises**, 10 % of the members are large companies, 31 % are medium-sized enterprises, 49 % are small enterprises and 10 % are micro enterprises (Figure 5).

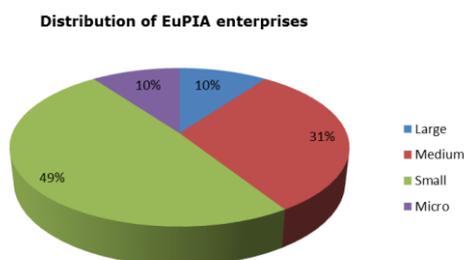


Figure 5: Approximate distribution of different types of enterprises represented by EuPIA producing printing inks in European countries

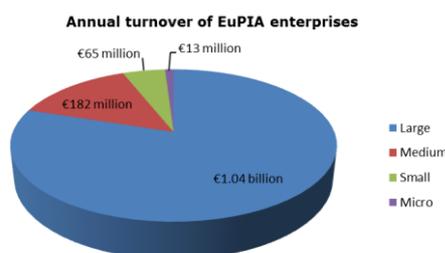


Figure 6: Approximate estimated annual turnover of different types of enterprises represented by EuPIA producing printing inks in Europe for FCMs (total estimated at EUR 1.3 billion)

The total market for inks in 2014 was estimated at EUR 3.5 billion or 1 100 000 tonnes, of which packaging inks accounted for EUR 1.7 billion or 400 000 tonnes — much of the rest accounting for publication inks. EuPIA members have an estimated **annual turnover** of about EUR 1.3 billion in food contact, which constitutes about 90 % of the market. Large, medium-sized, small and micro companies account for 80 %, 14 %, 5 % and 1 %, respectively, of the overall annual turnover of EUR 3.5 billion. As no data was available for the FCM portion, it is assumed that the same distribution is true for the estimated sales for food packaging inks, i.e. EUR 1.3 billion (Figure 6).

The **Imaging and Printing Association Europe (I&P Europe⁽¹⁷⁾)** is a European association of product manufacturers and technology providers for the imaging and printing industry, and therefore also represents the printing inks industry. I&P Europe represents 25 companies, of which 19 (76 %) are large enterprises, five (20 %) are medium-sized enterprises and one (4 %) is a small enterprise. The large companies account for almost 100 % of the annual turnover. For digital printing related to food packaging the percentage is in the single digits. For varnishes and other coating materials food contact applications account for up to 30 %.

Ion exchange (and adsorbent) resins

The main applications of ion exchange resins and adsorbents are in processing liquid feed streams, and typically they are used as a fixed bed contained in a pressure vessel. In some applications they are used in combination with different ion exchangers and adsorbents. Ion exchangers and adsorbents protect equipment and machinery against scale and corrosion and remove unwanted contaminants from process waters. Most synthetic ion exchangers are manufactured with a polystyrenic or polyacrylic structure, with a cross-linking agent that helps form the bead structure and makes the resin insoluble in a wide range of liquids. There is a wide range of ion exchangers, some with specialised functional groups to achieve the targeted removal of specific ions. The majority of applications in the areas of drinking water or food production use standard

(17) www.ip-europe.com

resins, with either strong or weak acid functionality or weak or strong base functionality.

The organisation **Synthetic Organic Ion Exchangers and Adsorbents (SOIA⁽¹⁸⁾)** represents the leading European manufacturers of ion exchange resins and adsorbents. SOIA is a sector group of CEFIC and the industry contact point for regulatory matters impacting ion exchange resins, in particular in food processing and potable water applications.

No information related to trade data on FCM was received.

Varnishes and coatings

Varnishes and coatings are non-self-supporting layers composed of substances applied on another material or article in order to impart special properties on it or improve its technical performance. Principally organic coatings are typically applied in a liquid or powder state and need to dry, cure or solidify to reach their finished state. A typical use of coatings is to protect the surface of metal food cans, prevent food spoilage and enhance the performance of the packaging material. Coatings are also used at the industrial level on food vats and tanks, and they are also used on the non-food contact side of the packaging, for instance to protect the ink and improve the gloss.

The **European Council of producers and importers of paints, printing inks and artists' colours (CEPE⁽¹⁹⁾)** represents businesses that manufacture paints, coatings and inks, including varnishes and coatings used for FCMs. It represents c.85 % of this industry, employing 120 000 people with an overall value of around EUR 17 billion.

The **supply chain** of food contact coatings for metal packaging has been described in industrial guidelines⁽²⁰⁾. It is summarised in Figure 7 below.

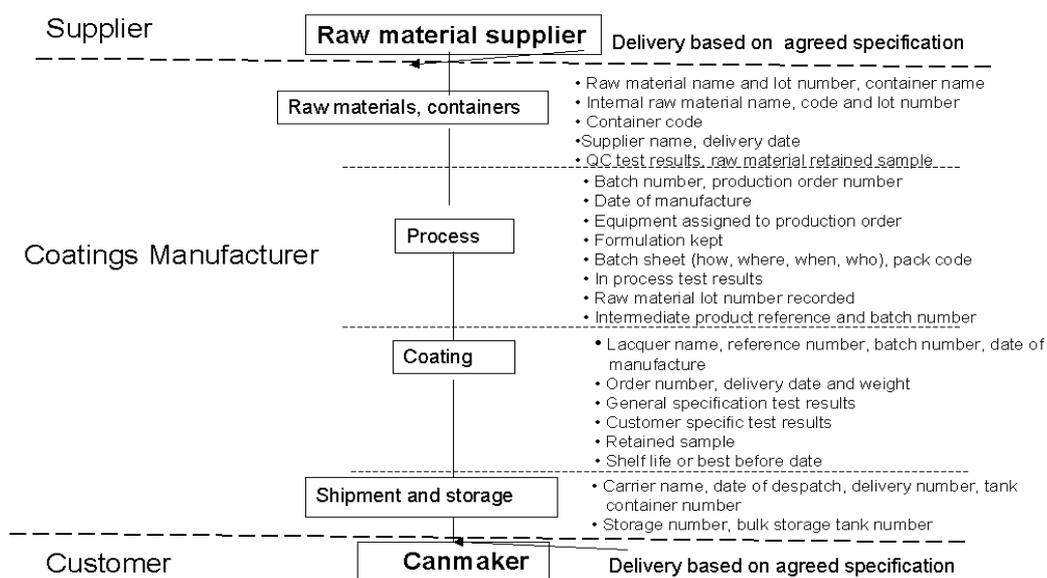


Figure 7: Supply chain for coatings in relation to metal packaging (source: CEPE)

The **annual turnover** relevant to FCMs is estimated at EUR 400 million. The majority of this (95 %) is generated by the five large enterprises represented by CEPE, the remainder by the one small business that it represents (Figure 8). Conversely, 2013 Pira data estimates EU FCM packaging coatings sales to be in the region of EUR 2 billion, split relatively evenly between coatings for metal packaging, paper and board and plastics. Pira also estimates that the **SMEs** make up to half of the revenue sales and is therefore

⁽¹⁸⁾ <http://soia.cefic.org>

⁽¹⁹⁾ www.cepe.org

⁽²⁰⁾ Industrial Guidelines On Traceability Of Materials And Articles For Food Contact, 2006.

not comparable with the data provided by CEPE, although the Pira data may also include printing inks (Figure 9).

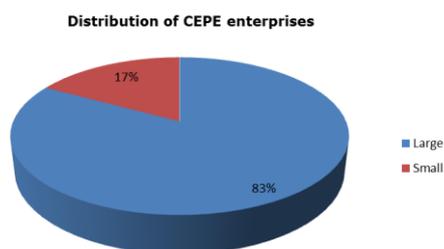


Figure 8: Distribution of different types of enterprises represented by CEPE producing FCM varnishes and coatings for FCMs

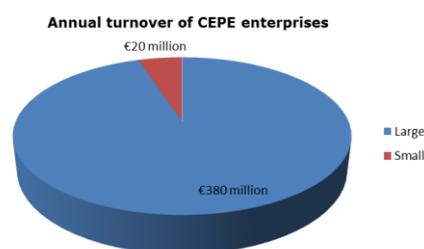


Figure 9: Approximate annual turnover of different types of enterprises represented by CEPE producing varnishes and coatings for FCMs (total: EUR 400 million)

Wax

Wax is a generic term for a range of natural or synthetic products that can be broadly divided into natural waxes, synthetic waxes, mineral hydrocarbon waxes and petroleum waxes. Waxes are usually defined by characteristic properties such as their melting point or viscosity. They can be used as additives or processing and production aids in many types of FCMs. They are also used as the sole or a predominant component of surface coatings. This is the case for instance of paraffin waxes, including synthetic paraffin, and/or micro-crystalline waxes and for mixtures of these waxes with each other and/or with plastics.

The **European Wax Federation (EWF⁽²¹⁾)** represents manufacturers, formulators, importers and sellers of waxes. EWF has 31 members, including 22 full members, two for natural wax, one for soft petroleum, one affiliated and five associated members. Members account for about 80 % of the market. The overall **production** is approximately 500 000 tonnes/year, with 15 % used for FCMs. As regards the **distribution of enterprises**, 40-80 % of the members are large companies, 20-50 % are medium-sized and 5-10 % are small. **No additional trade data** was received.

2.5.2. Other materials sectors

Ceramics and enamel

Ceramics are inorganic and non-metallic materials used to produce such items as bricks, and tiles and, as FCMs, in particular tableware, such as plates, dishes, cups, bowls and jugs. Ceramics are generally made from mixtures of clay, earthen elements, powders and water shaped into desired forms. Once the ceramic has been shaped, it is fired at high temperature in a kiln, and decorative, waterproof, paint-like substances known as glazes are often subsequently applied.

Vitreous and porcelain enamels are used as coating on steel/cast-iron articles in order to prevent corrosion of the metal underneath and to provide a closed, abrasion-resistant and physiologically safe surface that is perfectly fit to come into contact with foodstuffs. The main vitreous enamelled articles that are used as FCMs are cookware and baking trays in kitchen ovens.

The **European Ceramic Industry Association (Cerame-Unie⁽²²⁾)** represents the European ceramic sectors, including the ceramic tableware and ornamental ware sector and the porcelain enamel sector. Its members and associate members are both federations of national associations and direct members and are established in 30

⁽²¹⁾ www.wax.org

⁽²²⁾ <http://cerameunie.eu/>

European countries, including 26 EU MSs. It is estimated that there are around 2 000 ceramic companies in the EU across eight sectors covered by Cerame-Unie. The **distribution of the size** of enterprises indicates a large proportion of SMEs (80 %), as reported in Figure 10.

Cerame-Unie website reports that the **annual production** value of the ceramics industry is around EUR 28 billion, accounting for approximately 25 % of global production and over 200 000 direct jobs in the EU. The major producing MSs in the EU (in decreasing statistical order, from Pira) are Germany, the United Kingdom, Portugal, Italy and France for tableware and ornamental ware. Other MSs such as Poland, Romania, Czech Republic, Spain, and Finland also have strong ceramic sectors. The proportion of tableware and ornamental ware in the ceramics market was reported at 6 % in a 2008 study published by the European Commission (²³), equivalent to EUR 1.8 billion. The same report also noted that a significant proportion of tableware and ornamental ware is from imports (60 %), particularly relatively low-value 'everyday' tableware, predominantly from China. Pira estimates the EU value in 2013 of ceramic and porcelain tableware and kitchenware to be EUR 915 million, and the split of large, medium-sized and small enterprises is shown in Figure 11.

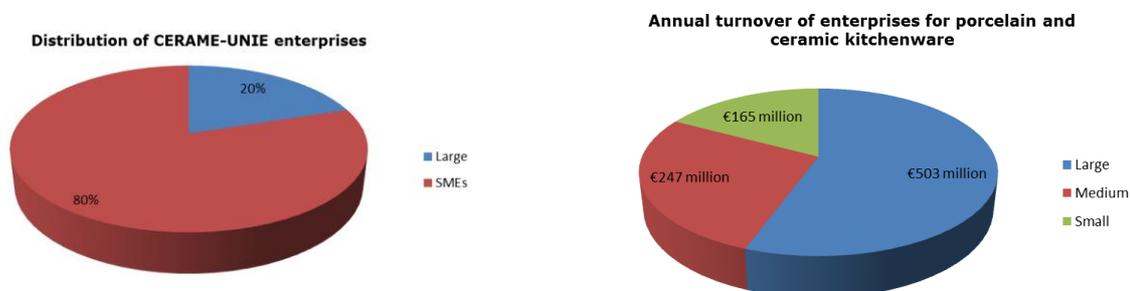


Figure 10: Approximate distribution of different types of enterprises represented by Cerame-Unie for ceramicware

Figure 11: Approximate sales of enterprises supplying porcelain and ceramic FCM kitchenware. Total sales estimated at EUR 915 million (source: Pira, 2013)

The EU ceramic industry is export oriented, with 30 % of its production sold outside the EU market. It was noted that the market had changed in the last decade with the rise of low-cost products from new competitors in emerging and developing countries (Brazil, China, India and the United Arab Emirates). No additional information related to trade details on FCM was received.

The **European Enamel Authority (EEA (²⁴))** is a European federation under Cerame-Unie bringing together nine EU national associations, along with those from Ukraine and Turkey, dealing with 'porcelain and vitreous enamel' industrial articles and representing 150 European companies. Although there are no national associations in some countries such as Spain and Portugal, there is nevertheless a significant presence of porcelain enamel businesses.

The EEA could only provide **incomplete trade data** due to disparate membership (e.g. missing data from the Czech Republic, Slovakia and Turkey). It reported that 75 % of the annual consumption of porcelain enamel is used by enterprises that are members of the EEA. In terms of distribution, 45 % of the members are large companies, 30 % are medium-sized and 25 % are small. The sum of the turnover for porcelain enamel-related materials/articles in the member countries of the EEA (excluding the Czech Republic, Slovakia, Turkey and Ukraine) is EUR 164 billion, with large, medium-sized and small enterprises accounting for 23 %, 22 % and 55 %, respectively, of the annual turnover. About 43 % of the amount of enamel is used for FCM.

(²³) FWC Sector Competitiveness Studies — Competitiveness of the Ceramics Sector. Within the Framework of Contract of Sectoral Competitiveness Studies — ENTR/06/054. Final report, 13 October 2008.

(²⁴) <http://www.european-enamel-authority.org/en/home>

Glass

Glass is a non-crystalline amorphous solid that is often transparent. The principal raw material used in the production of glass is silica, with alkalis, stabilisers, refining agents and small quantities of other additives used to give specific characteristics. Chemically speaking, soda-lime glass is most relevant for FCMs, having excellent light transmission properties with tensile and thermal performances, and is used in tableware, glass packaging, flat glass and some special glasses. Lead crystal, which has a high density and a high refractive index and is used in crystal tableware, is also relevant.

The main category of glassware used as FCM is glass containers and tableware articles. The glass is delivered in small, defined quantities (generally gobs) to be shaped into glass articles, for instance bottles and drinkware. Bottles are supplied to packers to be filled and drinkware is sold to be used by consumers to drink beverages.

Flat glass is a specific case, as use of flat glass for food applications is extremely limited (less than 0.5 % of flat glass production taking into account all other applications). This limited number of articles includes cutting boards, decorative serving plates, tables, counter tops and fridge shelves.

The glass industry within the EU is diverse, both in the products made and the manufacturing techniques employed. The glass sector is represented by **Glass Alliance Europe (GAE⁽²⁵⁾)** and is composed of five main European sectors of glass industries:

- Fédération Européenne du Verre d'Emballage (FEVE) (container glass) ;
- Glass for Europe (flat glass);
- European Domestic Glass (EDG) (domestic glass);
- European Special Glass Association (ESGA) (special glass);
- Glass Fibre Europe — European Glass Fibre Producers Association (APFE) (glass fibre).

Of these, FEVE (glass packaging and tableware) is the most relevant for FCMs. GAE also comprises 14 national glass associations. Several additional countries are represented via one or the other sectorial associations. For example, FEVE member companies cover, directly or indirectly, almost all of the MSs of the EU.

The **suppliers** of raw materials used as intermediates according to the REACH definition for the glass sector are producers of minerals and certain chemicals. These raw materials and the cullet (recycled glass) are melted and react together at high temperature (> 1400 °C) to produce glass, a new substance, the starting material in the sense of the Regulation (EC) No 2023/2006 on GMP.

The **turnover** in volumes is available from various commercial sources but is difficult to compare. According to Europen, the total amount of glass packaging (i.e. both food and non-food) placed on the market in 2011 was 16 170 000 tonnes, a value that was similar to each of the previous years back to 2005, albeit showing a minor decline. Most of this contribution is from the MSs in the EU prior to 2004. Euromonitor data (in millions of units sold) suggests a slightly larger decline, from 172 420 million to 161 426 million units sold in 2011, and subsequently down to 155 182 million in 2015, which is comparable with the 155 732 million units sold in 2013.

Data on turnover expressed in values are available both from commercial sources and as estimates from GAE. According to the Eurostat Prodcom database, the glass sector, including transformation of flat glass products and insulating glass fibres, represented an annual turnover of EUR 36.75 billion in 2011. GAE reported similarly that the total glass market represents a volume of approximately 31 million tonnes and a turnover of approximately EUR 36 billion. GAE estimates that it can be assumed that two thirds (approximately) of glass production in the EU is concerned by FCM legislation, meaning approximately EUR 20-24 billion. This does not necessarily equate to sales of glass for

⁽²⁵⁾ www.glassallianceeurope.eu

FCM. Alternatively, figures from Pira for 2013, which report a total value of EUR 7 157 billion in sales for glass packaging for FCMs, may be an underestimation as they do not include kitchenware and tableware.

Data on the number of units sold from Euromonitor, on the volumes in terms of thousands of tonnes from European and on sales from Pira illustrate that the main EU MSs are Germany (production volume of 45 222 million units sold and EUR 1 299 million sales in 2013), France, Italy, the United Kingdom and Spain (all in the range of 12 000-16 000 million units sold and EUR 700-1 300 million sales) as shown in Figure 12 (distribution in terms of sales also represent the same trends).

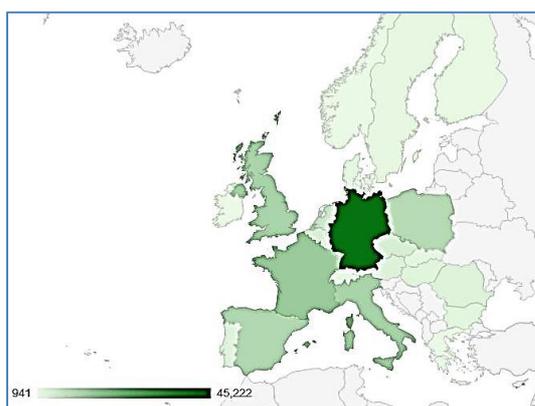


Figure 12: Approximate distribution of volumes for FCM glass across EU MSs for which data was available

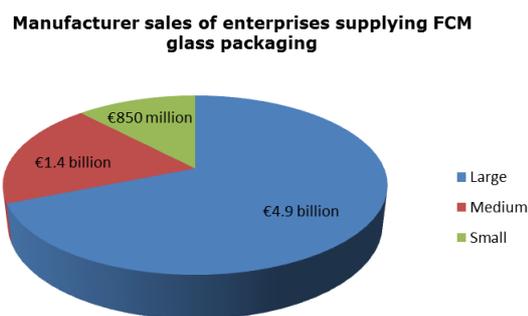


Figure 13: Approximate sales of producers of glass FCM. Total sales c. EUR 7 157 million (source: Pira, 2013)

GAE stated that the glass industry includes a **range of enterprises** across the EU, from SMEs to large enterprises, although no precise data are available. In some sectors, such as flat glass or container glass, large enterprises represent the vast majority of the glass industry. Pira data from 2013 on FCM glass packaging indeed indicate that large enterprises constitute 68.5 % of manufacturer sales, medium-sized enterprises 18.9 % and small enterprises 12.6 % (Figure 13). GAE indicated that there are higher percentages of SMEs in several other subsectors, such as domestic glass (crystal glass) and flat glass transformers (which include some FCM applications for house wares).

Metals and alloys

Metals and alloys are used in a range of different FCM applications, from flexible packaging materials including multimaterial multilayers and containers to household cooking utensils such as saucepans and coffee pots, as well as in the industrial food processing sector. Different types of metal packaging include food and drink cans, drums and pails, aerosol containers, tubes, open trays, caps and closures (e.g. lids on glass jars, bottle tops and yoghurt and butter containers). Typical metals used in FCMs include aluminium — which in turn may also contain elements such as magnesium, silicon, iron, manganese, copper and zinc — steel and tin. Metal packaging is often also used in combination with other materials, namely varnishes and coatings, principally for cans, containers, caps and closures.

The professional association **European Metal Packaging (Empac⁽²⁶⁾)** brings together more than 200 manufacturers, suppliers and 11 national associations of rigid metal packaging. It counts over 60 000 employees across 26 European countries. Other European professional associations relevant to FCMs include the **Association of European Producers of steel for packaging (APEAL⁽²⁷⁾)**, the **European**

⁽²⁶⁾ www.empac.eu
⁽²⁷⁾ www.apeal.org

Aluminium Association (EAA ⁽²⁸⁾) and the Nickel Institute (NI ⁽²⁹⁾).

With respect to the **supply chain**, nickel producers supply downstream users such as manufacturers of metal intermediate materials (e.g. producers of stainless steel), which in turn supply end users such as manufacturers of stainless steel articles and other products for the food and beverage industry as well as other sectors. No information on the supply chain was received from EMPAC.

Regarding **market volumes and values**, according to Europen, 4 612 000 tonnes of metal packaging was placed on the EU market in 2011, a value that has remained stable since 2005. Most of this contribution is from the 15 MSs in the EU prior to 2004. In comparison, the Euromonitor data for volumes in millions of units sold also showed fairly stable values, from 140 665 million units sold in 2004 to 134 865 million in (and 142 000 million in 2011-2013). The data from Euromonitor are also from 2013.

Pira data from 2013 report a total **value** of around EUR 7 billion for metal FCM packaging. In comparison, the estimated annual turnover from the enterprises reported by Empac was about EUR 15 billion, thus a value of over twice that of Pira, but the Empac data may refer to all metal packaging rather than FCMs only. APEAL estimates a value of EUR 3 billion for steel packaging. Data from Euromonitor (volumes) and Pira (values) indicate that Germany, France, Spain, Italy and the United Kingdom were the most important MSs, in the range of 20-30 billion units sold (volumes) and EUR 700-1 300 million in sales (Figure 14).

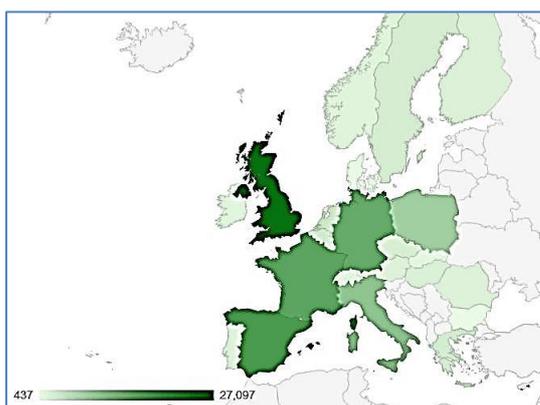


Figure 14: Approximate annual volumes and sales of FCM metal packaging by EU Member State

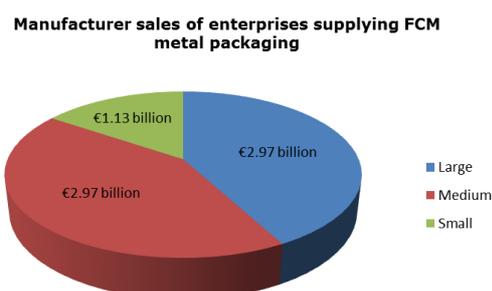


Figure 15: Approximate manufacturer sales of enterprises supplying metal FCM packaging. Total sales estimated at EUR 7 068 million (source: Pira, 2013)

On the **distribution of the size of enterprises** accounted for by Empac, 11 % of the members are large companies, 62 % are medium-sized and 22 % are small. With regard to the distribution by size of enterprises, large, medium-sized and small companies account for 88 %, 10 % and 2 %, respectively, of the annual turnover, which would amount to c.EUR 13.7 billion for large enterprises and EUR 1.3 billion for SMEs (for all metal packaging).

The EAA reports similar proportions for its members. On the other hand, Pira data indicate that the share of EU manufacturer sales for FCM metal packaging is more evenly distributed, as illustrated in Figure 15. One explanation could be a difference between food and non-food packaging as Empac represents both.

Since the information from Pira is only based on sales of food and beverage steel cans, casks, drums, cans, boxes and similar containers of aluminium, iron and steel crown corks, it may not truly represent the size of the total market concerning metal FCMs,

⁽²⁸⁾ www.european-aluminium.eu

⁽²⁹⁾ www.nickelinstitute.org

again possibly excluding kitchenware and tableware, and manufacturing and processing equipment. For example, although no trade details were received from the NI, the International Nickel Study Group (INSG ⁽³⁰⁾) reports that the largest use of nickel is in alloying, particularly with chromium and other metals, to produce stainless and heat-resisting steels used for pots and pans, cutlery and food processing equipment, amongst other things. Of the 2 million tonnes of world primary production of nickel, about 390 000 tonnes (approximately 20 %) is used in FCMs, the vast majority of which is used in the production of nickel-containing stainless steels.

Paper and board

Paper and board consists predominantly of bleached or unbleached cellulose fibres (approximately 99 %), along with naturally occurring minerals such as calcium carbonate and natural polymers such as starch. Paper and board may also be constructed from the recycling of these materials. In order to give specific properties to the paper, depending on its intended end use, functional additives are added along with process chemicals or aids that are used to improve the efficiency of the paper-making process but are not intended to remain in the final paper product.

Paper-based packaging products can broadly be divided into different categories, such as paperboard, which is a thick paper-based material used to produce milk and juice cartons, cereal boxes, frozen-food packaging, etc.; corrugated boxes, which can be used as outer packaging not intended to come into direct food contact or for direct-contact use with fresh produce such as fruit and vegetables and take-away foods such as pizzas; and paper bags, which may be intended for direct or indirect food-contact use. Paper shipping bags may also be used for certain commodities such as flour. Paper and board may also be coated, depending on the intended use, or as part of a multilayer multimaterial combination such as Tetra Pak[®].

The paper and board sector brings a complexity from the much larger number of European professional associations involved compared to other sectors. The **Confederation of European Paper Industries (CEPI ⁽³¹⁾)** represents 18 national members, which in turn account for over 95 % of European production.

The **Alliance for Beverage Cartons and the Environment (ACE ⁽³²⁾)** provides a European platform for beverage carton manufacturers and their paperboard suppliers. Hence all products are FCMs. ACE members include beverage carton producers, who are supplied with paperboard by a small number of companies (often in Sweden and Finland). The beverage carton manufacturers then design, coat and print packaging material according to the requirements of food/drink companies and retailers. As packaging 'system' suppliers, they provide these customers not only with the packaging material, but also with the equipment and filling machines.

The **International Confederation of Paper and Board Converters in Europe (CITPA ⁽³³⁾)** represents the interests of the paper and board converting industry. CITPA's membership comprises national federations in Belgium, Germany, Italy, Austria and Portugal, associations at European level such as the European Federation of paper sack manufacturers (Eurosac ⁽³⁴⁾), the European Association of Wax Paper Packaging Materials (EuroWaxPack ⁽³⁵⁾), the trade association for the self-adhesive labelling and adjacent industries (FINAT ⁽³⁶⁾) and the European Core and Tubes Association (ECTA ⁽³⁷⁾), and several associate members such as ProCarton, PaperImpact and Cepi Eurokraft. The European Pulp and Paper Chemicals Group (EPCG) represents the

⁽³⁰⁾ www.insg.org

⁽³¹⁾ www.cepi.org

⁽³²⁾ www.ace.be

⁽³³⁾ www.citpa-europe.org

⁽³⁴⁾ www.eurosac.org

⁽³⁵⁾ www.eurowaxpack.org

⁽³⁶⁾ www.finat.com

⁽³⁷⁾ www.ecta.info

suppliers of chemical additives for paper and board.

CITPA also represents the European Federation of Corrugated Board Manufacturers (FEFCO ⁽³⁸⁾) and the European Carton Makers Associations (ECMA ⁽³⁹⁾). FEFCO has 24 national associations as members, representing a total of 420 companies and 686 plants, mostly with production being derived from recycled content with around half its production supplied for the food industry. ECMA is the European umbrella association for 14 national associations, as well as having 42 companies with a broader European interest as direct members. ECMA represents, indirectly and directly, around 500 carton makers in Europe, supplier members and overseas members. The European Tissue Symposium (ETS ⁽⁴⁰⁾) represents the majority of tissue paper producers in the EU and about 90 % of total European tissue production, including direct company members in Germany, France, Portugal, Sweden and the United Kingdom.

With regard to the **supply chain**, the information is illustrated in Table 1.

Table 1: Overview of organisation of supply chain for paper and board

| association | Suppliers | Supplying to |
|--|---|--|
| CEPI | Fibrous and chemical raw material producers | Manufacturers of FCM articles (converters) |
| ACE beverage carton manufacturers and their paperboard suppliers | Substance/raw material suppliers: – round wood, chips, pulp – process chemicals for pulping/bleaching/ – chemicals for paper making incl. pigment coating – solvents Suppliers of formulation to be used in FCM: – adhesives, printing inks, coating/varnish, masterbatch, holtmelt FCM producers: – polymer granules, polymer articles, paperboard manufacturers, aluminium foil suppliers | Converters of final FCM paper and board (multilayer multimaterials; beverage cartons) Food producers The majority of the materials are supplied in reels or boxes to converters or food producers. |
| ECMA | Suppliers of: – cartonboard (board mills), window plastic film – paper and board intermediate materials – final ink, final coating/varnish, adhesive materials – plastic intermediate materials | Users of final paper and board FCM or articles |
| FEFCO | Paper industry, ink industry and starch industry | Converting plants or brand owners/packer fillers |
| ETS | No data | No data |

According to European data, 31 780 000 tonnes of paper and board packaging was placed on the market in 2011, a value that has been stable since 2005. Most of this contribution is from the 15 MSs in the EU prior to 2004. Euromonitor data indicates fairly stable values from 108 015 million units sold in 2004 to 119 800 million in 2015.

Specifically for FCM, CEPI has provided a figure of 91 million tonnes in 2014 for the total **production** of paper and board. Of this figure, packaging delivered within the CEPI area accounted for about 36 million tonnes, and around 38 million tonnes was consumed. The subset for food packaging indicated by CEPI was 13.8 million tonnes produced per year taken from data from the three main sectors of folding box board, corrugated boxes and paper sacks. This equates to approximately 44 % of the total amount of paper and board packaging put on the market annually. ACE estimates beverage cartons alone constitute 1 million tonnes per year. Conversely, ETS states that FCM constitutes a very small proportion of its tissue manufacturers. CEPI reports the overall value of paper and board for FCM from its members (95 % of the entire sector) to be around EUR 81 billion per year. Pira data reported from 2013 indicate a total value of EUR 26.7 billion per year for FCM paper and board, which is around one third of the overall value quoted by CEPI. This is made up of approximately EUR 11 billion for corrugated packaging, EUR 10.2 billion for carton board and EUR 5.5 billion for flexible paper packaging, including paper bags with film layers. Data from both Euromonitor and Pira highlight that Germany, Italy, France, the United Kingdom and Spain (in statistical decreasing order) have the greatest share of values and volumes as shown in Figure 16.

⁽³⁸⁾ www.fefco.org

⁽³⁹⁾ www.ecma.org

⁽⁴⁰⁾ www.europeantissue.com

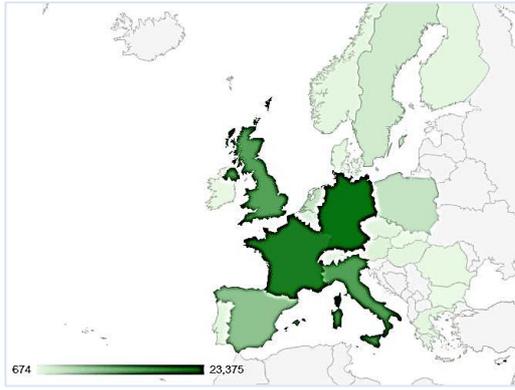


Figure 16: Approximate annual volumes (and sales) of FCM paper and board packaging by EU Member State

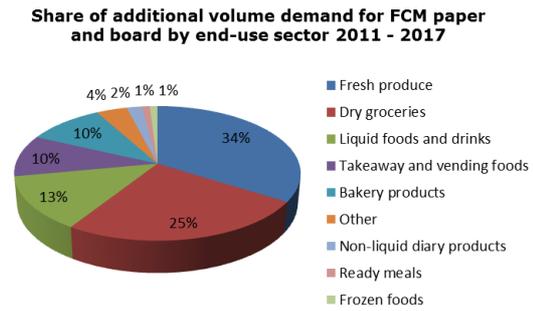


Figure 17: Share of additional volume demand for FCM paper and board by end-use sector, 2011-2017 (source: Pira, 2012)

Data from Pira published on their website ⁽⁴¹⁾ indicate that the global food contact paper market was valued at approximately EUR 47 billion in 2012, indicating that the European value makes up over half of the total global value. The same data also give information on the share of additional volume demand for food contact paper and board by end-use sector from 2011 estimated up to 2017, represented in Figure 17. The same sources indicate that 'Global market for food contact paper & board forecast to reach an estimated \$70 billion by 2017'. Of the more specific European professional associations, ECMA estimated an **annual turnover value** of EUR 4 455 million for FCM in 2011 (representing about 70 % of the market), compared with EUR 4 432 million for non-food packaging and an overall value of EUR 8 887 million. CITPA estimates an overall annual production value of around EUR 60 billion. The EPCG also estimated an annual value of approximately EUR 1 billion.

Concerning the **types of enterprise**, data from Pira for 2013 indicate a relatively even split of small (29.7 %), medium-sized (34.7 %) and large (35.6 %) enterprises across the FCM paper and board packaging sector, which is illustrated in Figure 18. Pira data also indicate a similar split for each of the three main paper and board sectors, although large enterprises account for slightly more as regards corrugated packaging.

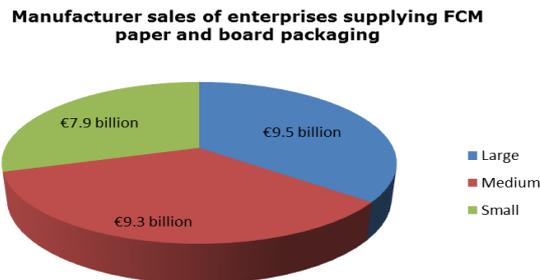


Figure 18: Approximate sales of producers of paper and board FCMs. Total sales c. EUR 26.7 billion (source: Pira, 2013)

In contrast, the distributions vary to some extent when given by each of the European professional associations. CEPI reported that 67 % of members are SMEs and 33 % are large enterprises. ECMA indicated that, of its 500 members, medium-sized enterprises account for 20 % and small enterprises for 70 %, whereas large enterprises only account for 10 %. In terms of turnover of these members, 50 % comes from large enterprises, with 35 % and 15 % from medium-sized and small enterprises, respectively. The EPCG indicated that 70 % of its members are medium-sized

⁽⁴¹⁾ www.smitherspira.com/news/2012/november/food-contact-paper-and-board-forecast-to-2017

enterprises and 30 % are large enterprises. FEFCO indicated that 25 % of its members are medium-sized enterprises 75 % are large enterprises.

CEPI also notes that, in almost all companies in the paper and board packaging sector, the whole production chain is run in line with food contact standards, as the sector operates large-scale industrial continuous production processes.

Regenerated cellulose

Regenerated cellulose is manufactured by the conversion of natural cellulose to a soluble cellulosic derivative and subsequent regeneration, typically forming either a fibre or a film⁽⁴²⁾. The raw materials used to manufacture regenerated cellulose casings are cellulose pulp, plasticisers and water. Pure cellulose or reinforced fibrous casings are typically used for cooked and smoked meats such as sausages and hams, along with cheeses. Regenerated cellulose film, more commonly known by the trade marked name Cellophane, is a thin transparent sheet. It is commonly used as packaging material, particularly for certain greasy foods such as baked goods, confectionary, nuts, dried fruits and spices.

The Comité International de la Pellicule Cellulosique (Cipcel) has been transformed into the **European Man-Made Fibres Association (CIRFS (43))**, which is the representative body for the European man-made fibres industry. 100 % of CIRFS members are medium-sized enterprises, and they have an estimated annual turnover of about EUR 300 million in food contact. No further data was received on the supply chain or trade values.

No trade data was received or available from EU databases and sources.

Cork

Cork is an impermeable, light, buoyant and elastic material derived primarily from the bark of the cork oak tree that is common to southern European countries, such as Portugal, France, Spain and Italy (in decreasing statistical order), and north-west Africa. Its properties make it suitable for acoustic and thermal insulation in house walls, ceilings, facades and wall tiles, but its primary use is as bottles stoppers, especially for wine bottles. Cork closures and stoppers are produced using natural and composite cork. A wide range of different corks exist, from natural cork stoppers to agglomerated corks, colmated⁽⁴⁴⁾ corks and capsulated corks, to which wood or plastic disks are adhered.

The **European Cork Federation (C.E.Liège (45))** represents the entire European cork industry and leads the development of joint promotions supporting cork, its products and applications. C.E.Liège represents six national federations from Portugal, France, Spain, Italy, Germany and the United Kingdom. The principal roles of C.E.Liège are to carry out research, to establish international standards and to share knowledge with other institutes and viticultural organisations. Natural cork is currently used for around 70 % of wine bottles produced, with screw caps and plastic corks accounting for just under one third⁽⁴⁶⁾. In context, the wine industry is one of the leading segments in European agriculture, with a production of 17.4 billion litres and revenues of EUR 16.4 billion. The EU accounts for 60 % of worldwide wine production⁽⁴⁷⁾. Encork⁽⁴⁸⁾, a core group of European SMEs and R & D organisations, reports on its website that Portugal produces around 80 % of the world's cork, followed by Spain. According to Encork, wine corks represent two thirds of the cork industry by value, although in Europe they represent only 15 % of cork usage by volume. The cork industry represents about 100 000 people.

⁽⁴²⁾ Alger, M., Polymer science dictionary (second edition, 1996).

⁽⁴³⁾ www.cirfs.org

⁽⁴⁴⁾ Colmated: cork stoppers that have sealed lenticels or are finished with disks of a mixture of glue and cork powder.

⁽⁴⁵⁾ <http://celiege.eu>

⁽⁴⁶⁾ www.corklink.com

⁽⁴⁷⁾ Encork Report Summary FP7-SME (see reference section).

⁽⁴⁸⁾ http://cordis.europa.eu/project/rcn/111040_en.html

Information derived from Pira illustrates the distribution of cork sales across the key EU countries for which data were available (Figure 19). Pira estimates **total sales** for cork FCMs at EUR 1.2 billion. It should be noted that Belgium, the Czech Republic, Denmark, Germany, Ireland, Greece, Hungary, the Netherlands, Austria, Romania, Slovakia, Finland, Sweden and the United Kingdom reported no sales of cork. Data were not available for other MSs. It illustrates again that Portugal is the major country concerned with cork (sales of EUR 689 million), followed by France (EUR 236 million), Spain (EUR 148 million) and Italy (EUR 142 million).

The **distribution of the size** of enterprises shows that small enterprises constitute over 50 % of sales, medium-sized enterprises 25 % and large enterprises making up the rest of the market. No further data was received from European professional organisations. Based on the annual turnover, the proportion of enterprises is shown in Figure 20.

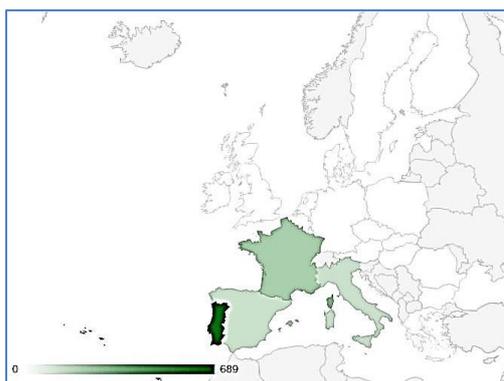


Figure 19: Approximate distribution of sales for cork across EU MSs for which data were available

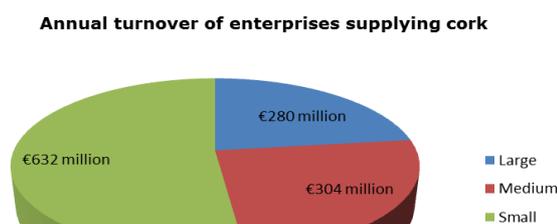


Figure 20: Approximate sales of producers of FCM cork. Total sales estimated at EUR 1 216 million (source: Pira, 2013)

Wood

Wood as an FCM can be in the form of raw timber or reconstituted wood and be varnished, lacquered or painted. The main examples of primary packaging that may be in direct contact with food are crates, boxes and baskets that are designed to hold or transport such foods as fruit and vegetables, seafood, dairy products, cakes and patisseries, along with some types of confectionery. Wood is also used to manufacture certain tableware and kitchenware, such as cooking utensils, serving bowls or chopping boards. Wooden crates and pallets are also used to transport and store food that has already been packaged and is therefore not in direct contact with the food.

The **European Confederation of Woodworking Industries (CEI-Bois (49))** represents 25 European and national federations from 16 countries and is the organisation backing the interests of the whole European industrial wood sector. CEI-Bois represents an industry with more than 184 000 companies generating an annual turnover of EUR 130 billion and employing 1.1 million workers in the EU. Another European organisation, the **European Federation of Wooden Pallet and Packaging Manufacturers (Fefpeb (50))**, represents national associations in the field of timber packaging (pallets, lightweight packaging and industrial packaging). No trade data were received.

According to Eurostat, among the EU MSs Sweden produced the most round-wood in 2014, followed by Finland, Germany and France. However it should be kept in mind that the EU's wood-based industries cover a range of downstream activities, including paper and board packaging materials. Within the EU's wood-based industries in 2012, the highest share was recorded for pulp, paper and paper products manufacturing (around

(49) www.cei-bois.org
 (50) www.fefpeb.org

one third or EUR 42 billion).

According to data from Pira, the **total value** of wood packaging in the EU in 2013 was approximately EUR 713 million, mostly relating to food contact packaging, a large majority of which was accounted for by France (80 %). The estimated **distribution of small enterprises** constitute over 50 % of sales, medium-sized 30 % and large making up the rest of the market (Figure 22). This is based on sales of casks, barrels, vats, tubs and cooperers' products and parts thereof of wood. Although this is a very small proportion of the total value of the European wood industry, it does not account for downstream use of wood in FCMs and is unlikely to include all uses of wood in FCMs. For example, information is available from Trademap and Prodcum via the market intelligence report on wooden tableware and kitchenware (salad sets) ⁽⁵¹⁾ of the Centre for Promotion of Imports from developing countries (CBI), which indicates that European imports of wooden tableware and kitchenware in 2014 were estimated at around EUR 342 million, with China being the leading supplier. European production was estimated at around EUR 154 million in 2013, with consumption at around EUR 281 million.

Data are also available from Europen from 2011 on **volumes** of wood packaging placed on the EU market but are not comparable to the values reported by Pira in 2013. 12 381 000 tonnes of wood packaging was placed on the EU market in 2011, with Germany, France, Italy, Poland and United Kingdom being the main contributors, as illustrated in Figure 21 below, although the volumes and sales do not always tally, likely owing to the fact that Europen data include all wood rather than wood for FCMs alone.

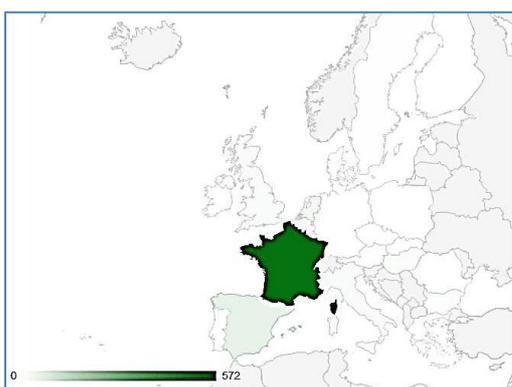


Figure 21: Approximate annual volumes and sales of FCM wood by EU Member State

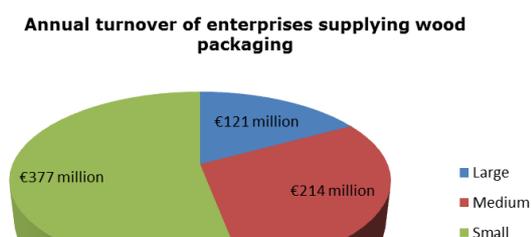


Figure 22: Estimated sales of enterprises supplying FCM wood. Total c. EUR 712 million (source: Pira, 2013)

No further information was found on the proportion of wood used as FCMs or the different proportions of enterprises.

Plastics

Plastic is the general term for a synthetic material made from a wide range of organic polymers. The two main types of plastics are thermosets, which do not soften once they have been moulded, and thermoplastics, which soften upon heating. Examples of thermoplastics include polycarbonate (PC), polyethylene terephthalate (PET) and polystyrene (PS). Plastic is used extensively for FCMs at most if not all stages of the food supply chain: in the industrial and processing environment, in storage and transport, in the domestic environment as kitchenware and tableware and for plastic packaging, which represents almost 39 % of the European plastics market.

The plastics industry value chain can be divided into broad segments, including plastic producers, plastic converters and plastic product distributors and users. **PlasticsEurope** ⁽⁵²⁾ is a pan-European trade association representing European plastics

⁽⁵¹⁾ www.cbi.eu/market-information
⁽⁵²⁾ www.plasticseurope.org

manufacturers. PlasticsEurope has 53 member companies, all of whom are large enterprises. The members of PlasticsEurope that **supply** food contact (plastics) resins represent manufacturers of plastic intermediate materials. PlasticsEurope members supply food contact (plastics) resins to plastics converters, which represent the manufacturers of final plastic FCM or articles. In some cases, the members can also supply food contact (plastics) resins to manufacturers of plastic intermediate materials.

European Plastics Converters (EuPC⁽⁵³⁾) represents the plastic converters who form the plastic resins and compounds into finished products. EuPC represents about 51 European plastics-converting national and European industry associations.

Flexible Packaging Europe (FPE⁽⁵⁴⁾) represents the flexible packaging industry at European and international levels. It has 70 members, with a number of companies operating multiple sites in more than one country. In addition, five national associations (France, Italy, Spain, Turkey and the United Kingdom) are associate members, representing a further 120 companies. FPE members use raw materials as in Table 2.

Table 2: Overview of supply chain for FPE members

| Type | Subtype |
|-----------------------|---|
| Webs (on the reel) | Aluminium foil, Paper and board, Regenerated cellulose film (RCF) Plastic films and sheet, including metallised products |
| Granules/other solids | Plastic resins, waxes, masterbatches |
| 'Wets' | Solvents, printing inks, adhesives and primers Coatings (lacquers, varnishes, sealants) |

With the possible exception of solvents, the great majority of these materials are bought directly from the manufacturer. In addition, 20 % of FPE members' flexible products are multimaterials (e.g. combining plastic with aluminium or plastic with paper). Less than 10 % of their production is 100 % plastic, over 60 % contains inks and over 25 % contains an adhesive. A diagram from the FPE guide is reproduced in Figure 23. The great majority of production is supplied in reels to the food packer, yet a significant minority find another route to market (e.g. printing by a third party, made into pouches or bags, die cuts (made into lids or sheeted), made into laminate tubes, used as a liner for composite cans, used as a peelable membrane for metal cans or used to make lined cartons). A small proportion is sold to distributors. They can supply food packers, usually in a smaller 'artisanal' category, the catering industry and the consumer.

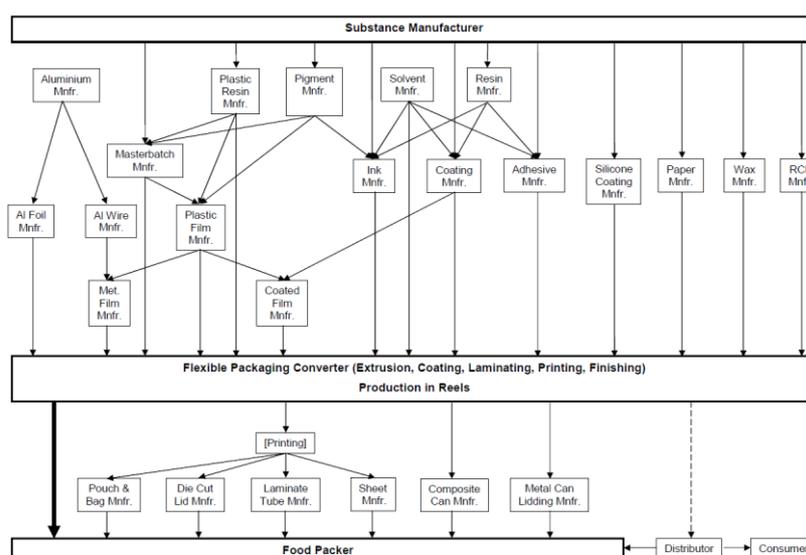


Figure 23: Supply chain for flexible plastics sector as represented by FPE in its guidance

⁽⁵³⁾ www.plasticsconverters.eu

⁽⁵⁴⁾ www.flexpack-europe.org

PETcore Europe ⁽⁵⁵⁾ is the trade association representing the whole PET value chain in Europe, from PET manufacture to conversion into packaging and recycling, and associated equipment. The membership of the association is made up of four leading industry sector European associations, i.e. the PET resin producers represented by the Committee of PET Manufacturers in Europe (CPME ⁽⁵⁶⁾), EuPC including Forum PET Europe and EuPET (the converters), the recyclers represented by Plastics Recyclers Europe (EuPR ⁽⁵⁷⁾), along with several individual companies involved in the value chain. Petcore Europe also works together with other downstream users such as packers, fillers and retailers.

Additional specific European professional organisations exist, such as the European Federation of Bottled Waters (EFBW ⁽⁵⁸⁾) representing bottled water producers, bottlers and companies at European and international levels; the European Polyvinyl Film Manufactures Association (EPFMA ⁽⁵⁹⁾) representing the major PVC cling film producers in Europe; the Packaging Recovery Organisation Europe (PRO Europe ⁽⁶⁰⁾), which is the umbrella organisation for European packaging and packaging waste recovery and recycling schemes – this includes 31 member organisations active in 31 countries, with 28 packaging recovery organisations in 28 countries.

According to 2011 European data, 14 495 000 tonnes of plastic packaging was placed on the market, a value that has remained relatively stable since 2005, with most of the contribution coming from the MSs of the EU prior to 2004. Euromonitor data also confirms the relative contributions from different MSs. Data from Pira indicates that, in total, **sales** of plastic FCM packaging for the EU per year are around EUR 30 billion. This is divided further into rigid plastic packaging (around EUR 19 billion) and flexible plastic packaging (around EUR 11 billion). The volumes (Euromonitor data) are illustrated in Figure 24, where Germany, Italy, France, the United Kingdom and Spain have the greatest share. Values (Pira data) also show a similar trend.

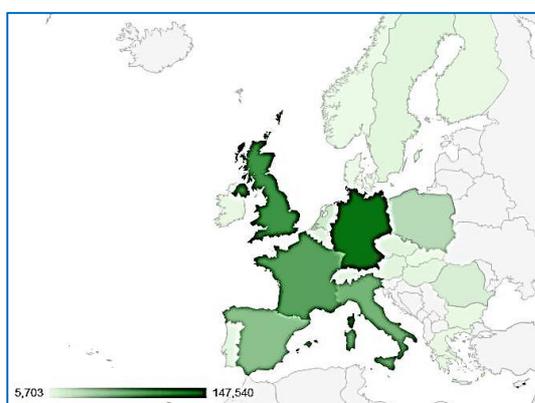


Figure 24: Approximate annual volumes and sales of FCM plastic packaging by EU Member State

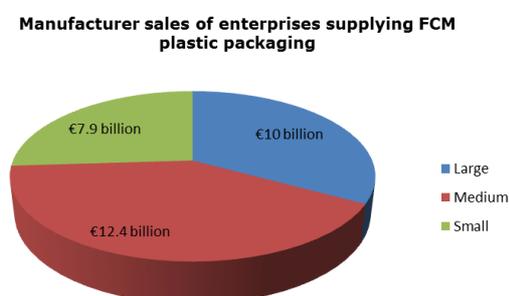


Figure 25: Approximate manufacturer sales of enterprises supplying plastic FCM packaging. Total sales estimated at EUR 30.3 billion (source: Pira, 2013)

No data was received from plastic Europe. EUPC quoted the production of 45 million tonnes of plastic products each year, mainly from small and medium-sized companies in the converting sector, to create a turnover in excess of EUR 280 billion per year. Conversely, FPE members have an estimated annual turnover of about EUR 12 billion, which is about 75 % of the market. 53 % of the members are large companies and 47 % are medium-sized enterprises. FPE estimates the European market

⁽⁵⁵⁾ www.petcore.org
⁽⁵⁶⁾ www.cpme-pet.org
⁽⁵⁷⁾ www.plasticsrecyclers.eu
⁽⁵⁸⁾ www.efbw.eu
⁽⁵⁹⁾ www.epfma.org
⁽⁶⁰⁾ www.pro-e.org

for 'added value' flexible packaging to be around EUR 12.5 billion. The 'added value' part of the definition excludes items such as stretch and shrink wrap, carrier bags, lightweight grocery bags used in store for fruit, vegetables and meat, and heavy duty sacks and liners for industrial containers. Around 75 % of the value is for food contact.

Concerning the **distribution of the size of different enterprises**, data from Pira for 2013 suggest that the share of EU manufacturer sales for plastic FCM packaging is relatively evenly distributed between small (26 %), medium-sized (41 %) and large enterprises (33 %), which is illustrated in Figure 25. Given the emphasis on packaging from the Pira data, it is again possible that the volumes and values discussed above may underestimate somewhat the overall size of the plastics market for all FCMs.

Rubbers and elastomers

Rubber falls into two broad types: natural rubber (latex from plants) and synthetic rubber synthesised using petrochemicals. Vulcanisation is often used as a chemical process by which the physical properties of natural or synthetic rubber are improved; finished rubber has higher tensile strength and resistance to swelling and abrasion, and is elastic over a greater range of temperatures. In its simplest form, vulcanisation is achieved by heating rubber with sulphur. Rubber articles are flexible, resilient, mechanically strong and durable. Rubber materials are used in contact with food for applications mainly associated with food processing/handling. The main food contact applications are conveyer belts, hoses, tubing, rotating transport rollers and rolling mills, handling applications such as gloves, machinery components such as seals and gaskets, general seals used in machinery and storage vessels, sealants for cans and bottles, teats for baby feeding and household appliances including seals in pressure cookers.

The **European Tyre and Rubber Manufacturer Association (ETRMA⁽⁶¹⁾)** represents seven national associations in Belgium, Germany, Spain, France, Italy, the Netherlands and Finland, along with corporate members. ETRMA states that its primary objective is to represent the regulatory and related interests of the European tyre and rubber manufacturers at both European and international levels. The **International Institute of Synthetic Rubber Producers (IISRP⁽⁶²⁾)** is also an international non-profit trade association with more than 50 producers/members in 23 countries worldwide.

With regard to the **supply chain**, ETRMA's suppliers are chemical manufacturers. ETRMA supplies both finished and semi-finished products (such as seals) to industry, distributors, retailers and final users. IISRP's suppliers are substance manufacturers (manufacturers or suppliers of monomers, additives, catalysts, fillers, polymer production aids, packaging and equipment manufacturers, etc.); their converters are the manufacturers of final rubber material and articles, for example tyres and tyre products, wire and cable coating, adhesives and sealants, footwear and elastomeric roofing membranes and bitumen modification. No information specifically on the use of rubber in FCMs was available from the commercial databases used. According to ETRMA, the annual production of general rubber goods was around 2.6 million tonnes in 2013. General rubber products are mainly used in non-food sectors such as the automotive and transport industries, household appliances and industrial applications. The food contact, drinking water and baby care/medical devices sector represents only 4-5 %.

The **annual turnover** for the general rubber goods sector, excluding tyres and imports, is in the region of EUR 18 billion, with the FCM sector a small proportion of that, i.e. possibly in the region of EUR 500 million.

ETRMA state that the **distribution of the size of enterprises** is estimated as 2 % of the members being large companies and 98 % being SMEs, many of which are micro enterprises (Figure 26). The membership of ETRMA represents c.80 % of the sector's enterprises. Large, medium-sized, small and micro companies account for 50 %, 15 %, 15 %, and 20 % respectively.

⁽⁶¹⁾ www.etrma.org

⁽⁶²⁾ <http://iisrp.com>

25 % and 10 %, respectively, of the annual turnover. IISRP producers represent more than 80 % of global synthetic rubber capacity. Large and medium-sized companies account for 57 % and 43 %, respectively, of the annual turnover (Figure 27). Production is 2 450 200 tonnes (in production capacity), with FCM representing 10-15 % in the EU.

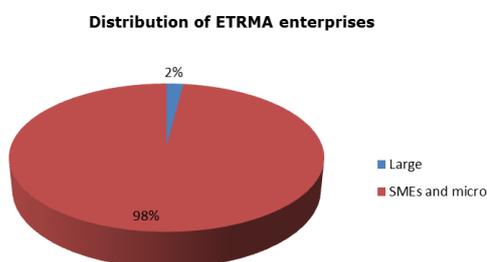


Figure 26: Approximate distribution of different types of enterprises represented by ETRMA producing rubber in Europe (FCMs, baby care, medical devices and drinking water products c.4-5 %)

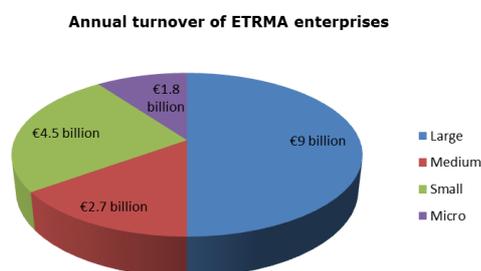


Figure 27: Approximate annual turnover of different types of enterprises represented by ETRMA producing general rubber goods in Europe (FCMs, baby care, medical devices and drinking water products c.4-5 %)

Silicones

Silicones are polymers that include any inert, synthetic compound made up of repeating units of siloxane, which is a chain of alternating silicon atoms and oxygen atoms, frequently combined with carbon and/or hydrogen. They are typically heat resistant and rubber like, and are used in sealants, adhesives, lubricants, medicine and thermal and electrical insulation. Silicone is used in the cookware industry, particularly for bakeware and kitchen utensils such as baking or freezing moulds, bottle teats, oven gloves, spatulas, sippy cups, food containers, steamers, egg boilers or poachers, cookware lids, pot holders, trivets and kitchen mats.

CES – Silicones Europe ⁽⁶³⁾ is a non-profit trade organisation representing all major manufacturers of starting materials and importers. It has six members, which are all large enterprises. All silicone producers located in Europe are members of CEFIC-CES and they represent 100 % of the market. Total **sales** of silicones in Europe are estimated at EUR 2.5 billion a year. accounting for around 10 000 jobs. It is not known what proportion of this is FCM but it is likely to be relatively small. **No distribution** was available across sizes of enterprises.

In terms of the **supply chain**, CEFIC-CES members are producers of silicone starting materials. Customers are any downstream users or converters of such materials, supplying to all sectors manufacturing FCMs and typically intermediate manufacturers. In some cases the raw materials are supplied directly to the final converter.

2.5.3. Food cutlery, kitchenware cookware and equipment

The **Federation of the European cutlery, flatware, holloware and cookware industries (FEC)** ⁽⁶⁴⁾ represents these different sectors across Europe. In relation to FCMs, this includes kitchen and professional knives, metallised flatware and holloware including stainless steel and metallised cookware such as cake moulds and miscellaneous household items including coffee makers, kitchen gadgets and party utensils. Its professional associations or companies are established in Belgium, Croatia, Denmark, France, Germany, Italy, the Netherlands and Switzerland. Most of the national associations and members are involved in all four sectors. There are 76 active members of FEC and 25-40 members that are partially active or inactive. According to FEC, more than 50 % of its members' activities are related to culinary products such as pots and

⁽⁶³⁾ www.silicones.eu

⁽⁶⁴⁾ www.fecinfo.org

pans, cutlery and serveware (forks, spoons, knives, etc.) made of different metals as a base material. A significant percentage of companies sell tableware such as plates, cups and drinking utensils made of different materials such as stone, ceramics, porcelain and glass or specific products such as salt and peppermills or coffee and tea pots. According to FEC, the **distribution of the size of enterprises** shows that approximately 90 % of the active members are producing only for food contact. FEC members include 15 % large enterprises, 35 % medium-sized and 50 % small (Figure 28). Large, medium-sized and small companies account for 50 %, 30 % and 20 %, respectively, of the annual turnover (Figure 29). About 15 % of the large companies, 30 % of the medium-sized and 50 % of the small enterprises are not members of FEC.

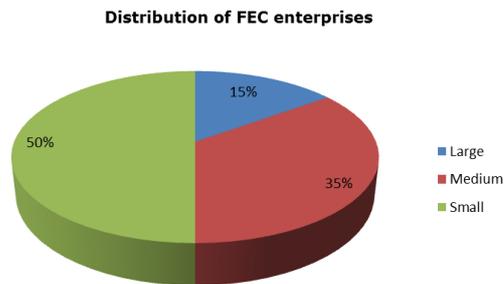


Figure 28: Approximate distribution of different types of enterprises represented by FEC producing cutlery, flatware, holloware and cookware in Europe

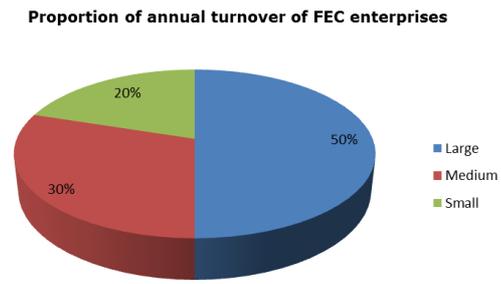


Figure 29: Approximate proportion of annual turnover of different types of enterprises represented by FEC producing cutlery, flatware, holloware and cookware in Europe

With regard to actors in the **supply chain**, FEC suppliers are the most diverse companies, and include steel and stainless steel manufacturers, non-ferro suppliers, raw materials for stoneware, ceramics, porcelain, glass/sand, wood, plastics, coatings for surface treatments, including non-stick, silicones, adhesives, tool/machine suppliers etc.

The **European Committee of Domestic Equipment Manufacturers (CECED⁽⁶⁵⁾)** represents the household appliance manufacturing industry. Its member companies are mainly based in Europe. CECED's member associations cover the majority of European countries, along with Turkey and Russia, and it also has a number of direct member companies. CECED members produce appliances such as refrigerators, freezers, ovens and toasters, along with heating, ventilation and cleaning appliances. The total annual turnover of the industry in Europe is EUR 48 billion (2013), although it is not known what proportion of this is relevant to FCMs. Large members cover about 80 % of the turnover, while medium-sized members cover about 95 % of the market. With regard to the supply chain, CECED suppliers are producers of plastic materials, metal and alloys, wood, enamel/ceramic, coatings, glass, multilayer materials, silicone rubbers, paper, inks and ion-exchange resins. CECED supplies end users through wholesalers' chains.

The **European Vending Association (EVA⁽⁶⁶⁾)** is a not-for-profit organisation that represents the interests of around 80 % of the European coffee service and vending industry. The EVA has 14 national vending associations and 76 companies as members. FCMs included in the vending machines include internal water pipes, product canisters, coffee canisters, grinders, mixing bowls and disposables (including cups), and in total are estimated to make up around 40 % of machine parts. EVA indicates there are 3.8 million machines in Europe, representing an annual turnover of EUR 11.3 billion, with 75 % of machines located in the workplace and 25 % in public locations. Around 60 % of the market is hot beverage machines, 17 % is for cold drinks and 23 % is glass-front snack machines. EVA estimates a distribution of around 50 % SMEs and 50 % large companies.

⁽⁶⁵⁾ www.ceced.eu
⁽⁶⁶⁾ www.vending-europe.eu

2.5.4. Other

The **International Technical Centre for Bottling and related Packaging (CETIE⁽⁶⁷⁾)** is a professional association that publishes technical reference documents for bottling in the food and beverage, cosmetics and perfumes, and pharmaceutical sectors. No data related to FCMs was found or received. The **World Association of Manufacturers of Bottles and Teats (WBT⁽⁶⁸⁾)** has 15 members and covers about 80 % of the market. 1 % are large enterprises and the rest are medium-sized companies. Around 67 % is relevant for FCMs. WBT suppliers are manufacturers of plastic raw materials or finished articles or of elastomer. WBT members supply finished products to wholesale retail/supermarkets, pharmacies, baby shops and directly to consumers (internet sales).

Euratex⁽⁶⁹⁾ is the European Apparel and Textile Confederation representing the interests of the European textile and clothing industry. Euratex member federations represent some 174 000 companies in the EU with a turnover of EUR 162 billion. The EU is the second largest world exporter of textiles and clothing, with extra-EU exports reaching 28 % in 2014. No information was available on relevance to FCMs.

EDANA⁽⁷⁰⁾ is the international association serving the nonwovens and related industries. Member companies produce everything from raw materials to finished products, including roll goods (nonwovens, films, laminates and composites), converters (including absorbent hygiene products, medical, wipes, filtration, construction, automotive), chemicals/polymers (including binders, SAP, treatments), fibres and filaments. EDANA unifies over 240 member companies along the supply chain. No data related to FCMs was found or received.

The **European Association of Craft, Small and Medium-Sized Enterprises (Ueapme⁽⁷¹⁾)** is the European SME umbrella organisation. It incorporates around 80 member organisations from 34 countries consisting of national cross-sectorial SME federations, European branch federations and other associate members, which support the SME family. Ueapme represents more than 12 million enterprises across Europe. No information related to trade details on FCM was available or received.

The trade and industry group **Normpack⁽⁷²⁾** has around 200 members representing all production stages in the value chain, including producers of raw materials and final FCMs, the food industry and wholesale/retail. The Normpack system is based on self-assessment, helping its members to take the legal responsibility for FCMs. This help is provided in the form of advice, training and various tools and guides for interpreting regulations. The Normpack Norm is the framework for Normpack's operations. The standard has been developed in collaboration with the member companies and relevant authorities, and is based on Swedish and EU legislation. Warenwet (Netherlands), BfR (Germany) and FDA (United States) regulations are also applied. Around 70 % are large companies and 30 % are medium-sized enterprises.

2.6. Overview

Table 3 below summarises the values and distributions of different-sized enterprises for each material. The figures are based on information from Pira where this was available and supplemented for other sectors by information provided by European professional associations. It illustrates EU manufacturing sales per annum of different packaging materials, cutlery and FCM machinery and revenue share by size of enterprise. Small/SME shares may also include micro enterprises. The EUR figure for rubber is a

⁽⁶⁷⁾ www.cetie.org

⁽⁶⁸⁾ www.thewbt.org

⁽⁶⁹⁾ www.euratex.eu

⁽⁷⁰⁾ www.edana.org

⁽⁷¹⁾ www.ueapme.com

⁽⁷²⁾ www.normpack.se

maximum estimate based on the value of the rubber industry. Little or no information was available for regenerated cellulose, ion-exchange resins, silicones, textiles and waxes.

Table 3: EU manufacturing sales per annum of different packaging materials, cutlery and FCM machinery and revenue share by size of enterprise. Small/SME shares may also include micro enterprises

| Material | Million EUR | % EUR small enterprises | % EUR medium-sized enterprises | % EUR large enterprises | Source |
|---------------------------|-------------|-------------------------|--------------------------------|-------------------------|--------------|
| Plastic | 30 029 | 26 | 41 | 33 | Pira 2013 |
| Paper | 26 713 | 30 | 35 | 35 | Pira 2013 |
| Glass | 20 000 | 13 | 19 | 68 | GAE/Pira2013 |
| Metals | 7 068 | 16 | 42 | 42 | Pira 2013 |
| Printing inks | 1 300 | 6 | 14 | 80 | EuPIA |
| Cork | 1 216 | 52 | 25 | 23 | Pira 2013 |
| Adhesives | 1 200 | 35 | 15 | 50 | FEICA |
| Ceramic & porcelain | 915 | 18 | 27 | 55 | Pira 2013 |
| Wood | 713 | 53 | 30 | 17 | Pira 2013 |
| Rubber | 500 | 35 | 15 | 50 | ETRMA |
| Varnishes & coatings | 400 | 5 | 0 | 95 | CEPE |
| Cutlery | 202 | 50 | 30 | 20 | Pira 2013 |
| General-purpose machinery | 11 134 | 24 | 33 | 43 | Pira 2013 |
| Special-purpose machinery | 12 572 | 27 | 32 | 41 | Pira 2013 |

In the table, general-purpose machinery includes machinery for cleaning or drying bottles or other containers for filling, closing, sealing, capsuling or labelling bottles, cans, boxes, bags or other containers, machinery for aerating beverages and for packing or wrapping (excluding for filling, closing, sealing, capsuling or labelling bottles, cans, boxes, bags or other containers). Special-purpose machinery includes a wide range of non-domestic industrial machinery, including that used in the dairy industry such as homogenisers and cheese makers, in the milling industry (excluding farm machinery), bakery ovens, presses and crushes used in the beverage industry, brewing equipment, cookers, heaters and dryers, processing and preparation machinery and machinery used for the cleaning, sorting and extraction of food.

Whilst it is difficult to estimate with precision the overall value of the FCM industries in total, the figures above indicate that it is likely to be somewhere in the region of EUR 100 billion per annum. Whilst some of the information provided above may be an overestimation, for example due to some double counting, some industries are not included as no data were available. Furthermore, it is possible that some of the estimations for major material packaging sectors do not include reusable domestic materials and articles, such as plastic, glass or metallised kitchenware and tableware.

Focusing on values, the data indicate that plastic has the highest share of manufacturer sales (EUR 30 billion), with paper and board having a similarly significant turnover (EUR 26 billion). The glass sector is also significant (EUR 7 or 20 billion according to either Pira or GAE). General- and special-purpose machinery are, according to Pira, also significant for FCM, and together may make up approximately one quarter (in the range of EUR 11 billion each) of the overall FCM market. Although considerably lower, metal and alloy packaging is relevant (EUR 7 billion). Sales for many of the other materials, such as ceramic, cork and wood, along with printing inks and adhesives, are in the EUR 1 billion range, with rubber, varnishes and coatings estimated as being slightly less.

The sales of the different materials vary greatly from country to country, with Germany, France and Italy often being the leaders for most of the materials. The United Kingdom, Spain and Poland also present high sales for most of the materials. This confirms the conclusions reached from the Euromonitor data on the market leaders. The most notable deviations from this pattern are represented by sales of flexible paper packaging for Sweden and cork for Portugal (which represents over half of sales concentrated in only a

handful of countries).

Table 3 also illustrates the breakdown of sales according to the size of the enterprises. The data were preferentially taken from Pira for 2013, but where these data did not exist the information was taken from the data provided by the European professional organisations, where this was given.

The market share of EU manufacturer sales for SMEs and large enterprises varies from material to material. For the two highest-value sectors, i.e. paper and plastic, the distribution of small, medium-sized and large enterprises in the market is comparable and relatively evenly split, with a slight predominance of sales from medium-sized enterprises for plastics. However, it should be noted that these figures relate to values rather than the number of enterprises, and information from CEPI indicates that only a handful of large enterprises exist (most members are SMEs). This is also demonstrated by ECMA members, for whom only 15 % of revenue is estimated to come from small enterprises although the majority of its members (70 %) are small enterprises.

For glass packaging, the market share of EU manufacturers' sales seems to be in the hands of large enterprises, with around a two-thirds share. For metal packaging large and medium-sized enterprises dominate, with around a 42 % share each. For general- and special-purpose machinery large and medium-sized enterprises also tend to dominate, although small enterprises still make up around one quarter of sales. On the other hand, some markets are more strongly represented by small enterprises: for cork and wood they represent at least 50 % of market sales, with up to 77 % and 83 % respectively for SMEs. Sales by large enterprises constitute only one quarter of the market for cork FCMs and less than 20 % for wood packaging.

For some materials large manufacturers take up a significant proportion of sales, for example varnishes and coatings (95 %), printing inks (80 %), glass (68 %) and adhesives (50 %), whilst for others the proportion between small, medium-sized and large enterprises is relatively equally split, such as for paper and board and metals where, collectively, small and medium-sized enterprises make up a large proportion. In contrast with the distribution of the size of enterprises based on manufacturing sales, the landscape is different when looking at the numbers of enterprises of different sizes. In many cases SMEs make up a significant proportion of the actual number of businesses. For example, for adhesives, most members of FEICA are micro businesses (60 %), with another 36 % accounted for by SMEs and only 4 % by large enterprises. Similarly, only 10 % of EuPIA members are large enterprises, yet they make up around 80 % of the turnover. Around 80 % of Ceram-unie members are SMEs, yet according to Pira they represent less than 50 % of the sales for ceramic kitchenware, although this is still a significant proportion of the market.

3. Analysis of availability and contents of national/supranational measures and industry self-regulation

3.1. Introduction

The basic rule in EU food legislation specifies that only safe food shall be placed on the market (general food law ⁽⁷³⁾, Article 14). Consequently, Article 3 of the FCM framework regulation (Regulation EC No 1935/2004) states that FCMs shall be manufactured under GMP so that they do not transfer their substances into food in concentrations that could endanger human health or bring about an unacceptable change in the composition or a deterioration in the organoleptic properties of the food. Official controls fall under the general regulation of official feed and food controls according to Regulation (EC) No 882/2004 ⁽⁷⁴⁾.

The regulation also gives the possibility for specific measures to be introduced at EU level, such as lists of authorised substances. Whilst MSs are responsible for the implementation and enforcement of EU and national legislation, the main players to ensure safety as regards FCMs are all businesses carrying out activities related to any stage of the manufacture, processing or distribution of FCMs. Further rules exist on labelling, traceability and the need for sanctions in the case of non-compliance.

At EU level, substances used in FCMs must be authorised where the substances are evaluated by EFSA as the risk assessor based on toxicological as well as exposure data. The risk management — authorisation and any other specific measures such as legal limits or special conditions of the use of substances or material — is then carried out by the European Commission. The materials must subsequently be demonstrated to be compliant with the rules by appropriate experimental or equivalent tests that form part of the documents supporting a declaration of compliance (DoC). It is the responsibility of the business operator to provide the DoC to the next actor in the chain. This implies the necessity for an efficient dialogue between these actors to achieve compliance with the legislation. For plastic FCMs, the European Commission has published a number of guidelines ⁽⁷⁵⁾ to help business operators to comply with this obligation.

As already noted, the absence of such specific measures at EU level does not prevent MSs from maintaining or adopting national provisions provided that they comply with the Treaty of the Functioning of the European Union. Rules or standards may also exist at the 'supranational' level, covering more than one country. In addition, industry codes of practice or guidance may exist, since all business operators have the responsibility to ensure FCMs are safe and comply with the other basic requirements at EU level.

The framework regulation also states that MSs shall carry out official controls in order to carry out enforcement in accordance with relevant provisions of Union law relating to official feed and food controls. Such controls fall under Regulation (EC) No 882/2004 on official feed and food controls (OFFC). The OFFC regulation establishes a hierarchy of methods used for sampling and analysis for official controls. A system involving a European Union reference laboratory (EURL) and national reference laboratories (NRLs) has been established under the OFFC to achieve uniformity in the application and the performance of laboratories in the official controls. This system became fully functional in 2006, and for FCMs the Joint Research Centre is acting as the EURL.

3.2. Objectives

The objective of this work package was to compile existing available regulatory

⁽⁷³⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council.

⁽⁷⁴⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council.

⁽⁷⁵⁾ Union Guidelines on Regulation (EU) No 10/2011, 2014 and Union Guidance on Regulation (EU) No 10/2011 as regards information in the supply chain, 2013.

frameworks at national level such as national legislation, recommendations, guidance documents or guidelines, scientific opinions or other reference documents or standards that are used in the EU and European Economic Area countries for managing chemical risks from FCMs. It included supranational documents such as from the Council of Europe (CoE) ⁽⁷⁶⁾ or Norden ⁽⁷⁷⁾. It also included guidelines and reference documents produced by sectorial associations or industries, for example guidance related to registration of business operators, declarations of compliance, certification systems, provisions on GMP or risk assessment for the authorisation of substances.

3.3. Materials and methods

The starting point was DG Health and Food Safety's 2011 list ⁽⁷⁸⁾ on **national provisions**. Searches were conducted of public websites (national authorities' official websites, CoE ⁽⁷⁹⁾, Norden ⁽⁸⁰⁾), the Decernis Database ⁽⁸¹⁾ and by direct requests to the Members States' competent authorities ⁽⁸²⁾ or via their NRLs ⁽⁸³⁾. Documents were retrieved in English where possible and/or in the original languages. Input was also sought with several (three to four) rounds of direct queries or questionnaires sent to stakeholders, which aimed to ensure information on regulatory measures and supporting tools was complete, up-to-date and correct.

The content of the measures collected for non-harmonised materials covered under Regulation EC No 1935/2004 was examined under both a generic standpoints (general requirement common to all FCMs) and from a material-specific standpoint (legislation or national guidance for specific individual materials).

The general requirements examined included registration of food contact businesses, documentation of compliance (and supporting documents), details on GMP, risk assessment prior to authorisation, legal provisions providing for sanctions, actions and enforcement (i.e. details on how to undertake official controls such as sampling, responsible control authorities and their tasks, descriptions of test methods used, if applicable) and certification systems (i.e. authorisation of laboratories to perform compliance testing, details on requirements for compliance testing laboratories).

The existence of rules or implementation tools specific to individual materials was examined more specifically. This included lists of authorised substances for use in manufacturing processes and/or banned substances. It also considered supporting tools such as limits for specific migration or release ⁽⁸⁴⁾ (SML, SML(T)), limits for overall migration (OML) ⁽⁸⁵⁾, residual limits or limits on the amounts that can be added in material such as a quantity in material, i.e. limits for extractable/residual content ⁽⁸⁶⁾ (QM, QM(T)) or per surface area QMA, QMA(T)) and compositional limits restricting the amount added to a material. It considered the nature of the substances regulated in different countries and restrictions imposed. It also included other documents such as recommendations, guidance, and scientific opinion provided by national bodies ranging from risk assessment to risk management.

⁽⁷⁶⁾ The Council of Europe (French: Conseil de l'Europe), or CoE, founded in 1949, is a regional intergovernmental organisation of 47 countries. Unlike the European Union, the CoE cannot emit binding laws.

⁽⁷⁷⁾ Norden represents a Nordic cooperation scheme that involves Denmark, Finland, Iceland, Norway and Sweden, along with the Faroe Islands, Greenland and the Åland Islands. The Nordic Council of Ministers is its official intergovernmental body.

⁽⁷⁸⁾ DG Health and Food Safety document 'INT/REF_LEG+Compend'(14/02/2011).

⁽⁷⁹⁾ <http://chp.edqm.eu/Packaging/>

⁽⁸⁰⁾ <http://www.norden.org/en> and <http://www.norden-ilibrary.org/>

⁽⁸¹⁾ <http://www.decernis.com/>. Searches were done by country, by materials.

⁽⁸²⁾ DG Health and Food Safety — addresses of European and national authorities (updated where applicable).

⁽⁸³⁾ <https://ec.europa.eu/jrc/en/eurl/food-contact-materials/network-laboratories>

⁽⁸⁴⁾ Specific migration limit (SML), the maximum the maximum amount of a component that may be allowed to migrate into the food, expressed in mg/6 dm² or mg/kg foodstuff.

⁽⁸⁵⁾ Overall migration (OM): total amount that migrates from a packaging to a food simulant expressed in mg/6dm² or mg/kg.

⁽⁸⁶⁾ Residual content — maximum permitted quantity of the substance in the finished material or article expressed as mg/kg of the finished article (QM).

An additional check was conducted to query whether the measures and tools collected were still in use and/or whether guidance from other countries or sources were applied in the absence of national measures or tools. Existing measures from non-EU countries were reviewed from peer-reviewed references or searches on the corresponding national websites (e.g. FDA, Japan, Mercosur and China). An overview of these can be found in Annex 20.

Regarding **GMP**, the information was collected from earlier research conducted in 2012 by DG Health and Food Safety and updates from desk research from an exchange with stakeholders with a focus on (1) GMP guidance documents from MSs (availability and summary of content) and (2) GMP guidance documents from professional associations (availability and summary of content). An exercise was also conducted with professional associations on the completeness and accuracy of GMP documents collected.

Regarding **risk assessment**, searches were conducted with a focus on EFSA ⁽⁸⁷⁾, national risk assessment bodies and international organisations such as the Organisation for Economic Cooperation and Development (OECD) ⁽⁸⁸⁾, the European Chemicals Agency (ECHA) ⁽⁸⁹⁾, Codex Alimentarius ⁽⁹⁰⁾, scientific committees and consultancies. Particular attention was paid to the information already collected in the EFSA report of the ESCO Scientific Cooperation ⁽⁹¹⁾ working group (therein EFSA ESCO report). An update on and confirmation of what schemes were applied to carry out risk assessments with respect to the statements reported in the EFSA ESCO report was done via queries to the national members of the Food Ingredient and Packaging (FIP) Network of EFSA.

For the industry sectors, the information was sought from the professional associations' (listed ⁽⁹²⁾) websites and from previous information collected in 2012 by DG Health and Food Safety. Additional direct questionnaires and queries were sent to cover incomplete or missing parts. Documents were collected, where applicable, on industry guidance for business operators (including traceability, codes of practice, safety, hygiene, etc.), sector-specific GMP and industry or consultancy documents related to risk assessment.

The **availability and content of the national measures** were analysed in a first phase with the documents in their original language, since those were the only ones available. The first part of the work consisted in finding the relations between the different pieces of legislation. Preliminary approximate machine translations allowed identification and categorisation of the implementation tools provided for (or not) by national legislation and whether references in overarching national measures were actually implemented by specific measures, which was not always the case. The result of this work enabled the organisation of the content of the IT tool on dedicated templates and the development of its structure. It should be noted that the excerpts were kept in their original language as it was the only one with the true and accurate information.

In order to derive a more in-depth analysis, more reliable translations were sought. Requests were made in end 2014 to the Commission's Directorate-General for Translation to have national measures translated into English from their respective national languages. As many texts exceeded 100 pages each, these translations could be of significant value not only for this baseline but also for future reference. However, the time to obtain these translations put a strain on the timeline of the final analysis.

The second phase of the work was dedicated to the analysis of content material by material and down to the level of the nature of substances regulated and their respective restriction levels in different MSs. Use was made of the EFSA ESCO report as a background work. The annexes to the ESCO report contained a list of substances for which a risk assessment evaluation had been made and was traceable to a MS and

⁽⁸⁷⁾ <http://www.efsa.europa.eu/>

⁽⁸⁸⁾ <http://www.oecd.org/>

⁽⁸⁹⁾ <http://echa.europa.eu/>

⁽⁹⁰⁾ <http://www.fao.org/fao-who-codexalimentarius/en/>

⁽⁹¹⁾ EFSA — Report of ESCO WG on non-plastic FCMs. Supporting publications 2012:139 [63 pp.].

⁽⁹²⁾ DG Health and Food Safety register of commission expert groups and other similar entities.

available. Lists were compiled by a group of experts for coatings, colorants, cork and wood, paper and board, printing inks, rubber and silicones. No common lists were compiled for adhesives, ceramics, glass, ion exchange resins, metals and alloys, multimaterials or wax. The presence of a substance included in the ESCO lists was based on the requirement of an evaluation prior to (list B) or after (list A) 1991 and based on the materials contributed by the experts. This was considered a valuable basis on which to review substances that are regulated by national measures (regardless of the availability and quality of a risk evaluation). A global update was undertaken in this study, which considers in a much larger sense the term 'regulated'. The tasks included validating the data contained in the ESCO lists, systematically analysing every available national documents of either legal or softer nature (along with CoE policy statements and guides) and compiling the corresponding data.

With regard to GMP, the content of the information found in guidance documents (either national or industrially produced) were tabulated according to information on raw materials, quality assurance (QA), quality control (QC) and the nature and extent of certification systems.

With regard to risk assessment the information and usage of general nature provided by industry and by risk assessment bodies were compiled as annexed data.

3.4. Risk assessment frameworks

Human exposure and the toxicity of the substance(s) used in the formulation of FCMs are the two main components that constitute a risk assessment in relation to human health. This section presents a general overview of the risk and exposure assessment approaches from EFSA⁽⁹³⁾ and on practices of national bodies as reported by the members of the EFSA network to JRC queries. It also includes information collected from the industrial professional associations.

3.4.1. The European Food Safety Authority (EFSA)

EFSA has published guidelines on the authorisation process for substances in materials that are regulated at EU level, i.e. plastics⁽⁹⁴⁾ and active and intelligent substances⁽⁹⁵⁾. EFSA has also published a guidance document for recycling processes⁽⁹⁶⁾ to produce recycled plastic to be used in contact with food, which contained criteria⁽⁹⁷⁾ to be used for the safety evaluation of a mechanical recycling process to produce recycled PET.

EFSA has published several documents on the risk assessment of chemicals in general and that may be of relevance to substances present in food as a result of migration from FCMs. These include documents on the use of the concept of threshold of toxicological concern⁽⁹⁸⁾ (TTC), on human risk assessment of combined exposure to multiple chemicals⁽⁹⁹⁾, on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain⁽¹⁰⁰⁾, on risk assessment terminology⁽¹⁰¹⁾,

⁽⁹³⁾ It should be noted that, in Europe, risk assessment was conducted by the Scientific Committee for Food (SCF) from 1991 to 2002. Since 2002, Regulation (EC) No 178/2002 (general food law) has established EFSA as the independent EU body that conducts risk assessments related to food safety. The FCM framework legislation also states that provisions liable to affect public health shall be adopted after consulting EFSA. The SCF introduced a tiered approach for risk assessment of plastic FCMs, which is still used by EFSA.

⁽⁹⁴⁾ EFSA — Guidance document on the submission of a dossier on a substance to be used in FCMs for evaluation, j.efsa.2008.21r.

⁽⁹⁵⁾ EFSA — Guidelines on submission of a dossier for safety evaluation by EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food. j.efsa.2009.1208.

⁽⁹⁶⁾ EFSA — Guidelines on submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food — j.efsa.2008.717.

⁽⁹⁷⁾ EFSA — Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184.

⁽⁹⁸⁾ EFSA — Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree.

⁽⁹⁹⁾ International frameworks dealing with human risk assessment of combined exposure to multiple chemicals, j.efsa.2013.3313.

⁽¹⁰⁰⁾ EFSA — Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed

on genotoxicity testing strategies applicable to food and feed (¹⁰²), on proposed harmonised default values for use in risk assessment (¹⁰³) and on the applicability of the margin of exposure approach for impurities which are both genotoxic and carcinogenic (¹⁰⁴). EFSA also has a comprehensive European food consumption database (¹⁰⁵) that feeds into the exposure part of the risk assessment.

EFSA recently published a report on developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials (¹⁰⁶), which also addresses a potential impact on EFSA's processes.

An EFSA Scientific Cooperation Working Group collected information on non-plastic FCMs to anticipate emergency situations linked to the potential presence in food of substances released from FCMs (ESCO report).

3.4.2. National and professional guidance in the EU

The EFSA ESCO report analysed the situation and risk assessment approaches in European countries in its Section III.A, 'Overview of the risk assessment and of the national Regulations, as provided by the MSs'. JRC desk research used this information along with two rounds of feedback from EFSA's FIP-network and NRLs. The information from these sources in regard to risk assessment is included in Annex 3.

Risk assessment bodies for food contact issues can be identified for Belgium, the Czech Republic, Germany, Greece, Spain, France, Croatia, Italy, Lithuania, Hungary, the Netherlands, Norway, Poland, Finland and Switzerland, whereas Luxembourg reported not having a risk assessment body. Slovakia does risk assessment as part of the work of its NRL for FCMs.

Risk assessment procedures specific to food contact are in place for 10 countries (Austria, the Czech Republic, Denmark, France, Germany, Italy, the Netherlands, Poland, Slovenia and Switzerland), and they perform assessments.

Thirteen MSs report that they have a risk assessment procedure but few or no assessments have been done, or that they have a process not specifically designed for FCMs (Croatia, Cyprus, Finland, Greece, Hungary, Ireland, Latvia, Luxembourg, Norway, Slovakia, Spain, Sweden and the United Kingdom). Two MSs (Estonia, Lithuania) report that they are in the set-up phase of a risk assessment procedure for food safety. Figure 30 illustrates the extent of risk assessment in EU MSs.

A relevant proportion of MSs (40 %) report using the SCF-FCM guidelines and the EFSA note for guidance for plastic FCMs or a mix of EFSA or other references depending on the type of materials (for the non-harmonised ones). Examples include the Czech Republic, Germany, Ireland, France, Croatia, Italy, Hungary, the Netherlands, Austria, Slovakia, Finland, and Switzerland. Denmark, Cyprus and Slovenia state that they have their own approach.

chain, j.efsa.2011.2140.

(¹⁰¹) EFSA — Scientific Opinion on Risk Assessment Terminology, j.efsa.2012.2664.

(¹⁰²) EFSA — Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment, j.efsa.2011.2379.

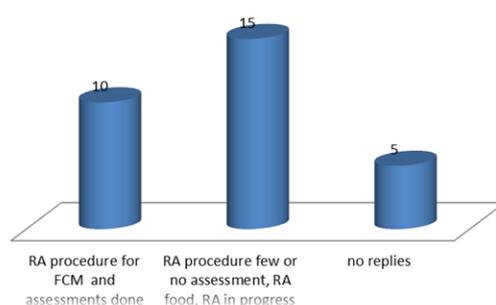
(¹⁰³) EFSA — Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data, efsa.2012.2579.

(¹⁰⁴) EFSA — Statement on the applicability of the Margin of Exposure approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food/feed, j.efsa.2012.2578.

(¹⁰⁵) EFSA — Use of EFSA Comprehensive European Food Consumption Database for estimating dietary exposure to genetically modified foods, j.efsa.2015.4034.

(¹⁰⁶) EFSA — Scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials, j.efsa.2016.4357.

Figure 30: RA extent in EU + Norway and Switzerland



Two types of risk assessment approaches for FCMs are identified. One approach is to assess the risk of the individual substances used in FCMs, to allow risk management decisions to be made on the relevant restrictions or absence of restrictions (in legislation or recommendations). This goes in conjunction with the assessment of the risks of non-compliance during official controls and possible follow-up RASFF notifications. Countries that follow this approach are the Czech Republic, Denmark, France, Germany, Italy, Norway, Poland, the Netherlands and Switzerland. The Czech Republic, France, Germany, Italy, the Netherlands, Poland and Switzerland report that they use the SCF-FCM guidelines and/or the EFSA note for guidance for plastic FCMs in the risk assessment of a substance.

The other main risk assessment approach cited is to focus on the assessment of the risks of non-compliance in official controls and RASFF notifications only. MSs using this approach, such as Finland, Ireland, Greece, Croatia, Cyprus, Latvia, Luxembourg, Hungary, Austria, Slovenia and the United Kingdom, may use all types of sources for assessing the risk of non-compliance, including risk assessment information from other MSs. The information given by Belgium and Cyprus does not allow categorisation of their risk assessment approach yet.

Considering **national risk assessment procedures with respect to those of EFSA**, specific protocols for authorisation of FCM substances developed at national level appear to differ to some extent from the EFSA procedure in the case of non-harmonised FCMs. The main deviations that could be identified in the context of this study are on the exposure assessment (Germany, the Netherlands), migration testing (Italy, the Netherlands, Switzerland) and toxicity data (France, the Netherlands).

Germany has specific guidance for the determination of exposure to (chemical) substances from paper and board. France states in the ESCO report that a substantial proportion of substances on the lists of authorised substances have been evaluated on the basis of a reduced dossier not in agreement with the SCF guidelines. The Netherlands notes that it has accepted, on a case-by-case basis, toxicity data sets deviating from the EFSA requirements in cases where the data was considered adequate to demonstrate the safe use of the substance.

MSs may use other MSs' or the CoE's restrictions on substances to set up their own lists of authorised substances. This implies that they recognise the risk assessment and management of that MS or of the CoE. It should be noted that proper documentation on the specific protocols on risk assessment by national bodies could not be retrieved from publicly available sources, nor were they provided in the different rounds of contacts with MSs. A summary of the information collected regarding who does what in the field of risk assessment in the EU is more specifically tabulated in Annex 3.

As regards industry, Plastics Europe has produced guidance for the risk assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS)⁽¹⁰⁷⁾. The

⁽¹⁰⁷⁾ Plastics Europe — Risk assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under Article 19 of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to

document considers the exposure and toxicological assessment of a substance and its risk characterisation. With this guidance document, PlasticsEurope intends to explain how the plastics (plastic intermediate material) producers interpret and respond to their risk assessment obligations for NLSs and NIAs under Article 3 of the framework regulation (Regulation (EC) No 1935/2004) and Article 19 of the regulation on plastic materials and articles intended to come into contact with food (Regulation (EU) No 10/2011), based on internationally recognised tools and the scientific knowledge available to them at the time of writing. This is a living document that will be updated as and when needed.

CEPE published in 2009 the 'Code of practice for coated articles where the food contact layer is a coating – working document' ⁽¹⁰⁸⁾ that in Annex VI describes very briefly the risk assessment that should be performed by industry for migrants from coated articles in contact with foodstuffs. It divides the migrants in three classes, based on their use or nature, and provides some very basic directions to comply with Article 3 of the framework regulation.

3.4.3. Additional tools for exposure assessment

Flavourings, Additives, FCMs Exposure Tool (FACET)

FACET is an exposure tool that was created as an EU-funded research project under the seventh research programme (KBBE-211686) and ran from 2008 to 2012. FACET was developed to estimate dietary exposure to flavouring, additive and FCM substances with the aim of significantly reducing the uncertainties in the level of dietary exposure for these classes of substances in the EU population. The project produced an exposure assessment tool consisting of databases containing information on the levels of food additives, flavourings and food packaging migrants and corresponding food consumption data. For food packaging, data was collected on the chemical composition of food packaging materials, along with information on the extent and conditions of use. It included comprehensive data on substances in inks, adhesives, plastics, metal, paper and board (provided by the food packaging industry), and data on the construction of different packaging types (provided by the food packaging industry), and led to an inventory list of 6 475 substances that were either single substances or defined or non-defined mixtures of two or more substances. It linked to 15 dietary surveys from eight MSs (Ireland, France, Italy, Hungary, Poland, Portugal, Finland and the United Kingdom), harmonised into targeted coding systems aligned with those used by EFSA (FoodExI). These databases were linked to a migration model that can estimate the amount of a substance leaching from packaging into food, allowing exposure to the substance to be calculated for the food consumption data. The resulting FACET exposure tool is a downloadable software ⁽¹⁰⁹⁾ that can be used to estimate consumers' exposure. This tool can for example be used to measure how different population groups (age, gender, people staying loyal to a given brand or changing products) are exposed to different types of packaging substances.

In 2014-2015, FACET was tested and used within the EFSA exposure assessment of Bisphenol A (BPA) from light metal packaging (canned foods). The model gave similar results to the classical assessment obtained from deterministic data, showing the validity of FACET as a modelling tool in EU-wide assessment scenarios for FCMs. A novel module of FACET was sponsored by the FACET Industry Group (FIG, representing more than 10 FCM sectorial associations). Its functionality allows in particular the estimation of the exposure of NIAs migrating from a food packaging into a food.

Considering that the new proposed guidelines from EFSA (see section 3.4.1.) are bringing a stronger focus on exposure, FACET can present a uniqueness and added value

come into contact with food.

⁽¹⁰⁸⁾ CEPE – Code of practice for coated articles where the food contact layer is a coating – working document, 2009.

⁽¹⁰⁹⁾ <http://expofacts.jrc.ec.europa.eu/facet/>

not otherwise available for FCMs. However it must also be noted that updates are fundamental to the future expansion and sustainability of FACET:

- The food consumption data is becoming outdated. FACET will need to recode data and update to the new system of EFSA (Foodex2).
- New surveys on food consumptions will need to be part of updates. This implies the need for a level of acceptance by EFSA of FACET, which can represent a valuable probabilistic tool in an area of gaps in the context of FCM exposure assessment.
- A review and update of the Euromonitor data for FCMs will become indicated.

Matrix

Matrix is a web-based tool for risk assessments of NLSs and NIASs to be performed under Article 19 of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. Under the provisions of the regulation, a number of substances present in food contact plastics are exempted, according to Article 6, from the requirement to be included in the Union positive list (Union list). The substances exempted from positive listing include solvents, colourants, polymer production aids (PPAs), aids to polymerisation (APs), oligomers and NIASs. The website warns that Matrix can only be used for risk assessment of authorised substances exempted from listing at the EU level according to Article 19, unless already listed in national law and subject to restrictions. It presents itself as a client-server application without need for downloading. The tool builds on the equation $\text{exposure} = \text{migration} \times \text{surface}$. The term 'migration' is either an experimental value or a calculated one (worst-case or migration modelling). It is based on data from five MSs (Germany, Spain, France, Italy and the United Kingdom). Each surface table (for each MS) consists of 51 food classes and 77 packaging materials. It is sponsored by five associations (CEFIC-FCA, EUPC, FPE, PlasticsEurope and Giflex) and is freely available online ⁽¹¹⁰⁾. Updates are also fundamental to the value of this tool for its continued use.

Belgian authorities – CoE database

The Database of Substances known by Member States of the Council of Europe and used in FCMs ⁽¹¹¹⁾ is an initiative of the Belgian authorities. This database is owned and managed by a public institution, the Belgian Scientific Institute for Public Health (WIV-ISP). Belgium received a mandate from the CoE to maintain and expand the database via an advisory group that will frame the contents and the use of the database. The database is accessible for the CoE MSs' delegates and is accessible for public bodies and enterprises for a yearly fee.

The database consists of a compilation of lists of known substances that are or were used in FCMs. The lists are a compendium of the Swiss ordinance ⁽¹¹²⁾, the EU plastic regulation, resolutions of the CoE ⁽¹¹³⁾, the list from the EFSA ESCO group and previous lists from the SCF ⁽¹¹⁴⁾. Assessments and relevant data on substances are based on structural alerts relationships ⁽¹¹⁵⁾.

Usage of tools

The FACET tool has more than 800 registered users (i.e. users that have signed up to download the tool). Of those, close to 60 % cite FCMs as their area of interest (rather than flavourings or additives). Registrations show that 42 % are from industry and 20 % are national bodies (the rest being split across third-party laboratories, academia and others). The main sectors using FACET are inks, can coatings, plastics and chemicals.

⁽¹¹⁰⁾ www.matrixcalculation.eu

⁽¹¹¹⁾ <https://fcm.wiv-isp.be/Default.aspx>

⁽¹¹²⁾ Swiss ordinance on materials and articles (817.023.21) (2005).

⁽¹¹³⁾ On paper and board, coatings, silicones, rubber, cork stoppers, ion exchange and adsorbent resins.

⁽¹¹⁴⁾ SCF lists from the note for guidance for petitioners for authorisation of FCM substances. 30 July 2008. (synoptic document SANCO D3/LR(2003).

⁽¹¹⁵⁾ Toxtree, Derek.

The plastics sector also uses Matrix for NLSs in plastics.

3.5. Regulatory frameworks in the European Union

MSs legislation is based on different principles as can still be observed in those areas that are not yet covered by EU legislation. Three main legal systems can be observed based on different type of measures in operation at national level, as listed below.

- System of authorised substances and migration limits comparable to the Union system: this system has been applied for example in the Netherlands (Warenwet)
- System of recommendations for substances to be used in the final material or article: this system is applied in Germany (BfR recommendations).
- System of no specific legislation but with an industry code of practice defining the due diligence of business operators (applied for example in the United Kingdom).

In the following sections, the review of contents and analysis is presented in one unique flow to make it more useful as a desk reference. The data collection stopped at the end of 2015 and may be subject to updates in the future.

With regard to the national measures of EU MSs, the tabulated contents for both generic and material-specific measures have been placed in annexes (Annexes 4 to 19) that can be read as companions to the summarised descriptions. The coverage includes measures, published recommendations or opinions, standards, sectorial approaches, including guidance documents, and references used by the different sectors.

In addition, the relevant rules for non-EU countries are also summarised in Annex 20, since the material-specific analysis of the current situation in the EU on what is used in practice includes references to rules from beyond the EU.

Issues in performing the research

A first difficulty comes when national rules can only be found in the national language. Another major difficulty is the complex inter-relationships of multiple pieces of legislation for one given field or sector (material). For example, France has multiple types and taxonomies of measures ⁽¹¹⁶⁾, and it is not always clear to a non-expert what is legally binding and what is not. The chronology can also go back over several decades in some cases. Similarly, in Italy a ministerial decree can give rise to a number of linked elements ⁽¹¹⁷⁾ or multiple amendments of the original ministerial decree of 1973, which includes all materials. In addition, amendments can be also found embedded in 'multipurpose' decrees not specifically on FCMs, further complicating the desk research. It was particularly difficult to navigate such issues for metals and alloys.

There can also be blurred lines between documents that are strictly legally binding and others that may not be but are taken as such, such as recommendations that include substances evaluated by national risk assessment authorities. For the purpose of this scoping study, it was decided that no distinction could be made between a measure that is strictly legally binding and a recommendation used by many as virtually binding (e.g. BfR recommendations), since both types were sometimes used equally. The collection is thus by excess, as long as the rules or opinions are not repealed by the emitting MS.

In many cases MSs may refer to or use legislation from another MSs but do not state an explicit reference for each type of material. As far as possible, this information was sought from queries with MSs competent authorities.

- **Warning** — *The information presented is what was found or received following our request to MS competent authorities. It is only as exhaustive as the replies and feedback obtained for the purpose of this report.*

⁽¹¹⁶⁾ Examples include: 'BOCCRF' (Bulletin Officiel de La Concurrence, de La Consommation et de La Répression des Fraudes), 'avis', 'instruction', 'lettre-circulaire' or 'circulaire', 'arrêté' and 'note d'information'.

⁽¹¹⁷⁾ Examples include 'amending decrees', 'nota del ministero (della salute)', 'Decreto del Presidente della Repubblica' (DPR).

3.5.1. Generic provisions

General provisions applicable to FCMs exist in different MSs. The level of information that such provisions contain can be related to the registration of food contact business operators, the declaration of compliance and supporting documents and the basis for enforcement. It also includes the information on GMP at national level.

NB: Legislative acts are mentioned in some cases by their acronyms. In order to avoid multiple footnotes the reader is directed to the list of references at the end of this report. The reference section contains all legislation, standards, opinions, recommendations and guidance documents (cited or reviewed) and includes a direct link when available.

Registration of FCM operators

The data found or received illustrates that nine MSs have some provisions that could be easily found on registration specific to business operators, with a registry set up and an application process developed. The data is presented as tables in Annex 4a.

The data obtained also illustrates that a system may be more or less described, with more detailed descriptions in Denmark, Spain (with a correspondence to an industry guideline), followed by Estonia, Norway, Poland, and Slovenia, while Finland will issue provisions in the future and Austria has only an indication.

While this means that relevant examples are available to use potentially as a model, it also indicates that MSs for which this section could not be found may not provide or clearly state requirements, or do not consider mandatory requirements for this aspect, or do not have a system to do it systematically. This constitutes a gap.

Declaration of compliance (DoC) and supporting documents

Specific guidance and requirements on DoC and supporting documents appear in 13 MSs, with France, Italy, the Netherlands, Sweden and Norden giving some details. The detailed data is presented as a table in Annex 4b. A summary from Germany is reported but only applies to applying requirements of Regulation (EU) No 10/2011 for plastics as reference for the other materials. The documentation summary from Slovenia is reported but it should be noted that the law was repealed at the end of 2015. Three industry guidance documents exist, of which two were prepared by a joint group of professional associations representing different sectors of FCMs.

The requirements highlighted in the 'Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain' and in the 'Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food' were used as a basis to evaluate the information provided and/or requested in different MSs for non-harmonised materials. The contents of the national documentation was analysed to find information and/or requests on the following.

For declaration of compliance:

- *Identity and address of the business operator -- Type of material -- Date of the declaration*
- *Declaration that the material is compliant with the requirements of the reference legislation*
- *Information on the presence of any restricted substance with its levels of specific migration*
- *Specific use(s) intended for the material*

For supporting documentation:

- *Declaration of compliance with its relative supporting information documented (declaration of compliance also received from suppliers)*
- *Quality control documentation*
- *Information on formulation*
- *Results of migration testing or migration modelling*
- *Relevant information on the process undergone by the material*

The evaluation indicates that Bulgaria, Germany, France, Italy, the Netherlands, Sweden and Norden have information that appears more developed and explicit or closer to a

template as used for plastics, followed by Denmark and Spain, and simpler references found for Belgium, the Czech Republic, Norway and Slovenia. For Switzerland, a joint industry group (JIG) on packaging for food contact provides a checklist to assess the completeness and quality of a declaration of compliance. It includes information based on that for plastics, with reference to legislation for compliance on substances used in and intended for use in a FCM. The explanatory part of the checklist implies that supporting documents are necessary, yet without explicitly requiring them.

It should be noted here that inspections of the health and food audits and analysis office (HFAA, ex-FVO) have also often found the supporting documentation scarce if not faulty in their audits (see section on HFAA audits under the chapter 4 on indicators for safety).

Basis for enforcement

NB: In the analysis of enforcement information, a broader meaning of the term has been used. Thus, the material researched not only encompassed provisions on the setting/management of enforcement bodies or enforcement campaigns, but also considered available information on the means to perform the enforcement (e.g. availability of testing methods).

Article 24 of Regulation (EC) No 1935/2004 requires MSs to carry out official controls to enforce compliance, and Regulation (EC) No 882/2004 sets out the rules for the performance of official controls. Based on their requirements, a list of adapted basic and general criteria was established for the purpose of this study to assess national legislation in the EU MSs, as follows.

- *Established frequency of controls (control plans) and specific procedures*
- *Designation of competent authorities responsible for official controls and the relative network of control bodies, control laboratories and NRLs and their duties*
- *Qualification, training and duties of officials involved in controls*
- *Availability of appropriate sampling and analytical methods and adequate equipment*
- *Accreditation of control bodies and laboratories*
- *Transparency and confidentiality of official controls*
- *Designation of points of entry into national territory and collaboration with customs services*
- *Actions in case of non-compliance, as well as costs, fees and charges*

The data compiled (Annex 4c for tabulation details) indicates that 15 MSs have references related to a basis for enforcement that could easily be found. The information is sometimes scattered across different pieces of legislation (Germany, Estonia, Austria and Switzerland). For other countries (Belgium, the Czech Republic, France, Italy, the Netherlands, Norway, Slovakia and Slovenia) it is concentrated in one or two relevant measures, albeit with lesser details or clarity.

In the context of the basis for enforcement, an evaluation was also conducted on the generic references to migration limits to all FCMs since national measures for non-harmonised materials were found to take the form of lists of authorised substances with restrictions based on migration limits or compositional limits.

Four MSs provide specific references, including the Czech Republic, Germany, Italy and the Netherlands. The Czech Republic mentions lists of authorised substances and the competent authority reports that some substances for specific materials (particularly for paper and board) come from BfR recommendations. Germany reports that BfR publishes 'recommendations', which are treated like recommendations for GMP and contain lists of authorised substances. Italy reports that a positive listing is laid down by the Ministry for Health, the Management Body, after advice from the Consiglio Superiore di Sanità (Higher Health Council). The Netherlands provides a positive list for substances or categories of substances that can be used or be present in **all** packaging and consumer articles. For the other three MSs the main pieces of national legislation refer to an approach using lists of authorised substances. Lists of authorised substances that target specific materials are described more in details in the material-specific section.

With respect to negative lists, the presence of lists of banned substances (i.e. a list of substances that are prohibited for use in the manufacturing process) does not seem a common occurrence in the EU MSs (more common for one substance, e.g. Bisphenol A).

Sanctions

National measures have sanctions described for infringement of both the framework regulation (EC) No 1935/2004 and Regulation (EC) No 2023/2006. The sanctions may range from fines or penalties to imprisonment, confiscation of non-compliant goods (or rejection at borders, and/or bearing costs of destruction of goods), the closing down of premises and other liabilities. These are summarised in Annex 4d.

Overall, 14 MSs have information accessible or provided the relevant information. Sanctions are detailed for Belgium, the Czech Republic, Denmark, Germany, Estonia, France, Norway, Austria, Poland, Slovenia, Finland, Switzerland and the United Kingdom. Some are part of food legislation, or consumer goods legislation, or of a national law that references its applicability to FCMs. Some are already specific to FCMs and refer to the framework regulation, the articles to which it applies and the nature of the sanctions. Some differentiate across a scale of gravity of infringements, for example from involuntary to gross negligence. Most depict further penalties (sometimes a factor of 10 in monetary fees) if offences are repeated within a time span (e.g. 3 years), and often modulate the penalties based on the conduct of the subject/entity. Some MSs may also have detailed rules and administrative procedures for proceedings and individual rights during these proceedings. When sanctions are defined specifically on infringement of the framework regulation, the articles to which it refers to are clearly spelled out for some MSs (e.g. Germany or the United Kingdom ⁽¹¹⁸⁾), or can be more generic (e.g. Poland and Slovenia). Sanctions are also referred to contravening Regulation (EC) No 2023/2006, in particular Article 4 (Poland and the United Kingdom).

Certification systems

A much greater emphasis can be found placed on certification systems in the context of GMP than in the context of controls. The information collected on certification systems with mentions pertinent to accreditation and official controls is summarised in Annex 4e.

Certification systems for controls refer to the authorisation of laboratories to perform compliance testing and details on requirements for those laboratories. The most complete at national level seem to be those of Austria and Switzerland, and these are also relatively recent (2014). Details on can be found in Annex 5.

3.5.2. Implementation of GMP further to Regulation (EC) No 2023/2006

An analysis of GMP frameworks and implementation is presented in Annex 5. It considers the analysis of the content of measures with regard to information on raw materials, (QA), (QC) and the nature and extent of certification systems.

With regard to generic national measures, there are references to GMP in the Czech Republic, Denmark, Estonia, Hungary, Italy, Lithuania, the Netherlands, Slovakia, Sweden, Switzerland, the United Kingdom and Norden. Full guidelines have been developed by Italy ⁽¹¹⁹⁾. Guidelines are also provided by Norden ⁽¹²⁰⁾, with three guidance documents (paper and board, printing inks and FCMs in general), which also include checklists for industry and trade. The United Kingdom had a fairly comprehensive guidance document ⁽¹²¹⁾ but it has been under revision and a new version was not available at the time of the enquiry.

⁽¹¹⁸⁾ For Germany Articles 15(1) and (3) and 17(2)), and for the United Kingdom Articles 3 and 4 and Articles 11(4) and (5), 15(1), (3), (4), (7) and (8), 16(1) and 17(2)

⁽¹¹⁹⁾ IT – Guidelines for the application of the Regulation 2023/2006 to the supply chain of materials and articles intended to come into contact with foodstuffs – Rapporti Istisan 11/37 – CAST project: ISSN 1123-3117.

⁽¹²⁰⁾ Paper and board FCMs, food contact materials and articles: printing inks. Check lists for compliance in industry and trade and control by food inspection, Food contact materials – metals and alloys. Nordic guidance for authorities, industry and trade, food contact materials: In-house documentation and traceability, Nordic check lists to industry and trade.

⁽¹²¹⁾ Guide to United Kingdom legal compliance and good practice for business documentation – Materials and articles in contact with food.

The Swiss Packaging Institute (SVI) has developed and revised a checklist for industry to assess declarations of compliance ⁽¹²²⁾. It is used by inspectors for controls. No guidance document is available, but they provide courses. Estonia suggests that business operators use GMP guidelines drafted by industry organisations, in addition to the United Kingdom GMP guidelines. A short guidance document ⁽¹²³⁾ is available from the Netherlands on how to apply Regulation (EC) No 2023/2006. General mentions on the use of GMP without further specifications are present in the Czech Zakon 258-2000, the German GMP and compliance declaration for FCMs, the Danish DVFA chemicals contaminants in food checklist, Hungarian Regulation 49/2014, the Italian Nota del Ministero della Salute No 2964 del 24/01/2006, the GMP rules for FCM from the Lithuanian packaging association ⁽¹²⁴⁾, Sweden's Normpack general guide on food packaging safety and the Slovak Foodstuffs Code 1799/2003 with two lists for controls.

As regards specific references or guidance documents for certain materials, the only references found (see material-specific sections) were for cork (CoE), glass (Slovakia), metals and alloys (Italy, Hungary, CoE), rubber (CoE) and coatings (CoE). These references are conceptual and without further specific practical guidance provided.

The most comprehensive GMP guidance documents across sectorial associations and MSs were found for the paper and board sector (Norden ⁽¹²⁵⁾, CEPI ⁽¹²⁶⁾). The Norden document is a GMP document intended for producers of paper and board based on the CoE resolution and its related five technical documents. The CoE policy statement on paper and board, the CoE statement on tissue paper, kitchen towels and napkins and the Spanish guidance are all based on the CEPI 'Guide for good manufacturing practice for paper and board for food contact', adapted where needed to the production processes used in tissue mills in the case of the CoE statement for napkins.

No references were found for silicones, waxes, wood, adhesives, ion exchange resins, multimaterials or ceramics. No GMP beyond Regulation (EC) No 2023/2006 was reported for Ireland, Cyprus, Latvia, Luxembourg, Malta, Poland, Portugal, Romania or Slovenia. No replies were received from Belgium, Bulgaria, the Czech Republic, Greece, France, Croatia, Hungary or Austria. The details of documents from MSs can be found summarised in Annexes 5a and 5b, and the self-guidance from industrial sectors in Annexes 5c and 5d.

3.5.3. Material-specific regulatory frameworks

The information overview on national measures that are specific to individual materials is depicted in Table 4 and Table 5. The contents are presented in subsequent sections for each type of material. This information aims to represent what is used in practice based on desk research and queries sent to MSs. It should be noted that, for the purpose of this report, the replies of Norway and Switzerland have been integrated together with the 28 EU MSs. An IT tool was created to store all original documents and extracts of documents for both general and specific information (e.g. toolkits).

Table 4 shows the distribution of countries with measures or national norms specific to different materials. It illustrates that no country regulates all materials, but 19 countries, along with the CoE and Norden, regulate more than one material. Some countries may have only a measure on one or two materials. The remaining countries rely on EU legislation and in principle on mutual recognition of rules in place in other countries. Some of these remaining countries have however provisions on regulation of business operators, sanctions etc. and perform controls.

⁽¹²²⁾ CH — SVI — Bewertung von Konformitätserklärungen.

⁽¹²³⁾ NL — 'Infoblad documentatie FCM mei 2014'.

⁽¹²⁴⁾ All documents are fully referenced in the reference section.

⁽¹²⁵⁾ Norden guidelines on paper and board 'Paper and Board Food Contact Materials', (TemaNord 2008:515).

⁽¹²⁶⁾ CEPI, Guide for good manufacturing practice for paper and board for food contact.

Table 4: Summary of the presence of legislation or standards for various non-harmonised materials, organised in statistical order of presence. (Note: CoE and Norden are included as entities, as are Switzerland and Norway)

| MS | Adhesives | Printing inks | IEs | Varnishes | Waxes | Ceramics | Glass | Metals and alloys | Cork | wood | Paper and board | Rubbers | Silicones | SM or OM generic to all FCMs | reference |
|----------------|-----------|-----------------|---------|----------------|-------|----------|--------|-------------------|-------|----------|------------------|-----------------|-----------|------------------------------|-------------|
| France | multiple | multiple + norm | x +norm | multiple | x | | x | multiple + norm | x | multiple | multiple | multiple | x | x (metals) | multiple |
| Netherlands | x | x | x | x | x | x | x | x | x | x | x | x | | x | Com Act |
| Croatia | x | x | | x | | x | x | x | x | x | x | x | x | | NN125-2009 |
| Czech Republic | | x | | x | | x | x | x | x | | x | x | x | | V38/2001 |
| Germany | xx | (x) | | multiple +norm | x | norms | norm | | | | multiple + norms | multiple + norm | x | | BfR Rec. |
| Italy | x | x (DoC) | | x | | | x | multiple | norm | | multiple | x | x | x | DM 73 ++ |
| CoE | | x | x | x | | | x | x | | | x | x | | | |
| Slovakia | | x | | x | | | x | x | x | | x | x | | | 1799/2003 |
| Spain | x | | x | x | x | | norm | | | | | x | x | | RD 847/2011 |
| Switzerland | | x | | | x | | x | x | | | | | x | | ord 817 |
| Belgium | | | | (x) | | | x | x | | | x | | | | AR 1992 |
| Austria | | | | | | x | | x | | | | x | | | BGBI 258 |
| Greece | | | | x | | | | x | | | x | | | | Food code |
| Norden | | | | | | | | x | x | | x | | | | |
| Poland | | | | | | norm | norm | | | | x (norm) | | | | only norms |
| Denmark | | | | | | norms | norm | | | | | | | | BPA |
| Norway | | | | | | x | x | | | | | | | | |
| Portugal | | | | | | | x norm | | norms | | | | | | only norms |
| Romania | | x | | | | | | | | | | x | | | |
| Bulgaria | | | | | | | x | | | | | | | | only glass |
| Finland | | | | | | x | | | | | | | | x (metals) | 268/1992 |
| Sweden | | | | | | | | norm | | | | | | | |
| Cyprus | | | | | | | | | | | | | | | |
| Estonia | | | | | | | | | | | | | | | |
| Hungary | | | | | | | | | | | | | | | 49/2014 |
| Ireland | | | | | | | | | | | | | | | n/a |
| Latvia | | | | | | | | | | | | | | | |
| Lithuania | | | | | | | | | | | | | | | |
| Luxembourg | | | | | | | | | | | | | | | |
| Malta | | | | | | | | | | | | | | | |
| Slovenia | | | | | | | | | | | | | | | uses CoE |
| United Kingdom | | | | | | | | | | | | | | | |

A second overview in Table 5 indicates a prevalence of measures based on lists of authorised substances (and negative lists) with limits being the most common associated tool. It also highlights that GMP is a framework that is considered by MSs more under the generic umbrella of FCMs than as part of specific measures for a given material. The table also suggests that instructions related to declarations of compliance, supporting documents or a basis for sanction are much less explicitly described in material-specific national measures.

Table 5: Overview of material-specific national rules and tools

| Material | Positive list | Negative list | SML | OML | Limits for substance quantity | Details on GMP | DoC & supporting docs | Basis for sanctions | Basis for enforcement ^t |
|------------------------|---|---------------------------|---|---------------------------------------|---|----------------|------------------------------|---------------------|-------------------------------------|
| Adhesives | DE, ES, FR, HR, IT, NL | | ES, HR | ES, HR | DE, ES, FR, HR, NL | | | ES | ES, HR, IT |
| Ceramics | | | AT, CZ, DE, DK, FI, HR, NL, NO, PL | NL | | | AT, CZ, NO | | CZ, DE, NL |
| Cork | CoE, CZ, FR, NL, SK | CoE, (NL) | CoE, CZ, NL, SK | CoE, HR, NL | CoE, SK, NL | | | | CoE, HR |
| Glass | BE, (IT), SK | (HR), NL | BE, BG, CH, CoE, CZ, DE, DK, FR, HR, IT, NL, NO, SK | BE, NL | FR, (NL) | (SK) | IT | | BG, CZ, DE, DK, FR, IT, NO |
| Ion exchange resins | CoE, ES, FR, NL | | CoE, ES, NL | CoE, ES, NL | CoE, ES, FR | CoE | NL | ES | CoE, (ES) |
| Metals and alloys | CZ, EL, FR, IT, NL, SK | AT, CH, HR | AT,(CH), CoE, FR, HR, IT, NL, NO, Norden | FR, NL | AT, BE, CH, CoE, CZ, EL, FR, HR, IT, NL, SK | (IT) | CoE, FR, IT | IT | AT, CoE, FR, HR, IT, NO |
| Multimaterials | FR, IT, Norden | Norden | FR, IT | FR, IT | FR, IT, Norden | | | | FR |
| Paper and Board | BE, CoE, CZ, DE, (EL), FR, IT, NL, Norden, SK | CoE, DE, EL, (HR), Norden | BE, CoE, DE, EE, FR, HR, IT, NL, Norden, PL, SK | BE, DE, FR, NL, Norden | BE, CoE, CZ, DE, EL, FR, HR, IT, NL, Norden, SK | (HR), Norden | IT, Norden | IT | CoE, DE, EE, FR, HR, IT, Norden, PL |
| Printing inks | CH, CoE, DE_draft, FR, NL, SK | CoE, CZ, HR | CH, CoE, DE, (DE_draft), FR, NL | FR | CH, CoE, CZ, FR, (HR), NL, RO, SK | | DE_draft, FR, IT, Norden, RO | DE_draft, IT | CoE, Norden |
| Rubber | CoE, CZ, DE, ES, FR, HR, IT, NL, SK | CZ, DE, HR, SK | AT, CoE, CZ, DE, ES, FR, HR, NL, RO, SK | CoE, DE, ES, FR, HR, NL, RO | AT, CoE, CZ, DE, ES, FR, HR, IT, NL, SK | CoE | FR, IT, RO | ES | AT, CoE, DE, (ES), FR, HR, IT |
| Silicones | CH, CoE, CZ, DE, ES, FR, HR, IT | CoE, CZ, HR | CH, CoE, CZ, DE, ES, FR, IT | CH, CoE, DE, ES, FR, HR, IT | CH, CoE, CZ, DE, ES, FR, HR, IT | | | ES | (ES), FR |
| Varnishes and coatings | CoE, CZ, DE, EL, ES, FR, HR, IT, NL, SK | FR, HU, HR | BE_draft, CH, CoE, CZ, DE, EL, ES, FR, HR, IT, NL, | BE_draft, CoE, EL, ES, FR, HR, IT, NL | BE_draft, CoE, CZ, DE, EL, ES, FR, IT, NL, SK | CoE | BE_draft, EL | ES, IT | BE_draft, DE, (ES), HR, IT, NL |
| Wax | DE, ES, (FR), NL | | ES | ES | CH, DE, ES, (FR), NL | | | ES | (ES) |
| Wood | FR, NL | FR, (NL) | FR, HR, NL | NL | FR | | | | FR, HR |

With respect to the development of a repository of information, a categorisation of the contents of all original regulatory documents was conducted. The information came from national and supranational (CoE, Norden) levels, and industry where applicable. Measures were categorised by type of information (regulatory or relative to its implementation tools). The text of relevant extracts – and associated corresponding

broader legal references where applicable — were copied into a harmonised template. These were then made retrievable through links from a Microsoft Excel-based repository. This tabulation was then transformed into a query-based tool to enable quick consultation of the original excerpts.

As lists of authorised substances and restrictions (SML, QM, etc.) were most commonly used in each sector, a more in-depth comparison was conducted. Master lists were created where lists of authorised substances found in national legislation were reviewed and systematically integrated into individual lists for each sector using the templates of the ESCO lists (where available). Substances or lists of substances found in any type of measure/recommendation/opinion from the 28 MSs, Norden, Switzerland and CoE were integrated. This meant that, for example, German recommendations were taken into account along with French 'notes', 'circular letters', etc. Names and CAS numbers were reviewed, as were restrictions.

Major hurdles besides language in the compilation of the lists were that chemicals were listed either only as chemical names or synonyms using different nomenclatures (e.g. IUPAC, CAS, Einecs), and in a number of cases with no chemical reference number that could help to unequivocally confirm the identities of the same substances appearing under different names. This examination was conducted by chemists, and yet it was often found to be difficult to confirm univocal identifications, making comparisons difficult and time consuming. Challenges are reported in Annex 6a for future reference.

The tables produced in the context of this study represent substances mentioned in lists of authorised substances covering MSs, European Economic Area countries, Norden and CoE. The cumulative lists generated by materials allow the estimation of the total number of substances regulated for each sector in national measures, but also the evaluation of convergences across MSs.

The study specifically considered the substances included by two or more MSs and the CoE or alternatively three or more MSs in terms of the nature of substances and whether there were similarities in the restrictions imposed. The study also considered whether there were specific convergences between lists established by the CoE and lists established in MSs. This was taken as a potential indication of whether the work of the CoE was taken up by MSs, either sporadically, partially or systematically.

The structure for the review of regulatory frameworks by sectors is organised by classes of sectors as follows: chemicals and intermediates, which include adhesives, printing inks and ion exchange resins; 'inorganic' materials, which include ceramics, glass, and metals and alloys; and finally the sectors of cork/wood, paper and board, rubbers and silicones.

Chemicals sector and intermediates

Adhesives

From a general standpoint, adhesives, being substances for different applications, are regulated under the concept of positive list with residuals/contents, and overall and specific limits imposed using a process of authorisation of substances. A tabulated overview is presented in Annex 7 for both national measures and standards. National measures for adhesives are available in **six main MSs** (Germany, Spain, France, Croatia, Italy, the Netherlands). All apply a list of authorised substances (no negative list). OML and SML and QM ("quantity in material") or residuals are set out for two MSs (Spain, Croatia), whereas only QM-type limits or compositional restrictions are used in Germany, France and the Netherlands. References related to enforcement are mentioned in Spain, Italy (only in a generic manner) and Croatia. The basis for sanctions is mentioned specifically in Spain. Only one standard is available in the drinking water area.

The EFSA ESCO working group did not include adhesives in the review on non-plastic FCMs. It referenced a number of research publications ⁽¹²⁷⁾ ⁽¹²⁸⁾ ⁽¹²⁹⁾ on migration of adhesives and methodologies for migration testing and towards mathematical modelling within the EU. Specific hurdles in the field of adhesives stem from the fact that they form a complex group of chemical formulations. Their uses are also very varied, both in terms of the types of packaging or FCMs in which they are used and in terms of the type of applications. Such applications can include manufacture of rigid packs and multilayers, attachment of labels, sealing flexible packaging, etc.

A cumulative list was derived taking into account the lists of authorised substances of all six MSs that have national measures. This led to an estimated total of **1 323** substances regulated at national level. The analysis highlighted that **only nine substances (0.7 %) are common to three MSs or more** (details in Annex 7).

There is also an **absence of available standards**.

FEICA has developed a comprehensive **series of guidance documents**. Sectorial guidelines include a guidance document on legal aspects, which provides information on the declaration of compliance, supporting documents and an FCM status declaration ⁽¹³⁰⁾. It states a commitment to perform risk assessment for the migratable substances (< 1000 Dalton) and a template for food contact declarations. It also offers a manual ⁽¹³¹⁾ and a dedicated guidance document on GMP ⁽¹³²⁾ specific to the sector, which advises FEICA companies on how to provide adequate information to their customers. Companies are certified according to quality and/or hygiene standards.

The **approach of the adhesives industry** supply chain, including the food industry and raw-material suppliers, is based on demonstrating compliance with Article 3 of Regulation (EC) No 1935/2004 and how the risks from migrants could be assessed. A more detailed explanation on the approach of the adhesives industry on how to perform risk assessment and how to comply with food contact legislation can be found in the documents published by FEICA. In addition, FEICA recently published a guidance document on migration testing ⁽¹³³⁾.

A relevant **body of research** exists on adhesives including EU-funded RTD projects such as 'Migresives' ⁽¹³⁴⁾. It included aspects such as (1) classification of adhesives according to chemistry and uses, (2) test strategies based on the physico-chemical behaviour of adhesives, (3) modelling migration/exposure from adhesives, (4) guidelines to integrate a risk assessment approach into companies' practices and (5) extensive training or education of SMEs and large-scale dissemination for general adoption of the concept in Europe. The project outcome was intended to form a basis for future specific EU legislation and to provide industry, especially SMEs, with a tool to ensure that migration from adhesives is in compliance with the regulatory requirements. A freeware multilayer modelling software was developed further within the project ⁽¹³⁵⁾ and the use of the tools explained in a guideline document, and the reports from the project are available.

There is **some convergence of references used by the professional sector**. The FEICA sectorial guidelines refer to national legislation, in particular the German BfR Rec. XXVIII, and to the plastics regulation (Regulation (EU) No 10/2011). For the paper and board sector as a downstream user, both ACE and ECMA cite as a reference the EU

⁽¹²⁷⁾ Grunner A. and Piringer O., 1999. Component migration from adhesives used in paper and board packaging for foodstuffs. *Packaging Technology and Science* 12, 19-28.

⁽¹²⁸⁾ Nerin C., Canellas E., Aznar M., Silcock P., 2009. Analytical methods for the screening of potential volatile migrants from acrylic-base adhesives used in food-contact materials. *Food Additives and Contaminants: Part A* 26, 1592-1601.

⁽¹²⁹⁾ Vera P; Aznar M; Mercea P; Nerin C., 2011, Study of hotmelt adhesives used in food packaging multilayer laminates. Evaluation of the main factors affecting migration in food *Journal of Materials Chemistry*, 21(2), 420-431.

⁽¹³⁰⁾ Guidance for a food contact status declaration for adhesives, FEICA GUP-C02-001 (February 2013).

⁽¹³¹⁾ ASC-CATIA-FEICA Adhesives and Sealants Classification manual, 2012 edition manual.

⁽¹³²⁾ Guideline on Good Manufacturing Practices in the Production of Adhesives and Sealants Intended for FCMs (2008).

⁽¹³³⁾ FEICA — Migration testing of adhesives intended for food contact materials.

⁽¹³⁴⁾ The 'Migresives' project (COLL-CT-2006-030309) was carried out from 2007 to 2010 under the sixth framework programme (FP6) 'Horizontal research activities involving SMEs — collective research'. <http://www.migresives.eu/>

⁽¹³⁵⁾ Safe Food Packaging Portal version 3 (SFPP3) http://sfpp3.agroparistech.fr/SFPP3/SFPP3_migresives/

plastics regulation, the German BfR on cross-linked polyurethanes as adhesive layers for food packaging materials and the US FDA 21 175.105, 177.1390 and 177.1395. Adhesives are covered in the ECMA GMP ⁽¹³⁶⁾ in Sections 2.4.4, 4.4.5 and 4.14.1 and in a specific recommendation on adhesives issued in October 2014 ⁽¹³⁷⁾. The plastics sector (CEFIC FCA, FPE) also cites the EU plastics regulation, the German BfR Rec. XXVIII (and XIV), the same US FDA standards as above, the Italian D.M 1973 and the Spanish DR 847/2011. Norden makes reference to BfR Rec. XIV, Regulation (EU) No 10/2011 and the US FDA. Overall, the BfR Rec. XXVIII (and XIV) and FDA 21 175.105, 177.1390 and 177.1395 seem the most referred to.

Therefore, overall, the following points can be summarised for adhesives.

- *Presence of national legislation already implemented.*
- *Six MSs have provisions with lists of authorised substances (no negative lists).*
- *OML, SML and QM/residual set out in two MSs (Spain, Croatia), QM or compositional restrictions in Germany, France and the Netherlands.*
- *Approximately 1 323 substances are considered across MSs.*
- *Only nine substances (0.7 %) are common across three MSs or more.*
- *Absence of standards available at EU level for FCMs (CEN, ISO).*
- *Large body of research done as RTD project.*
- *From an industry standpoint, there is a large set of sector-specific guidance documents on self-regulation with guidelines on GMP, legal guidance, declarations of compliance and testing.*
- *Professional associations indicate a convergence of national rules taken as reference, where BfR Rec. XXVIII (and XIV), FDA 21 175.105, 177.1390, 177.1395 seem the most referred to.*

Printing inks

Printing inks represent a large and complex group of chemicals: 6 000 substances were notified to the Swiss authorities when setting up the national legislation in 2009. It also represents a varied usage in terms of the type of packaging and types of applications. Another source of complexity is the positioning of the sector at the beginning of the supply chain.

In terms of **national measures** there are four MSs with positive lists, including Switzerland, along with a list established by the CoE. An overview of national measures on printing inks for FCMs is tabulated in Annex 8, along with the limited number of standards found. The main source of regulatory frameworks for printing inks seems to be the Swiss ordinance (which was based on the list previously developed by the association for printing inks, EuPIA), with the CoE also having a relevant positive list and three main MSs having much more limited positive lists with SMLs and QMs.

Two main definitions are available at national level (France, Switzerland) for printing inks for use in food packaging. They are preparations applied to the non-food contact surface of materials and articles intended to come into contact with foodstuffs. In both definitions they are formulations made from dyestuffs (pigments, dyes), binders, plasticisers, solvents, driers and additives. They are solvent-based, water-borne, oil or resin (oleo-resinous) or energy-curing (UV or electron beam) systems. The inks, coatings and varnish printing referred to as 'inks for packaging' are applied by a printing or varnishing process, such as flexography, gravure, letterpress, offset, screen, non-impact or roller coating. The EFSA ESCO report noted that, in their finished state, packaging ink layers are thin films of dried or hardened printing ink or varnish on the surface of the materials and articles.

With regard to the composition of lists of authorised substances for printing inks, the EFSA ESCO working group compiled a list of substances for printing inks that contained 986 substances considered as having had a valid risk assessment carried out. The review done in the context of this study updated the data including measures from France, the Netherlands and Slovakia. CoE lists were also considered towards their integration. The list under development by Germany at the time of writing was not yet integrated.

⁽¹³⁶⁾ ECMA — Good Manufacturing Practice Guide (see references).

⁽¹³⁷⁾ ECMA — ECMA recommendation on the safe use of adhesives for food packaging (see references).

It is estimated that more than **5 200** substances are regulated for printing inks intended to be in contact with foodstuffs across Europe by various MSs, including the CoE list. The entries represent 5 069 substances regulated by Switzerland (of which 4 559 (85 %) are regulated only by Switzerland) and 831 (14 %) regulated by the CoE, with the remaining 1 % referring to substances regulated by France (43 substances), the Netherlands (17 substances) and Slovakia (15 substances). Figure 31 illustrates the distribution expressed as a percentage of the number of total substances subject to measures among countries and indicates that the Swiss legislation (lists of authorised substances) seemed the predominant legislation present for the EU market.

Taking into account the overlapping of certain substances from different sources for these lists of authorised substances, 4 559 substances are regulated by only one country, 621 are regulated in common by two countries and only 34 are regulated by three countries. Figure 32 illustrates this as a percentage of substances regulated by respectively one, two or three countries as an indicator of convergence. It highlights that out of 5 214 substances **only 34 (0.7 %)** were found to be regulated by three countries for printing inks. There are no substances regulated in common by more than three countries (Annex 8).

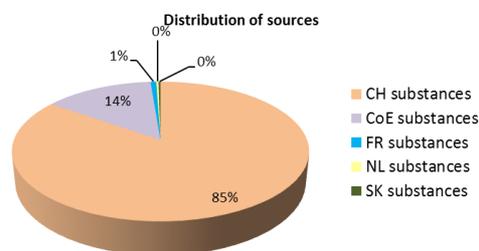


Figure 31: Pie chart distribution of sources regarding provisions on printing inks

The extent of harmonisation on the restrictions for printing inks in the EU countries is illustrated in two additional pie charts. Figure 33 illustrates the percentage of substances for which a convergence (on restrictions or no restrictions) can be found (green), compared to substances with only a partial convergence (orange) or no convergence of the imposed restrictions (red). It shows that 62 % of restrictions do not match across three countries considering the same substances, 12 % represent a partial match and 26 % match as regards the restrictions imposed. Thus, when considering instances in which given substances are regulated by three countries, the convergence in terms of the numerical or type of restriction imposed does not seem greatly harmonised.

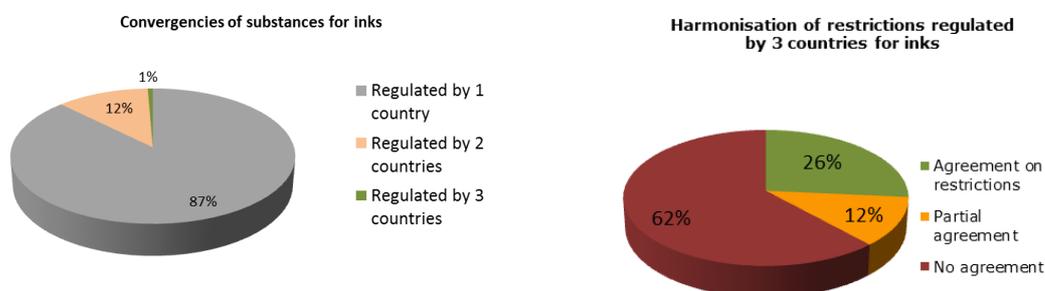


Figure 32: Substances reported as percentage of all substances regulated at European level

Figure 33: Pie chart on the extent of harmonisation or provisions on printing inks

The review also appears to indicate that the Swiss legislation has been used as a source to a large extent for the CoE policy statement and in part for the preparation of the German national legislation on printing inks. The latter appears to plan to regulate

approximately 90 % of similar substances, although the regulatory approach seems different from that of the Swiss ordinance with respect to direct contact of printed articles with food. Switzerland was the first country to issue a positive list for printing inks (in force since March 2010), which contained more than 5 000 substances ⁽¹³⁸⁾.

GMP seems to be well implemented, with specific guidelines that are sector specific (EuPIA) and with GMP guidance from Norden that each seem well accepted within their own scope. The various material sectors reported to be following the EUPIA sector-specific guideline on GMP for the implementation of Regulation (EC) No 2023/2006. These guidelines are also cited by some MSs lacking their own national measures. The Norden guidance on printing ink consists of 'Nordic check lists for industry and trade' and is solely used as guidance for establishing declarations of compliance and supporting documentation for FCMs. For the paper and board sector, the inks are covered in the GMP guidance from ECMA and the EuPIA position note on low migration inks.

The printing ink sector, via EuPIA, has published a number of guidelines for printing inks ⁽¹³⁹⁾, including inventory lists ⁽¹⁴⁰⁾, and on GMP ⁽¹⁴¹⁾ for the production of packaging inks for use on the non-food contact side of food packaging and articles. It has also published information documents ⁽¹⁴²⁾ or contributions to national initiatives ⁽¹⁴³⁾. For the paper and board sector, the inks are covered in the GMP guidance from ECMA ⁽¹⁴⁴⁾ and the EuPIA position note on low migration inks ⁽¹⁴⁵⁾.

From a **sectorial standpoint**, associations refer to Swiss Ordinance SR 817.023.21 (e.g. Annex 6, list A), US CFR 21 Parts 175–178, Resolution AP(89)1, BFR recommendations and Regulation (EU) No 10/2011 as amended. In some cases the Netherland's legislation for colorants is also mentioned for printing inks (e.g. for migration and for purity requirements).

With respect to negative lists, the most cited (e.g. by ACE, ECMA, FPE, EuPIA, I&P, WBT) are the CEPE exclusion list, the EuPIA exclusion list, the Japanese voluntary negative list and the SVHC list. Remaining discrepancies stem from the scope for printing inks (inner/outer surface, FCM other than packaging). The Swiss ordinance was most often cited as the first instance, followed by references to FDA and CoE. Additional references cited as being used are CFR 121-128 and Regulation (EU) No 10/2011.

Therefore overall, the following points can be summarised for printing inks.

- *Four countries (France, the Netherlands, Slovakia, Switzerland) have provisions with authorised substances.*
- *A CoE list also exists.*
- *Predominance of the Swiss national legislation.*
- *Approximately 5 124 substances are considered across MSs.*
- *Only 34 substances (1 %) are common across three MSs (only five with same restrictions).*
- *Absence standards available at EU level for FCMs(CEN, ISO); some at national level (France).*
- *From an industry standpoint, there is a large set of sector-specific guides on self-regulation with guidelines on GMP, inventory lists, information on legal guidance and contributions to national initiatives.*
- *The materials sector and a number of EU countries exhibits a convergence for predominance of the Swiss national rule.*

⁽¹³⁸⁾ <http://www.foodpackagingforum.org/food-packaging-health/food-packaging-materials/printing-inks>

⁽¹³⁹⁾ EuPIA — Guideline on printing inks applied to the non-food contact surface of food packaging materials and articles (2012).

⁽¹⁴⁰⁾ EuPIA — Inventory list –comprising packaging ink raw materials applied to the non-food contact surface of food packaging (December 2013); EuPIA Suitability List of Photo-initiators for Low Migration UV Printing Inks and Varnishes — February 2013.

⁽¹⁴¹⁾ EuPIA — Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials (3rd revised version, March 2009).

⁽¹⁴²⁾ EuPIA — Information leaflet: Printing Inks for food packaging (PIFOOD/Revised 2012-02-14); Swiss ordinance SR 817.023.21 Permitted Substances for Packaging Inks — Questions & Answers (1st revision 08 February 2011).

⁽¹⁴³⁾ EuPIA — Printing ink industry contribution to German paper, to reduce mineral oil in paper and board packaging (2010).

⁽¹⁴⁴⁾ In Section 2.4.2 and in Chapter 5.

⁽¹⁴⁵⁾ EuPIA — Customer Information Note regarding the use of sheeted offset printing inks/varnishes (setting and/or oxidative drying, or UV/EB curing) and water-based coatings for the manufacture of food packaging made from paper and board.

Ion exchange resins (IERS)

With respect to **national frameworks**, three MSs have reference to resins in their framework (Spain, France, the Netherlands), in addition to a CoE Policy statement at supranational level. An overview of the measures is tabulated in Annex 9. From a general standpoint, IERS are regulated under the concept of lists of authorised substances with residuals/contents, purity criteria and overall and specific limits imposed using a process of authorisation of substances.

The EFSA ESCO group did not include IERS in its review so there is no unified list other than those of the CoE, which is the most extensive, of Spain for the polymeric IERS and of France (with a recent update in 2015). The CoE list includes 253 substances, while the lists from Spain and France include 148 and six respectively (¹⁴⁶). The number of substances considered by CoE, Spain and France was estimated to a total of c.387. Yet, of those, only 34 substances (1 %) are common across three MSs, and including CoE. One national standard (France, AFNOR) exists specifically for IERS on release tests, but no standards exist specifically for FCMs at CEN level (only for drinking water).

Regarding **GMP**, declarations of compliance, supporting documents and sanctions specific to IERS, no exhaustive frameworks were found. Only generic references to sanctions for infringement of law (Spain), to obligations to provide a declaration of compliance (the Netherlands) or to manufacturing in accordance with a certified quality assurance system (CoE) are found. Regarding enforcement, only the Netherlands provides details for control laboratories (e.g. on migration conditions, methods, detection, calculation of results and the assessment of substances not included in the EU list). Spain provides some basic information on the verification of compliance.

SOIA stated it has published guidance for GMP for synthetic organic ion exchangers and adsorbents intended for food contact applications. This guidance was not received and could not be found. It is said to contain guidelines to meet Regulations (EC) No 1935/2004 (the framework regulation) and (EC) No 2023/2006 (GMP), specific to ion exchange and adsorbent resins.

No strong statement was given from MSs on **convergence** or on issues with respect to mutual recognition specific to IERS. There were no specific replies on the respective use of national legislation by industry sectors.

Overall, the following points can be summarised for IERS.

- *Three MSs (Spain, France, the Netherlands) and CoE have lists of authorised substances.*
- *Approximately 387 substances are considered across MSs and CoE.*
- *Only 34 substances (1 %) are common across three MSs.*
- *Existence of limited standards available at EU level (CEN); one at national level (France).*
- *No specific replies or presence of sectorial guides towards self-regulation.*
- *No specific replies on the respective use of national legislation by industry sectors.*
- *No strong statement from MSs on in using common measures or not.*

Varnishes and coatings

The sector consists in a large and complex group of chemicals, with varied usage (types of packaging, types of applications).

In terms of **national measures**, measures in the EU are available from 10 MSs and from the CoE. Measures based on lists of authorised substances and restrictions of individual substances were found from Belgium, the Czech Republic, Germany, Greece, Spain, France, Croatia, Italy, the Netherlands, Slovakia and Sweden. The details can be found tabulated in Annex 10 for both measures and standards.

There seem to be different definitions, with at least two definitions and a difference in the categorisation of materials. MSs regulate coatings with lists of authorised substances

⁽¹⁴⁶⁾ It should be noted that the substances listed are excluding those already included under the plastics legislation and therefore do not consider the measure from Italy.

using restriction tools such as residuals/contents, overall and with lists of authorised substances or SMLs/QMs imposed using a process of authorisation of substances. Categorisation is sometimes by end use (substrate).

The EFSA ESCO working group compiled a consolidated list for substances risk assessed for use in coatings. It contained 456 substances and only considered as valid the data from the Netherlands, whereas a relevant number of countries have measures. The list was updated with data from measures from Belgium, the Czech Republic, Germany, Greece, Spain, France, Croatia, Italy, Slovakia and Sweden. CoE lists were also considered towards their integration. This led to the estimate that more than **1 720** substances are considered across different MSs and CoE. Yet, of that number, only **88 substances (5 %)** are common to three or more MSs (or two or more MSs along with CoE). The tables of substances in common can be found in Annex 10. Different types of substances are typically considered by three MSs or more; those equally considered include oil and waxes, acids or salts, esters, and sugars and derivatives.

These substances were organised into four categories, based on the type of restriction and on the eventual convergence and degree of convergence of such restrictions.

- Agreement and absence of restrictions: 54 substances (monomers/additives) show a convergence as regards usage with no restrictions by MSs having measures.
- Agreement on restrictions: seven substances present restrictions that are converging in different national measures.
- Partial agreement: six substances show a partial agreement on restrictions (e.g. a majority but not unanimous use of a limit). Examples are given below.

- *Example 1: Ethyl cellulose (CAS 9004-57-3) has four countries setting no restrictions, and a fifth country setting the maximum allowed quantity in material.*
- *Example 2: For 2,2,4-trimethylhexane-1,6-diisocyanate (CAS 16938-22-0) and 2,4,4-trimethylhexane-1,6-diisocyanate (CAS 15646-96-5) all three sources agree on the same value for QM(T), but one of the sources adds a SML.*

- No agreement: 26 substances do not exhibit convergence in the restrictions applied.

The extent of harmonisation of restrictions for varnishes and coatings in the EU MSs is reported in the form of pie charts. Figure 34 depicts substances regulated by two or more MSs and the Coe or alternatively three or more MSs, with the number of substances (61) where a convergence (on restrictions or no restrictions) is shown (green) compared to those for which there is a partial convergence (orange) or no convergence (red) on restrictions. Figure 35 shows the same substances reported as a percentage of the total number of substances that are regulated at European level, including the substances that are regulated only in one or two MSs (in grey).

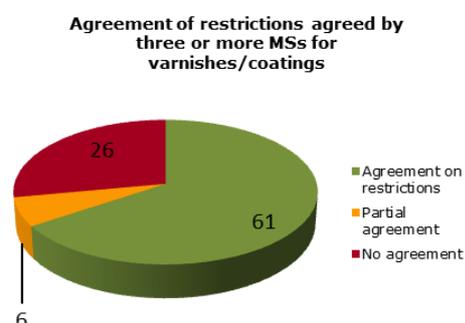


Figure 34: Pie chart on the extent of harmonisation on provisions on varnishes and coatings

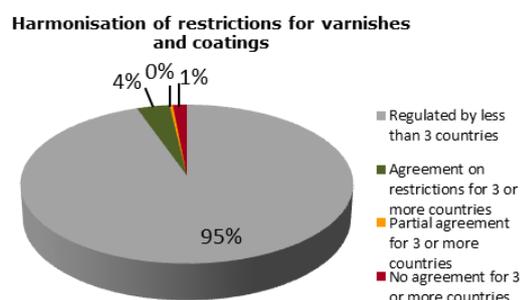


Figure 35: Substances are reported as a percentage of the total number of substances that are regulated at European level

An analysis was also carried out on possible convergences with the CoE lists of authorised substances. These are illustrated in the form of pie charts (Figure 36, Figure 37).

The conclusions are reported below.

- 415 out of the 576 substances (72 %) on the CoE list are not shared in the positive lists of MSs.
- Only 57 are common to two or more MSs (5 %) and 73 are common to only one MS (4 %).
- Out of the 57 substances common to two or more MSs, 39 have no restrictions and 18 have restrictions.
- Out of the 18 substances common to two or more MSs and for which CoE sets a restriction, 11 show a convergence in this restriction with one MS (the Netherlands).
- Out of the 57 substances common to two or more MSs, where CoE does not set any restriction, 39 (2 % of the total) show a convergence with at least one MS.
- Out of the six MSs (Germany, Greece, Spain, France, Croatia, the Netherlands) that have common substances with the same restrictions given in the lists of authorised substances of CoE, the MSs with most convergences are Greece and Spain (both 41 substances).

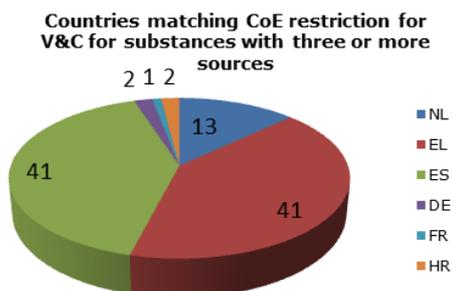


Figure 36: Pie chart of substances for which a given country matches a restriction of the CoE

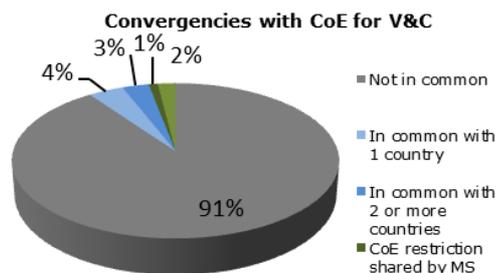


Figure 37: Substances as a percentage of overall substances for which a restriction of CoE matches that of 1, 2, 3 or more MSs

In addition, standards exist but can be limited in their scope, for example migration from substrates and individual substances. The development of standards has concentrated on epoxy coatings (e.g. for cans, EN 13130, 15136, 15137), polymeric coatings on paper substances (e.g. EN 14234, 14235), thermally sprayed coatings (DVS 2317), on drinking water (EN 16058, EN 12873-4, EN 15768) and steel with organic coatings for food applications (FR NF 36 713:2004).

Regarding information on **GMP**, declarations of compliance, supporting documents and sanctions specific to varnishes and coatings, only very few sources have references (CoE for GMP compliance, Belgium and Greece for necessity of providing supporting documents and Italy and Spain for sanctions). No MS presents exhaustive information and requirements. Regarding information on enforcement, testing methods and/or test conditions are indicated for Belgium, Germany, Croatia, Italy and the Netherlands, while Spain only makes reference to verification of compliance with migration limits.

CEPE has published several guides on GMP production of coatings for various applications such as can coatings ⁽¹⁴⁷⁾, heavy-duty coatings ⁽¹⁴⁸⁾, three separate codes of practice ⁽¹⁴⁹⁾, guidance to hygiene and GMP ⁽¹⁵⁰⁾ and guidance on traceability ⁽¹⁵¹⁾.

The professional associations who replied (CEFIC FCA, ACE, FPE) refer to Regulation (EU) No 10/2011, SR 817.023.21 (Switzerland), BfR Rec. XIV (Germany), Warenwet (the Netherlands, Ch. X), FDA 21 CFR 175.300 or 175.320 (United States) and potentially DM 1973 (Italy) and DR 847 (Spain). The ECMA guidance was also cited. The summary of the citations is reported in Table 6 by sector that replied. It is not clear why SR 817.023.21 and BfR XIV are cited for coatings as they do not seem the most applicable.

⁽¹⁴⁷⁾ CEPE — Good Manufacturing Practices for the production of coatings intended to come into contact with food, 2010.

⁽¹⁴⁸⁾ CEPE — Good manufacturing practices for the production of heavy duty coatings which come into contact with food

⁽¹⁴⁹⁾ CEPE — Code of practice for coated articles where the food contact layer is a coating, Working Document, 4th edition, 2/2/2009, Code of practice annex — 2007; Code of Practice for Coatings on finished light metal packaging articles for direct food contact.

⁽¹⁵⁰⁾ CEPE — Guide to good hygiene and manufacturing practices for metal cans, packaging and closures for foodstuffs

⁽¹⁵¹⁾ CEPE — Code of good industrial practices on traceability of materials and articles for food contact, 2004.

Table 6: National measures taken as references for the varnishes and coatings sector

| Sector | Regulation (EU) No 10/2011 | CH 817 | DE BfR | NL X | IT DM 73 | other |
|-----------------|----------------------------|--------|--|------|----------|--|
| Chemicals | x | X * | XIV | x | x | US DFA (21 CFR 175) |
| Paper and board | X | X * | XIV, XLI | x | x | ES 847/2011 EuPIA guide ECMA GMP |
| Plastics | X | X | XIV (plastics dispersion) XXI (based on rubber) | X | | CoE ResAp(2004)1 ES 847/2011; US FDA 21 CFR |
| Ink (I&P) | X | X | | | | US FDA (I&P)(unspecified) |
| Silicones | | | X which? | X | | CoE ResAp(2004)1 |
| Norden | X | — | XIV, LI | X | | US FDA (unspecified) |

Therefore overall, the following points can be summarised for varnishes and coatings.

- Presence of national legislation and CoE publications.
- 11 MSs have provisions for authorised substances, and CoE has a policy statement.
- SML and QM/residual and compositional limits are used.
- Approximately 1 721 substances are considered across MSs.
- Only 88 substances (5 %) are common to three MSs or more.
- A number of standards are available at EU, national and worldwide level for FCMs (CEN, ISO).
- From an industry standpoint, there are sector-specific self-regulation guidelines on GMP (CEPE) for several types of coatings, three separate codes of practice and a guide on traceability.
- The materials sector stated a convergence for taking as a basis the plastics regulation, and for national rules taken as reference where the most cited is the BfR Rec. XIV.
- Some sectors, but not all, also mentioned CH Ord. 817, ES 847/2011 and US FDA 21 175.300 or 320 so the convergence on the main national reference may vary depending on the sector.

Waxes

The waxes sector is fairly contained, although it can represent a complex group of chemicals with varied usage (type of packaging, types of applications). Only 15 % of the overall wax production in Europe is destined for FCM applications.

Only a few MSs possess **national measures** for waxes. These are tabulated in Annex 11. Four countries have national measures (Germany, Spain, the Netherlands and Switzerland) and function on the basis of a positive list accompanied by maximum content (Germany, Spain, the Netherlands, Switzerland) or migration limits (Spain). France only authorises one substance as a fungicide in waxes, specifying the maximum content. Different definitions exist, which seems a major issue (at least two definitions, and differences in categorisation of materials). Lists can be presented by types of waxes and crystalline-/semi-crystalline-type structures.

No **standards** were found for waxes.

The EFSA ESCO working group did not consider the waxes sector in its work. Consequently there is, to date, no consolidated list of substances.

No references were found for **GMP**, declarations of compliance, supporting documents and enforcement specific to waxes. Only Spanish legislation contains a stipulation that sanctions are based on a specific decree. In the context of GMP, there is no sector-specific additional guidance beyond Regulation (EC) No 2023/2006.

From a **MS standpoint**, general references are made to using the CoE or industry guidelines or using a case-by-case basis using the information provided by the business operators. The assessment is made from the standpoint of compliance with Regulations (EC) No 1935/2004 and (EC) No 2023/2006.

The sectors seem to refer to the German BfR Rec XXV ES DR 847, US CFR 105 and the Dutch II+X. The professional associations provided information both for the wax sector itself (EWF) and for other sectors (based on those who replied, i.e. ACE, CEFIC-FCA, FPE). In practice they tend to apply the German BfR recommendations, the Dutch 'Warenwet', and US FDA CFR 175.105. EWF also reports that it considers indirectly, for quantity in materials, the purity requirements of the same references to limit polycyclic aromatic hydrocarbons. The paper and board sector cites Regulation (EU) No 10/2011, German BfR Rec (unspecified) and US FDA CFR 175.105. The chemicals sector (CEFIC-

FCA) and the plastics sector (FPE) also cite the German BfR Rec XXV and US FDA CFR 175.105, with FPE also adding references to CoE Res AP (2004)¹, Food additives list, and Spain RD 847/2011. The Dutch II + X is also mentioned in the context of specific migration for FPE and the Spanish RD 847/2011 is particularly looked at for that sector (FPE) with respect to overall migration and quantity in materials. Norden only mentions the German BfR Rec. XXV.

Materials sectors: ceramics, glass, metals and alloys, enamel

Ceramics

Ceramics are regulated at EU level by Directive 84/500/EEC, as amended by Directive 2005/31/EC. The only substances regulated under these directives are lead and cadmium, with limits imposed for the release of these two elements into food and rules for migration testing using a 4 % acetic acid solution as a simulant.

Apart from implementing the European directive, three countries (Austria, the Netherlands and Norway) set specific release limits for metals other than lead and cadmium. Namely, barium is regulated in all three countries, while arsenic, boron, chromium, cobalt, mercury, lithium, rubidium, selenium and strontium are regulated in the Netherlands and zinc and antimony are regulated in Austria. In Finland, a limit exists for chromium and nickel. In five countries (the Czech Republic, Denmark, Germany, Poland and Norway), limits for the release from the mouth rim for lead and cadmium are applied either in mg/article or in mg/dm² of surface area. The measures in Germany and Poland are national standards, and compliance with these standards is considered as GMP. Norway applies a limit for the release of barium from the mouth rim. In Croatia, a limit for the release of lead and cadmium from unglazed clay cookware exists based on a repeated release test. The Netherlands applies an overall release limit of 60 mg/kg food specifically for ceramic articles. Measures and their contents can be found in Annex 12.

Those countries that set specific or overall release limits also provide instructions on how to perform the respective release tests, except for Austria and the Czech Republic where the instructions do not go beyond the provisions given in 84/500/EEC. In Norway, the instructions are also limited but it is stated that the same principles for sample preparation and analysis shall apply also for the determination of metals other than lead and cadmium if suitable (see NO 1381/1993 Chapter VI §26).

Directive 84/500/EEC already requires a declaration of compliance for ceramic articles with respect to the limits established for the release of lead and cadmium. In Austria, the Czech Republic and Norway, where additional provisions are set out in legislative measures, the declaration of compliance also covers the additional provisions, but apart from this it requires the same information as in Directive 84/500/EEC. For the Netherlands, no additional declaration of compliance is required apart from the specifications in Directive 84/500/EEC. From a worldwide standpoint, ceramics are regulated in many parts of the world (see also Annex 12), with lead and cadmium being the two metals regulated uniformly.

Standards exist at international level, both at the level of the CEN and ISO (Annex 12). They mostly target the release of lead and cadmium from ceramic ware or other silicate surfaces (EN 1388) or give requirements for ceramics/glass/glass ceramic cookware (CEN 12983, ISO 8391), dinnerware (ISO 6486), vitreous and porcelain enamels (ISO 4531), glass (ISO 7086) or cutlery/table/decorative metal hollowware (ISO 8442).

Cerame-Unie has published a position paper (August 2013) on the European Commission proposal for a legislative Package but no GMP guidance has been specifically developed for the sector to date.

The industry chain did not provide specific information on additional rules at national level that are followed for ceramics. No other sector replied for ceramics. Norden made

reference to the Swedish material norm ⁽¹⁵²⁾ (SLV FS or Normpack norm) and to the Dutch Warenwet V.

Overall, the following points can be summarised for ceramics:

- *Presence of EU and worldwide legislation already implemented.*
- *Six MSs have additional provisions with lists of authorised substances and SMLs.*
- *Additional harmonisation possible to include the rim (in effect by five MSs).*
- *Approximately 16 substances are considered across MSs.*
- *Barium as a metal considered by three MSs.*
- *6 % of other substances are common to three MSs or more.*
- *Many standards available (CEN, ISO)*
- *From an industry standpoint, there is no particular sector-specific guidance on GMP.*
- *No convergence expressed beyond Directive 84/500/EEC and FDA proposition 65 as references; other sectors expressed a wish to be covered under a ceramic umbrella.*

Glass

National/supranational measures

National measures are present in 12 MSs with restrictions that include SML/QM (three with lists of authorised substances). Overview tables can be found in Annex 13.

Lists of authorised substances exist for substances allowed in the treatment of the external surfaces of glass (e.g. Belgium, Slovakia) and for the definition of the types of glass that can be used in contact with food. Sixteen substances are covered in total. Lead and cadmium are regulated in priority but other metals as well (mirroring the individual MS approach to ceramics): 11 countries (including Norway and Switzerland) set limits for lead and cadmium, while Italy sets limits only for lead and four apply the same limits as established for ceramics (Bulgaria, the Czech Republic, Denmark, Switzerland). Overall migration limits exists in two MSs (Belgium and the Netherlands).

Mercury is banned in at least three MSs (the Czech Republic, Denmark, France), and glass wool is banned in Croatia.

In general the release limits imposed in the context of Directive 84/500/EEC are applied to glass. In some cases there are additional restrictions on the basis quantity per article ⁽¹⁵³⁾. For some MSs additional metals are included, for example there are SMLs for antimony, arsenic, barium, boron, cerium, fluorine, cobalt, lithium, manganese, nickel, rubidium and zirconium in the Netherlands and hexavalent chromium in France.

In addition, release from the rim is regulated by the Czech Republic, Denmark, France, Germany and Norway. The CoE considers the release for different types of glass FCM. Instructions for release tests are described in a number of measures (e.g. in Bulgaria, the Czech Republic, Denmark, France, Germany, Italy and Norway).

At the level of the **CoE**, the policy statement ⁽¹⁵⁴⁾ concerning lead leaching from glass tableware into foodstuffs reports limits set by the ISO 7086-2 and ISO 6486-2 standards for lead in different types of glass FCM (Chapters 9.3.1 and 9.3.2). The levels are not necessarily intended to be regarded as the maximum amount of these metals to which exposure can be considered safe, but somewhat harmonised levels consistent with GMP in the respective industries.

The EFSA ESCO working group did not consider glass in its report.

Standards are available for glass most often in combination with ceramics. Their focus is principally on the release of lead and cadmium for cookware (CEN 12983), dinnerware (ISO 6486), hollowware (ISO 7086) or in general (NFB 35 357, UNE 126301).

⁽¹⁵²⁾ Swedish material norm (the Normpack norm) for materials and articles in contact with foodstuffs, fifth update, 2014.

⁽¹⁵³⁾ For example < 2.0 mg lead/article (Czech Republic), 1 mg lead/dm² or 5 ppm (Belgium), <LOD (lead): 0.05 mg/l (Germany) and for cadmium < 0.20 mg cadmium/article (Czech Republic), 0.1 mg cadmium/dm² or 0.5 ppm cadmium (Belgium), <LOD (cadmium): 0.005 mg/l.

⁽¹⁵⁴⁾ Council of Europe, ResAP(96)4, Policy statement concerning lead leaching from glass tableware into foodstuffs. V1, 2004.

Regarding **GMP**, declarations of compliance, supporting documentation and sanctions almost no information was provided specifically for glass (only Slovakia stated the need to manufacture glass items according to GMP and Italy obliges producers to provide a declaration of compliance). Regarding information in support of enforcement, seven countries (Bulgaria, the Czech Republic, Denmark, Germany, France, Italy and Norway) provide reference to analytical methods to test migration. The requirement for compliance documentation is specified in Italy.

From an **MS standpoint**, either the Netherlands is mentioned as a reference or MSs make a judgement on a case-by-case basis using the information provided by the business operators. The assessment is made from the standpoint of compliance with Regulations (EC) No 1935/2004 and (EC) No 2023/2006. The Netherlands seems to have the most extensively accepted framework.

A number of guidance documents are available for the glass sector on REACH ⁽¹⁵⁵⁾, on FCM regulation in relation to glass ⁽¹⁵⁶⁾ and on life cycle assessment ⁽¹⁵⁷⁾.

From an **industry standpoint**, GAE and Normpack use the Netherlands' regulation (including for mercury as banned substance) and refer to France, Italy and the Netherlands for limits of overall and specific migration. For limits placed on quantity in materials, the sector refers to the EU packaging directive (Directive 94/62/EC – lead, cadmium, mercury and hexavalent chromium), to national regulations (e.g. Italy), and to Directive 69/493/EC on crystal glass. Guidance documents are available for the glass sector on REACH, on FCM regulation in relation to glass and on life cycle assessment. With regard to GMP specific to the glass sector, little information was received beyond the reference to Regulation (EC) No 2023/2006 from the professional associations for the glass sector. One association (WBT) mentioned ISO 22716:2007 ⁽¹⁵⁸⁾. GAE stated that they have prepared a draft guidance document on GMP.

Therefore, from a regulatory framework standpoint, the metals regulated for glass are similar to metals regulated in other sectors such as ceramics, with a similar approach.

Overall, the following points can be summarised for glass.

- *Twelve MSs have lists of authorised substances and OML, SMLs/SRLs or compositional restrictions.*
- *Testing on rims in effect by five MSs (Czech Republic, Denmark, France, Germany, Norway).*
- *Approximately 16 substances are considered across MSs.*
- *Mercury is generally considered to be banned.*
- *Standards available (CEN, ISO), often in common with ceramics (e.g. tableware).*
- *No particular sector-specific guidance on GMP but one may be in progress.*
- *A level of convergence seems to be present towards the Netherlands framework.*

Metals and alloys

The metals and alloys sector includes a variety of metal-based materials, coated or uncoated. Types of materials include rigid metal packaging, steel and stainless steel, aluminium and aluminium alloys, tin and tin alloys, cast iron, etc.

National measures in the EU are present for metals and alloys in 10 individual MSs. At the supranational level, Norden and the CoE have also developed specific guidance. An overview of the measures is tabulated in Annex 14. All converge under the concept of lists of authorised substances with residuals/contents, purity criteria and overall and specific limits imposed. The EFSA ESCO group did not include metals and alloys in its review on non-harmonised materials so there is no unified list.

Overall, the **national provisions** seem to present an assortment of rules that may differ or may be similar but are difficult to decipher for the non-specialist. France has a

⁽¹⁵⁵⁾ Guidelines for the glass industry, REACH (2010); Glass, Glass articles and the EU REACH regulation (May 2012).

⁽¹⁵⁶⁾ Glass and food contact regulation (version Dec. 2011).

⁽¹⁵⁷⁾ Gap analysis for the Life Cycle Assessment of Container Packaging (2012), M. Finkbeiner, ISBN 978-3-00-041338-4.

⁽¹⁵⁸⁾ ISO 22716:2007: Cosmetics – Good Manufacturing Practices (GMP) – Guidelines On Good Manufacturing Practices.

relatively consistent regulatory framework in one unique block, whilst Italy has relevant measures but they are dispersed into different provisions. The nature of the metals regulated is often similar (for example, lead, cadmium, arsenic, zinc, chromium, nickel and copper). The situation is less clear in terms of the quantitative restrictions imposed. Some national legislation (e.g. Italy) specifies limits by categorisation across different metals and alloys, for example varnished tin-free steel, stainless, tin-free steel (and tinfoil FCM), aluminium and aluminium alloys. National provisions often differ between MSs, for example Italy setting different migration limits for the same metal from the Netherlands. The two national laws also cover different metals.

CoE resolution CM/Res (2013)9 suggests limits as specific limits for release (SRLs, in mg/kg food) for metals and alloys for **15** metal ions ⁽¹⁵⁹⁾ for materials and articles at the end-use level, coated or uncoated, made completely or partially of metals and alloys. The values are stated to derive from toxicological information, the 'as low as reasonably achievable' (ALARA) principle where appropriate or relevant legislation. The CoE resolution SRLs do not differentiate between the types of metals and alloys, but mention that technical specifications for metals and alloys defined in European standards (EN ISO) should be taken into account, along with national legislation on the composition of metals and alloys.

The Nordic guidance takes into account the SRLs of the metals considered by the CoE, (both those as main components and those as impurities). It also includes, for information, levels allowed for drinking water and for plastics as a comparison. It provides explanatory notes on the risk assessments done (e.g. JEFCA, EFSA).

Considering that the CoE guidance post-dates all the national provisions reviewed, it seems that this document already encompasses the assessment of the limits for the different metals and their applicability to consider metal packaging as one unique block rather than by category of types of metals.

Standards exist both at EU level and at national level, usually published in categories that represent different metals as the primary driver and with a second classification that may target specific uses (see Annex 14). Standards include EN 610/1995 for tin and tin alloys ⁽¹⁶⁰⁾. Codex Standard 193-1995 sets maximum limits for tin in canned foods and in canned beverages ⁽¹⁶¹⁾. European standards ISO 8442-2 and 8442-3 apply to silver-plated nickel silver or silver-plated stainless steel cutlery and to coated brass, copper, nickel-silver, pewter and stainless steel hollowware and attachments. The EU packaging directive (Directive 94/62/EC) limits the lead content of tin cans ⁽¹⁶²⁾.

The stainless steel grades commonly used for food contact applications are defined by European Standard EN 10088 ⁽¹⁶³⁾. There are no universal composition limits for stainless steels used in food contact applications, although there are legislative requirements in France and Italy. In France, stainless steels for food contact products must contain at least 13 % chromium and can contain nickel and manganese. Maximum limits are imposed for certain other alloying elements (4 % for molybdenum, titanium, aluminium and copper; 1 % for tantalum, niobium and zirconium). The AFNOR 10333 standard relates to steel packaging. In Italy, there is a list of stainless steel grades for FCMs. These grades must pass tests for corrosion in distilled water, olive oil, an aqueous solution of ethanol and 3 % acetic acid in water, under specified conditions. New grades

⁽¹⁵⁹⁾ Aluminium 5 mg/kg, antimony 0.04 mg/kg, chromium 0.250 mg/kg, cobalt 0.02 mg/kg, copper 4 mg/kg, iron 40 mg/kg, magnesium — mg/kg, manganese 1.8 mg/kg, molybdenum 0.12 mg/kg, nickel 0.14 mg/kg, silver 0.08 mg/kg, tin 100 mg/kg, titanium — mg/kg, vanadium 0.01 mg/kg and zinc 5 mg/kg), and for metals as contaminants and impurities (arsenic 0.002 mg/kg, barium 1.2 mg/kg, beryllium 0.01 mg/kg, cadmium 0.005 mg/kg, lead 0.010 mg/kg, lithium 0.048 mg/kg, mercury 0.003 mg/kg and thallium 0.0001 mg/kg). Note for magnesium and titanium: CoE states that deriving an SRL was unnecessary (magnesium) / inappropriate (titanium).

⁽¹⁶⁰⁾ For items coated exclusively with tin or tin alloy, or partly tin-plated materials that, as finished products, recurrently come into direct contact with food. It specifies a maximum permissible lead content of 0.050 % and a specific migration limit for antimony of 0.01 mg/kg.

⁽¹⁶¹⁾ 250 mg/kg for tin in canned foods and 150 mg/kg for tin in canned beverages.

⁽¹⁶²⁾ To less than 100 ppm.

⁽¹⁶³⁾ European Standard EN 10088-1:2005 (CEN — European Committee for Standardization, June 2005).

can be added to the list following appropriate testing. In the United Kingdom, there are numerous specifications for a wide range of food contact applications for stainless steels. Other countries also have similar regulations. Italian, French, UK and German legislation/standards can exhibit variations. In addition, there are European standards for certain types of application of stainless steels. The composition limits for stainless steel for table cutlery are also specified in EN ISO 8442-2. The composition depends on the application of the table cutlery. Compositional information on some other grades of stainless steels used in food contact applications can be found in the 'Outokumpu stainless corrosion handbook' ⁽¹⁶⁴⁾. Aluminium alloys for FCMs may contain alloying elements such as magnesium, silicon, iron, manganese, copper and zinc (EN 601/602). Therefore, in terms of standards, the principles seem more based on differentiating by type of material or end use.

Replies on what is used in practice by MSs lacking their own legislation did not indicate a particular convergence with regard to the metals and alloys sector, as most replies indicated using a case-by-case type of approach. The CAST project ⁽¹⁶⁵⁾ has addressed the guidelines for the application of GMP to the supply chain of FCMs. It covers metals and alloys, both coated and non-coated.

Several specific guidance documents are present in the metals and alloys sector regarding **GMP**, including for steel, aluminium alloy and more generally on metal packaging in contact with food. These encompass guidance for steel ⁽¹⁶⁶⁾, an EAA guide for aluminium alloy semi and end products ⁽¹⁶⁷⁾ or more general guidance for metal packaging in contact with food ⁽¹⁶⁸⁾. There is no further specific guidance for sectors such as to stainless steel or cookware. With regard to GMP, the EAA GMP guide and the CAST project are also mentioned by other associations.

From an industry standpoint, there was a scarcity of feedback from the associations of the metals and alloys sector on what measures are taken as reference in practice for compliance. Other sectors that provided feedback — such as ACE and FPE — mention using FDA 178.3910 for lists of authorised substances and note they also consider heavy metals as banned substances. This would assume that national measures (e.g. Austria, Switzerland) that have bans on using lead, cadmium and zinc and their alloys are used, and the same would also be the case for limits applied by Austria on alloys containing arsenic or antimony. ACE and FPE indicate using CoE as reference for overall migration and EN 601/602 for specific migration/QM (and EN 573-3).

There is a lack of input or references to specific requirements or guidance documents for declaration of compliance, supporting document or sanctions. The only references in national measures are to stipulate that there is an obligation to provide a declaration of compliance and supporting documents.

Overall the points can be summarised as follows for the metals and alloys sector.

- | |
|--|
| <ul style="list-style-type: none"> • <i>Ten MSs with measures, along with Norway/Norden.</i> • <i>Measures are fairly diverse in their content.</i> • <i>Lists of authorised substances with SMLs/QMs.</i> • <i>Extensive CoE resolution exists, along with technical guidance.</i> • <i>SRLs for 15 metals as components and metals as contaminants/impurities.</i> • <i>Convergence between Norden and CoE.</i> • <i>Issue of categorisation: some measures apply a categorisation across different metals and alloys (e.g. varnished tin free steel, stainless, tin free steel (and tinplate FCM), aluminium and its alloys). CoE does not.</i> • <i>No universal compositional limits, but elements are given in national legislation (France, Italy).</i> |
|--|

⁽¹⁶⁴⁾ 'Outokumpu stainless corrosion handbook', 10th edition 2009.

⁽¹⁶⁵⁾ IT — Guidelines for the application of the regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come in contact with food. M.R. Milana, M. Denaro, R. Feliciani, A. Maggio, A. Maini and G. Padula.

⁽¹⁶⁶⁾ APEAL — Guide of Good Manufacturing Practices for the EU Steel for Packaging Industry (version: 09-01-07).

⁽¹⁶⁷⁾ EAA — Code for good manufacturing practices for the European aluminium industry: aluminium alloy semi and end products intended to come into contact with foodstuffs (2012). NB: Supersedes version of 2008.

⁽¹⁶⁸⁾ EMPAC — Guide to good manufacturing and hygiene practices for metal packaging in contact with food, Edition 1: May 2009.

- *Standards exist from Cen, Codex, ISO, NF (France), DIN (Germany), BSI (United Kingdom).*
- *Lack of input on what is used in practice (from both MS and industry sector) and if any convergence exists.*
- *Other sectors (paper, plastics) refer to CoE, standards (EN601/602, EN573-3), FDA (178.3910).*
- *Sector-specific guides on GMP exist for steel and aluminium alloy; more general on FCM metal packaging.*
- *GMP guidance for CAST project (especially coated/uncoated metals and alloys) mentioned as reference used.*

Materials sectors: cork and wood, paper and board, rubber and silicones

Cork and wood

National measures are present in five MSs (the Czech Republic, France, Croatia, the Netherlands, and Slovakia) for cork and the CoE has a policy statement⁽¹⁶⁹⁾. From a general standpoint, cork is regulated with authorised substances, using overall and specific limits. An overall limit is used and set at 60 mg/kg. It can be tested using the ISO 10106 standard. France bans some antifungal treatments for wood.

The CoE resolution on cork includes a positive list of assessed substances (monomers, starting agents, additives and processing aids) and a negative list of substances not assessed that should not be used in the production of cork FCM.

The definition of cork is laid out in an ISO standard (ISO 633). Cork stoppers or the cork part should contain at least 51 % manufactured cork (w/w). The cork part of cork stoppers can be made of a whole piece or two or more pieces of cork or granulated cork that are bound together by means of glues, adhesives, or by any other means.

With respect to wood, three MSs (France, Croatia and the Netherlands) have measures, with those of France being the most extensive.

The overview of the measures and standards available at national level for cork and wood was tabulated and can be found in Annex 15.

The EFSA ESCO working group considered cork together with wood in its report on non-plastic FCMs. It contained 59 substances, which represented only restrictions listed from the Netherlands' measure. The substances considered by the Czech Republic, France, Croatia and Slovakia and those found on the CoE lists were integrated. A total of **168** substances are found in national measures across different MSs for cork and wood. Of these, **19 substances (11 %)** are common to two or more MSs and the CoE (or three or more MSs).

Some standards are present at ISO and national (UNE/UNI) levels for cork (Annex 15)

From an MS standpoint, no strong convergences or divergences are expressed. The assessment of compliance in the absence of national rules is made from the standpoint of compliance with Regulations (EC) No 1935/2004 and (EC) No 2023/2006 on a case-by-case basis using the information provided by the business operators.

The industry approaches and guidance documents for cork include two codes of practice⁽¹⁷⁰⁾⁽¹⁷¹⁾, along with informative documents⁽¹⁷²⁾⁽¹⁷³⁾. The CoE policy statement on cork recommends the use of the guidance from CELiege as a manufacturing guide.

For the wood sector, Fedemco (Spanish Federation of Wooden Crates and their Components) has produced a GMP guide⁽¹⁷⁴⁾.

From a convergence standpoint, Normpack refers to the Netherlands (Warenwet IX), and

⁽¹⁶⁹⁾ Council of Europe, ResAP (2004)2, Policy statement concerning cork stoppers and other intended to come into contact with food, V2, 2007.

⁽¹⁷⁰⁾ C.E.Liège — Code International des Pratiques Bouchonnières (Version 6.03).

⁽¹⁷¹⁾ C.E.Liège — International Code of Cork Stopper Manufacturing Practices (ICCSMP) 6.04 Edition.

⁽¹⁷²⁾ APCOR — A new technology for volatiles reduction on natural cork stoppers: INNOCORK process.

⁽¹⁷³⁾ APCOR — Cork culture, nature, future; Cork information Bureau 2010. Quality (www.realcork.org).

⁽¹⁷⁴⁾ Fedemco — Guide to good hygiene and manufacturing practices for the sector of wooden packaging and their components intended to come into contact with food (2010).

the cork sector cites the abovementioned CoE document and the Dutch Warenwet IX. There was no real convergence (either from MS or from industry) for wood.

Overall the main points can be summarised as follows for the cork and wood sector.

- *Five MSs with measures (Czech Republic, France, Croatia, the Netherlands and Slovakia) for cork.*
- *A CoE policy statement exists for cork.*
- *Three MSs with measures (France, Croatia and the Netherlands) for wood, with predominance of France.*
- *Lists of authorised substances with SMLs/QMs for both cork and wood (and OM for cork).*
- *Specific migration limits for 168 substances in total.*
- *Standards present at ISO and national (UNE/UNI) levels for cork.*
- *Apparent convergence on using the provisions of the Netherlands (and in second position CoE) for cork.*
- *Unclear what is used in practice (both from MS and from industry) for wood.*
- *Sector-specific guides on GMP exist for cork and are recommended in the CoE guide.*
- *A code of practice is present for wood.*

Paper and board (P&B)

With respect to **national/supranational measures**, there are nine MSs (Belgium, the Czech Republic, Germany, France, Greece, Croatia, Italy, the Netherlands and Slovakia) that specifically cover the domain of paper and board. In addition, the CoE published two resolutions on paper and board and tissue paper respectively. The overview of measures and standards can be found in Annex 16.

The legislative measures in Belgium, the Czech Republic, Italy, the Netherlands and Slovakia, the national recommendations in Germany and the resolutions from the CoE provide extensive lists of authorised substances that may be used in the manufacture of paper and board materials. Besides paper and cardboard for general use, the measures in the Czech Republic, Germany and the Netherlands further differentiate between paper for use at boiling point, for hot filtration, for use as filtering layers (hot or cold filtration), for baking purposes and/or for use as absorber pads, whereas the CoE released a specific resolution for tissue paper kitchen towels and napkins. Separate lists of authorised substances and requirements are set for the different categories.

The EFSA ESCO working group developed a list of substances for paper and board. It contained 565 substances that were considered as valid for risk assessment from Germany, France, Italy and the Netherlands. This list was updated for regulated substances with data on measures from other MSs (including Belgium, the Czech Republic, Croatia and Slovakia). CoE lists were also considered towards their integration. An estimated total of **c. 1 710** substances were found in national/supranational measures (including 1 100 from CoE). Of these, **147 (9 %) substances** were common to two or more MSs and the CoE (or alternatively three or more MSs).

In several MSs (Belgium, the Czech Republic, Germany, Italy and Slovakia), lists of authorised substances include fibrous raw materials, fillers, processing/production aids (e.g. sizing agents/binders, precipitating/fixing/parchment agents, retention agents, dewatering accelerators, dispersion/flotation agents, defoaming agents, slimicides, preservatives) and refining agents (e.g. wet-strength agents, humectants, colourants, optical brighteners, surface refining/coating agents). In the Netherlands, the lists include only auxiliaries and refining agents; no fibrous raw materials are included. In France, only a few bactericides, optical brighteners, preservatives and grease-proofing agents (in total only about 20 substances or groups of substances) are authorised by different legislative measures. Along with the extensive lists of authorised processing aids and refining agents set up in Belgium, the Czech Republic, Germany, Italy, the Netherlands and Slovakia, restrictions are established for some of the authorised substances and impurities. These restrictions are mostly QM limits or limits for a maximum usable dose. Restrictions are not necessarily provided for all substances.

The CoE provides extensive lists of authorised substances for paper and board FCMs in general (excluding filtering layers of high grammage and consisting to a large extent of non-fibrous material, along with tissue paper, kitchen towels and napkins). It lists about

300 assessed additives (¹⁷⁵) and about 200 assessed monomers used for the manufacture of polymeric additives (¹⁷⁶).

For tissue paper kitchen towels and napkins, the CoE lists 46 functional additives and 90 processing aids that are typically used and that are all in line with BfR Recommendation XXXVI.

CoE Res AP (2002) technical document 1 instead mainly sets SML or SML(T) values. For about 30 % of the listed assessed additives and for about 50 % of the listed assessed monomers used for the manufacture of polymeric additives, SML or SML(T) values are provided. QM limits are set only for about 1 % of the listed assessed additives. For some contaminants, mainly originating from recycled fibres, and other substances of concern, QM limits or SML values are set in almost all available measures (Table 7).

Table 7: Examples of most commonly regulated substances from recycled fibres

| Substance | Countries or stakeholders of common occurrence | Limits applied | values reported as used by industry (¹⁷⁷) |
|---|--|--|---|
| Michler's ketone | CoE, HR, CEFIC, DE, Norden | ND (0.01 mg/kg): CoE, Norden | 0.0016mg/dm ² |
| Benzophenone (4-MBP, 4-OH-BP) | EE, CoE, HR, DE, CEFIC | 0.1 mg/dm ² | 0.1 mg/dm ² |
| 4,4' bis diethylamino benzophenone | CoE, Norden | ND in foods (0.01 mg/kg) | 0.0016mg/dm ² |
| N,N-diethylamino benzaldehyde (DEAB) | CoE, HR, CEFIC | — | — |
| Formaldehyde | DE, FR, IT, BE, CZ, SK | — | — |
| Glyoxal | FR, BE, DE, HR, CoE | — | — |
| PCP or polychlorinated phenols in general | HR, NL, CZ, DE, EL, FR, SK, CoE, Norden, CEFIC | 0.15 mg/kg P&B | 0.15 mg/kg P&B |
| Heavy metals (Cd, Pb, Hg, Cr and/or As) | HR, IT, NL, CZ, DE, EL, FR, SK, CoE, CEFIC, Norden | Cd: 0.002 mg/dm ² (CoE, Norden) Pb: 0.003 mg/dm ² (CoE, Norden) Hg: 0.003 mg/dm ² (CoE, Norden) | Cd: 0.5 mg/kg P&B Pb: 3mg/kg P&B Hg: 0.3mg/kg P&B |
| PCBs and Dioxins | CZ, FR, SK and Norden, HR, CoE | As low as possible (or 120 pg TEQ/kg food or simulant) | Not mentioned |
| PAAs/azo colourants | DE, CZ, HR, SK, CoE, CEFIC, Norden | 0.1 mg/kg P&B | 0.1 mg/kg P&B |
| PAH | CoE, HR, CEFIC, CZ | ND in foods (0.01 mg/kg) | 0.0016mg/dm ² |
| Phthalates (e.g. DBP, DiBP, DEHP, BBP, DINP, DIDP, DOP) | HR, NL, CEFIC, DE, CZ, SK, CoE, CEFIC | Plastics regulation (Regulation (EU) No 10/2011) used (CoE) | Different values expressed in mg/dm ² |
| BPA | CEFIC, DE | Under review | — |
| Diisopropyl naphthalene (DIPN) | DE, HR, CEFIC, CoE | As low as reasonably achievable (CoE) | No requirements |
| Partially hydrogenated terphenyls (HTTPs) | HR, CoE | As low as reasonably achievable (CoE) | No requirements |
| 3-MCPD, DCP | CoE | | |
| Solvents | CoE | Reduce levels to lowest possible | No requirements |

The 147 substances previously cited were organised into four categories (see Annex 16), based on the type of restrictions set by the legislation and on the potential convergence and degree of convergence of restrictions across countries.

- Agreement on absence of restriction: 29 substances (both monomers and additives) show a convergence in the MSs agreement on their authorisation and absence of restriction.
- Agreement on restrictions: 28 substances present restrictions that are convergent across different EU MSs. It should be noted that CoE sometimes states that the restrictions are under revision. In this case, as no further information was provided, it was decided to consider the agreement between the other countries and include the

(¹⁷⁵) NB: In addition, 300 additives approved in partial agreement and 400 not assessed.

(¹⁷⁶) NB: In addition, 34 monomers approved in partial agreement and 180 not assessed.

(¹⁷⁷) Internal document provided to DG Health and Food Safety, 2014-2015.

substances in the category of 'agreement on restrictions'.

- *Example: 2-Amino-2-methylpropanol (CAS 124-68-5). Germany and Croatia set the same restriction, and for CoE restrictions are to be set.*

- Partial agreement: 16 substances show a partial agreement on restrictions, either because one restriction is common to some countries or another restriction is common to another set of countries, or because not all countries agree on one restriction (or on absence of restrictions), but most of them do. Some examples are illustrated below.

- *Example 1: 1-bromo-3-chloro-5,5-dimethylhydantoin (CAS 16079-88-2) has a restriction (maximum quantity in material) that is common to two MSs, but one of the two MSs also added some restrictions for by-products of the substance. CoE stated that the restrictions have still to be set. Thus there is not a total convergence in restrictions, but the quantity in material seems to be a good starting point*
- *Example 2: Glucose syrup (CAS8029-43-4) has a non-detectable SML for five sources, while one country sets a different SML. CoE states that the restrictions have still to be set. Thus the non-detectable level in extracts seems to reach a certain extent of agreement.*
- *Example 3: Polyethyleneimine (CAS 99932-76-0). Four countries set the same maximum amount in material (0.5 %). A fifth country sets a similar limit (0.4 %) and one source does not set any restriction.*
- *Example 4: Reaction product of polyacrylamide with formaldehyde and dimethylamine, shows the same maximum amount in material in all the three sources. Two countries also set limits for dimethylamine and only one of the three countries also sets a limit for formaldehyde. As the restriction on the substance itself is common for all three sources it was decided to include it in this category.*

- No agreement: 74 substances were found with no convergence on restrictions applied by different MSs. Two examples are illustrated below.

- *Example 1: Dipropyleneglycol (CAS 25265-71-8, 110-98-5) cited by three sources: one does not set any restriction, the second one sets an SML and the third states that it has to be non-detectable.*
- *Example 2: Glutaraldehyde (CAS 111-30-8) for which two different SMLs, and two different maximum quantities in material were set. Moreover, two sources set no restrictions.*

The extent of harmonisation of restrictions for paper and board in EU MSs is shown as pie charts. Figure 38 shows substances regulated by three or more sources for which a convergence (restrictions/no restrictions) can be found (green), compared to substances with partial convergence (orange) or no convergence on restrictions (red). Figure 39 shows the same substances reported as a percentage of the total number of substances that are regulated at European level, thus including the 1 562 substances that are regulated only in one or two countries (in grey).

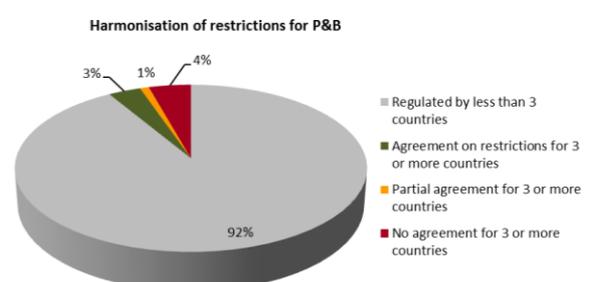
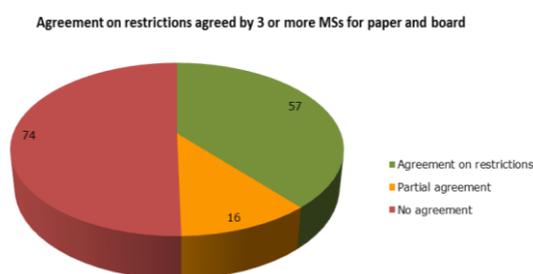


Figure 38: Pie chart on the extent of harmonisation or provisions on P&B

Figure 39: Substances are reported as a percentage of the total number of substances that are regulated at European level

Possible convergences with the CoE lists of authorised substances were examined (for both policy statements). These are illustrated as pie charts (Figure 40, Figure 41).

The conclusions ⁽¹⁷⁸⁾ are reported below.

- 932 out of the 1 100 (85 %) substances in the CoE lists are not found as authorised substances in MSs.
- Only 86 are common to two or more MSs (7 %) and 82 are common to only one MS (8 %).
- Out of the 86 substances in common, 77 have no restrictions and nine have restrictions.
- Out of nine substances with restrictions from CoE, one substance has that restriction in one MS (Netherlands).
- Out of the 86 substances in common for which CoE does not set any restrictions, 38 substances (3 % of the total) show a convergence with at least one MS.
- Out of the seven countries (Belgium, the Czech Republic, Germany, France, Italy, the Netherlands and Slovakia) that have common substances with the same restrictions given in the lists of CoE, the country with more convergences is the Netherlands (23 substances), followed by the Czech Republic (21 substances).

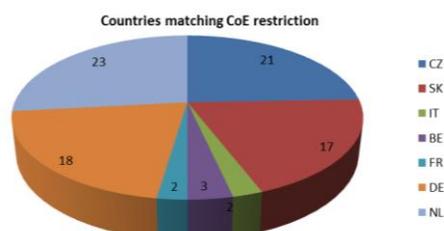


Figure 40: Pie chart of substances for which a given country matches a restriction of the CoE

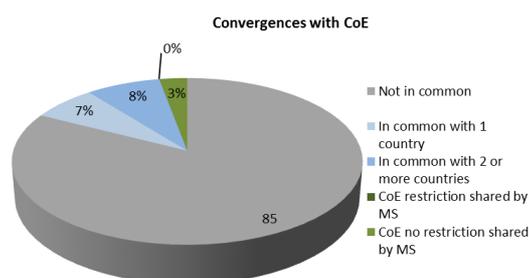


Figure 41: Substances in % of overall substances regulated across the EU (N = 1562) for which a restriction of the CoE matches that of none, one three or more MSs

With regard to **negative lists**, in all available measures, only a very few substances are banned ⁽¹⁷⁹⁾. In addition, there are recommendations to avoid the use of certain ink components ⁽¹⁸⁰⁾. Several measures prohibit the transfer of optical brighteners or fluorescent whitening agents (the Czech Republic, Germany, Croatia, CEFIC, CoE) and colourants to food, along with any preserving effect of the finished article on food (Germany, CEFIC).

With respect to overall migration, the legislative measures in Belgium and the Netherlands set up a total migration limit (Belgium: 60 mg/6 dm² of food contact surface; the Netherlands: 60 mg/kg food applying given specific factors for surface-to-volume ratio), whereas the measures in the Czech Republic, Germany, France and Slovakia set restrictions for the total dry residue in hot and/or cold water extracts instead. The measures in the Czech Republic and Germany additionally set limits for the total nitrogen content of the dry residue from hot and/or cold water extracts and the total inorganic content of the cold water extract from filter layers for cold filtration.

Only the Italian legislation (DPR n.777, 23.8.1982) establishes a legal obligation for the producer to produce a declaration of compliance. Norden requests and gives guidance on the requirement for a declaration of compliance and supporting documents. The industry associations CEFIC-CEPI-CITPA-FPE also provide guidance.

Several measures provide analytical methods for the determination of certain compounds in paper and board or in extracts thereof and instructions on how to perform release tests (Germany, France, Croatia, Italy, Poland, CEFIC-CEPI-CITPA-FPE, CoE and Norden). Some of these methods refer to EN standards or other internationally recognised test methods (also Germany, France, Italy, Poland, CEFIC-CEPI-CITPA-FPE, CoE and Norden).

⁽¹⁷⁸⁾ It should be noted that for 30 of the substances reported in the policy statement on paper and board the restrictions are stated as 'to be fixed' and were thus not taken into consideration in the analysis of convergences.

⁽¹⁷⁹⁾ Examples include azo dyes (Germany, CoE), colourants based on certain heavy metals (CoE), CMR substances (CoE), T/T+ substances (CoE), magnesium chloride (Croatia), barium sulphate/calcium carbonate (Greece) and salts of heavy metals (Greece).

⁽¹⁸⁰⁾ E.g UV cured inks, printing inks containing mineral oils, antimicrobial substances.

Standards for paper and board exist to a certain extent (Annex 16). They are focused on the determination of specific substances (organic and elements) in pulp or extracts (ISO 15318, ISO 15320, ISO 9198, ISO 11480, ISO 9197, ISO 5647, ISO 17812:2007, ISO 12830, ISO 10775, EN 1541, EN 16453, EN 12498, EN 14719, EN 12497) or overall migration (CEN/TS 14234). They also target the preparation extracts (aqueous, e.g. EN 645, EN 646, EN 647, or organic, e.g. EN 15519:2007), or the determination of certain aspects/contents such as fastness (EN 648), dry matter content (EN 920), tests with dry simulants (EN 14338), transfer of antimicrobial constituents (EN 1104), sensory analysis (CEN/TR 15645 series, EN 1230 series) or cytotoxicity (EN 15845). Germany and Switzerland adopted or adapted a number of EN/ISO standards.

Recommendations on **GMP** for the paper and board sector exist in a number of MSs, including Norden (Denmark, Finland, Sweden and Norway), Germany, Spain, Greece and Italy, and in joint publications of industry associations. The Greek guidance document on GMP provides a model layout for a declaration of compliance for paper and board FCMs and, with respect to stick-on labels, mentions which certificates should accompany adhesives, printing inks and label materials (including paper) when used as raw materials and provides an example for a declaration of compliance for printed stick-on labels. Germany includes information in its BfR recommendations XXXVI, XXXVI/1, XXXVI/2 and XXXVI/3. Recommendations on supporting documentation are also given in guidance documents from Spanish and Italian industry associations. In Spain, guidance ⁽¹⁸¹⁾ is based on the CEPI guide.

The Norden guideline ⁽¹⁸²⁾ is a GMP document intended for producers of paper and board to ensure compliance, and it is based on the CoE resolution on paper and board materials and articles intended to come into contact with foodstuffs and its related five technical documents. It provides information on GMP (Chapter 3, Annex 3).

The CoE, in its policy statement, states that paper and board should be manufactured in accordance with the CEPI guide for GMP for paper and board for food contact. The document reports the text of the CEPI guidance. The CoE policy statement concerning tissue paper, kitchen towels and napkins also presents GMP based on the CEPI guide and adapted to the production processes used in tissue mills and to reflect the specifics of kitchen towels and napkins (e.g. in Chapters 1.2.4 and 8).

A number of associations of the sector (CEFIC-CEPI-CITPA-FPE ⁽¹⁸³⁾, CEPI and Aspapel) jointly published sector-specific guidance documents on GMP ⁽¹⁸⁴⁾ and on compliance ⁽¹⁸⁵⁾. With regard to GMP, the guidelines that were developed jointly for the sector by CEFIC-CEPI-CITPA-FPE, CEPI and Aspapel are in use, along with the one developed jointly by CEFIC/CEPI/CITPA. Portions of the supply chain, such as converters (CITPA), also rely on guidelines developed in collaboration with the plastics sector (FPE guidelines ⁽¹⁸⁶⁾). In the case of tissue, the ETS uses the CoE policy statement on kitchen towels and napkins ⁽¹⁸⁷⁾. The corrugated board sector has its own GMP standard ⁽¹⁸⁸⁾ and more recently has also used the CEPI guidelines, while carton makers also have a GMP guide ⁽¹⁸⁹⁾.

With regard to **what is used in practice** as expressed by stakeholders, Norden allows the use of all substances approved by EFSA or FDA, even if the evaluation refers to use in other FCMs (e.g. plastics or regenerated cellulose) or as direct food additives. In addition, all substances approved and listed in BfR Recommendation XXXVI may be

⁽¹⁸¹⁾ Buenas prácticas de fabricación para la fabricación de papel y cartón para contacto con alimentos.

⁽¹⁸²⁾ 'Paper and Board FCMs', (TemaNord 2008:515, Copenhagen, Nordic Council of Ministers).

⁽¹⁸³⁾ CEFIC (suppliers of chemicals), CEPI (paper and board manufacturers), CITPA (paper and board converters), FPE (paper and board multilayer manufacturers).

⁽¹⁸⁴⁾ CEPI — Good manufacturing Practice for the Manufacture of Paper and Board for Food Contact (Issue 1 — 2010).

⁽¹⁸⁵⁾ CEPI — Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact (issue 2, 2012).

⁽¹⁸⁶⁾ FPE — Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food. Version 6.0, July 2011.

⁽¹⁸⁷⁾ ETS — information: <http://www.europeantissue.com/sustainability/production/good-manufacturing-practices/>

⁽¹⁸⁸⁾ FEFCO — International Good Manufacturing Practice Standard For Corrugated & Solid Board 2006.

⁽¹⁸⁹⁾ ECMA — Good Manufacturing Practice Guide (Version 1 — 2011).

used. For substances that are listed/evaluated by two or more institutions (EFSA, FDA and/or BfR), the newest EFSA opinion prevails. If no EFSA opinion is available, the newest BfR opinion prevails. Norden also advises that CoE ResAP (2002)¹ is used in the selection of substances for use in production (if evaluated by a scientific body).

The guidance document published by CEFIC-CEPI-CITPA-FPE recommends the use only of substances in BfR Recommendations XXXVI, XXXVI/1, XXXVI/2 and XXXVI/3 (from Germany) and in the Commodities Act (from the Netherlands). It should be noted that the substances regulated in the Netherlands and Germany are not the same. In many cases they are listed only in one MS, not the other (see ESCO report).

From an industry standpoint, there is a convergence of the references that are taken as the basis for compliance across national provisions. ACE cites that it uses national provisions from the German BfR Rec. XXXVI as reference, followed by US FDA 21 CFR 176.170, 176.180 and CoE Res AP (2002)¹, and looks at the Chinese CN GB9685 for lists of authorised substances. It also cites the CEPI guidance and the SVHC⁽¹⁹⁰⁾ ECHA list. The same reply of using Germany is cited by ECMA, which also mentions additional legal references (unspecified) from France, Italy, the Netherlands and the United Kingdom. The chemical sector (CEFIC-FCA) mentions that it refers to BfR XXXIV (1-3), BfR XIV, US FDA (unspecified), the Dutch Warenwet (Chapter II) and Italian DM 21.3.1973 as amended. The professional associations for the plastics sector mentions that it refers to BfR Rec. XXXVI, US FDA 21 (CFR 176.170, 176.180), CoE Res AP (2002)¹ and Italian DM 21.3.1973 as amended. The silicone association mentions CoE, BfR and Warenwet for silicone additives in paper. Normpack refers to BfR, US FDA and Warenwet.

Overall the main points can be summarised as follows:

- *Nine MSs (Belgium, the Czech Republic, Greece, France, Croatia, Italy, the Netherlands, Slovakia) have measures on paper and board.*
- *CoE also published two resolutions.*
- *565 substances risk assessed (ESCO lists).*
- *More than 1700 substances regulated across MSs (Including c.1100 from CoE).*
- *147 substances (6 %) common to three or more MSs (or two MSs including CoE).*
- *Limited number of standards available considering the vastness of the sector (3 ISO and 9 CEN).*
- *GMP guidance specific to paper and board from Norden.*
- *Several sectorial GMP guidelines exists (CEFIC-CEPI-CITPA-FPE, CEPI, Aspapel).*
- *No strong convergence expressed by MS.*
- *Industry refers to BfR, CFR, CoE, NL, IT.*

Rubbers and elastomers

National/supranational measures

The overview of measures available at national level for rubber is tabulated in Annex 17. Rubbers have lists of authorised substances developed by eight MSs. The CoE also presents an inventory of substances used for the manufacture of rubber products intended to come in contact with foodstuffs.

Articles containing rubber that come into contact with food are varied and encompass a non-homogenous group of items, such as bottle closures, industrial pipe systems in food production, gloves, baby rubber teats and soothers, children's toys, etc. Rubber quality and its permitted components are currently mostly regulated by national legislation in a format that tackles all materials that come into contact with food, including rubber. They are rarely used as food packaging and that is the reason why the EU plastics directive could not be applied directly to rubber articles. At present the transfer of N-nitrosamines and N-nitrosatable substances from teats and dummies from elastomers or rubber is the only case of rubber-related legislation at EU level (Directive 93/11/EEC).

⁽¹⁹⁰⁾ A substance of very high concern (SVHC) is a chemical substance (or part of a group of chemical substances) for which it has been proposed that the use within the European Union be subject to authorisation under the REACH Regulation.

The EFSA ESCO working group had already noted that the definition of rubber may vary across MSs. The summary of the findings were reported for Germany, France and the Netherlands. For example, terms such as 'rubber', 'elastomer', 'latex' or 'caoutchouc' are not always equivalently defined and may cause misinterpretation/misuse by users of the legislation (details tabulated in Annex 17). The CoE definitions are different from the Dutch legislation. In addition, CoE ResAp(2004) on rubber has a field of application that excludes articles that come in contact with the mouth (soothers). Categorisation of products can also be a source of confusion. Positive lists of substances in rubber products are influenced by the use of rubber products, time of contact with food or whether there is expected oral contact. MSs therefore classify rubber materials/rubber articles in categories that are based on expected migration and destination of use (e.g. lists of authorised substances for rubber products intended to be in contact with baby food are more restrictive). Table 8 shows the way some MSs are currently categorising rubber articles. Classification in five categories was somewhat prevalent (the Czech Republic, Germany, France, Croatia, Slovakia), or in three categories as in the case of the Netherlands (and CoE). The common category in all MS is the special or sensitive category, which is reserved for rubber items intended to be in contact with baby food or direct mouth contact (as a 'special' or 'most sensitive' category, and in which soothers are included).

Table 8: Categorisation of rubber items intended to be in contact with food in different EU MSs

| | CZ | HR | FR | DE | NL | SK | CoE |
|--|---|---|---|---|---|---|---|
| Type of contact | Elastomers and materials based on natural and synthetic rubber | Elastomers | Rubber (polymers) | Natural and synthetic rubber | Rubber products | Rubber materials and articles | Rubber products |
| Sensitive groups (children and babies oral contact) | Category I – Sensitive groups (children and babies, oral contact) | Special category items with oral contact (children/baby) | T-oral contact (children and babies) | Special category – Items with oral contact | Category I – Articles for oral contact (e.g. for children and babies) | Category I – Sensitive groups (children and babies, oral contact) | Category I – Articles for contact with baby food or mouth |
| Hot or long (> 24 h) contact | Category II – Contact time > 24h | Category 1 – Contact > 24 h | A – Hot contact, possibly followed by prolonged contact | Category 1 – Contact > 24 h | Category II – Migration factor > 0.001 | Category II – Contact time > 24 h | Category II – Based on the surface, temperature, time and frequency of contact with food |
| 10 min-24 h | Category III – Contact 10 min-24 h | Category 2 – Contact < 24 h | B – Prolonged contact C – Average duration contact | Category 2 – Contact < 24 h | Category III – Migration product factor < 0.001 | Category III – Contact 10 min-24 h | Category III – Based on the surface, temperature, time and frequency of contact with food |
| < 10 min or very short | Category IV – Contact < 10 min | Category 3 – Contact < 10 min | D – Brief contact | Category 3 – Contact < 10 min | n/a | Category IV – Contact < 10 min Category V – Short contact | n/a |
| Other | n/a | Category 4 – No direct contact with food or insignificant | n/a | Category 4 – No direct or insignificant contact | n/a | n/a | n/a |

The EFSA ESCO working group developed a list of substance for rubber. It contained 570 substances considering as valid risk assessments those from the Czech Republic, Germany, France and the Netherlands. This list was updated for regulated substances with data from additional national measures. Lists from CoE (close to 700 substances in total) were also integrated. It is estimated that **1 028** substances are considered across

the EU MSs. Of these, only **185 substances (18 %)** are common to two or more MSs and the CoE (or alternatively three or more MSs) (Annex 17).

These substances were organised into five categories, based on the type of restriction used in the national measures and on the potential convergence and degree of convergence of the restrictions, as follows.

- Agreement on absence of restrictions: 58 substances (both monomers and additives) where use is allowed without restrictions.
- Agreement on restrictions: six substances present restrictions that are convergent in the different national measures that three or more MSs have in common ⁽¹⁹¹⁾.
- Partial agreement on restrictions: 14 substances presented a partial convergence on how national measures consider respective restrictions, which could mean different restrictions in different measures or restrictions in some measures but not in others as a function of the country. This is illustrated by the examples below.

- *Example 1: For 2(1-Methylcyclohexyl)-4,6-dimethylphenol (CAS 77-61-2) Germany and Croatia report a restriction of a maximum of 1 % of the substance in material, while CoE does not report any restriction. But as CoE cites Germany as a source for the information on the substance, it was considered that also CoE should agree on the Germany restriction, thus showing convergence. A similar reasoning was followed for other substances.*
- *Example 2: For formaldehyde (CAS 50-00-0, FCM 98) France, Italy and Croatia agree on the SML value, while CoE applies an SML value that is three times higher than the other sources. But as CoE cites Italy as a source of information on the substance it was considered that CoE could also potentially be in agreement with the SML set by the other countries.*
- *Example 3: Acrylic acid (CAS 79-10-7, FCM 147) is regulated by France, Italy and CoE. It has a restriction from France and Italy, and states that the restrictions are under revision; whereas CoE, which sets no restriction, cites France and Italy as sources of information for data. Thus it was considered that CoE might agree with the restriction of France and the substance might fall into the category of partial agreement.*
- *Example 4: Acrylonitrile (CAS 107-13-1, FCM 225) has five sources agreeing on a non-detectable SML, and two other sources (the Czech Republic and Slovakia) setting no restrictions. Due to the high percentage of sources agreeing on the limit it was considered a partial agreement case.*
- *Example 5: Sebacic acid, dibutyl ester (CAS 109-43-3, FCM 242) has seven sources assigning no restriction and one setting a SML.*

- Lack of agreement: 107 substances were found not to have convergence on restrictions. Three examples are used for illustration, as follows.

- *2,2'-Methylenebis-(4-methyl-6-tert-Butylphenol) (CAS 119-47-1, FCM 285), for which two countries use quantity in material, two countries use same SML and two countries provide the same overall migration limit.*
- *Phthalic acid, bis(2-ethylhexyl) ester (CAS 117-81-7, FCM 283), for which three different SMLs and two different maximum quantity in material values were set.*
- *Carbon black, used as an additive in rubber: Germany (BfR Rec. XXI) restricts on the basis of 'max. 30 %', the Italian D.M. 21/3/73 sets purity requirements of 0.1 % in weight (in toluene), France (Arrêté du 9.11.1994) sets a maximum content (Q_{max}) of 50 % in article weight, brought back to 30 % for articles in contact with milk or oils, and toluene extract must be ≤ 0.15 %. Croatia regulates similarly to Germany, with a 30 % limit for category 2 elastomers (for articles remaining directly in contact with food between 10 minutes and 24 hours, e.g. tubes for conveying liquid food, bottle stoppers and caps, etc.).*

The extent of harmonisation of restrictions for rubbers in the EU MSs is illustrated in the form of pie charts. Figure 42 shows substances for which a convergence (restrictions or no restrictions) can be found (green), compared to substances showing partial convergence (light green) or no convergence on restrictions (orange). Figure 43 shows the same substances reported as a percentage of the total number of substances regulated, thus including the 853 substances that are regulated only in one or two MSs (in grey).

⁽¹⁹¹⁾ It should be noted that Italy has stated for all these substances that the restrictions are under revision.

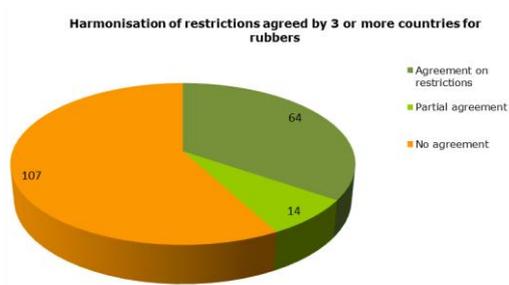


Figure 42: Extent of harmonisation for substances regulated in common by three or more MSs (or more than two MSs and the CoE) for rubbers

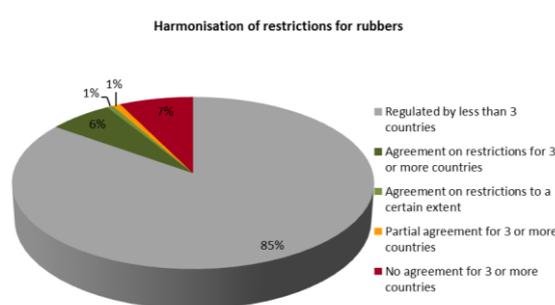


Figure 43: Substances are reported as a percentage of the total number of substances that are regulated at European level for rubbers

An analysis of possible convergences with the CoE list is illustrated in Figure 44 and Figure 45. Conclusions on the correspondence of MSs⁽¹⁹²⁾ and CoE lists include the following.

- 397 out of 705 substances (48 %) on the positive list of CoE are not shared in MSs' positive lists.
- Only 171 are common to two or more MSs (21 %) and 237 are common to only one MS (29 %).
- Out of 171 substances common to two or more MSs, 136 have no restrictions and 35 have restrictions.
- Out of the 35 substances common to two or more MSs for which CoE sets a restriction, only 15 substances (2 % of the total) show a convergence in such restrictions with at least one MS.
- Out of the 136 substances common to two or more MSs for which CoE does not set any restriction, 109 substances (12 % of the total) show a convergence with at least one MS.
- Out of the eight MSs that have common substances with the same restrictions given in the positive list of CoE, the MS with the most convergences is France (78 substances), followed by the Netherlands (56 substances).

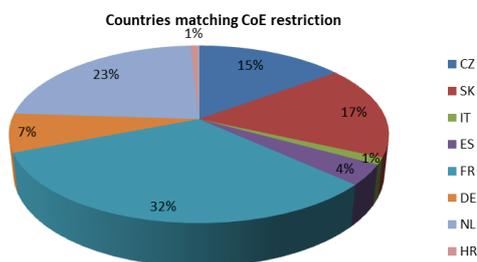


Figure 44: Pie chart of substances in national rubber legislation for which a given country matches a restriction of the CoE

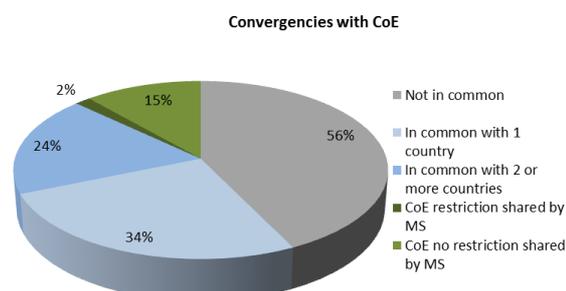


Figure 45: Substances in % of overall substances regulated across the EU (N = 1 028) for which a restriction of the CoE matches that of none, one, two or more MSs

With respect to limits, some migration limits are quite different across MSs, for example Italy has an overall migration limit (OML) of 50 mg/kg, while the Netherlands sets OMLs of between 20 and 100 mg/kg depending on the type of food application.

In addition, for rubbers, families of substances can be considered differently by different MSs. One example is given below.

- In the family of adipic acid esters, C4 (isobutyl) is restricted in France and Italy but not the Netherlands, whereas C5 (benzyl), C8 (octyl), C10 (decyl), C10 (di-benzyl), C18 (decyl-octyl) and C20 (didecyl) are restricted by the Netherlands only.

For rubbers limits are dependent on the categorisation of the article, which itself is dependent on the use with factors such as time-temperature and surface of contact. These examples illustrate the complexity of finding a convergence across national concepts and their provisions. This must be taken into consideration as to what mutual recognition would entail as a cumulative approach.

⁽¹⁹²⁾ It should be noted that IT legislation had limits under revision for most of the substances analysed.

Standards for rubbers and elastomers exist and are found tabulated in Annex 17. Standards at international level (ISO/CEN) focus on limits for extractable substances (ISO 14285, GB/T 5009.152) or on the release of substances in particular nitrosamines and nitrosatables (EN 12868, ASTM F1313-90(2011), GB/T 5009.79). Standards also exist for requirements specific to the food industry or to domestic use (DIN 11861, DIN 5080, DIN 7750, PN C-94150, GB 4806.2, GB/T 5009.64, GB/T 5009.65, KS M 6762:2014, ASTM D4316-95). Standards from other sectors include standards for drinking water (EN 12873-4, EN 15768).

Regarding **GMP**, the sources reviewed did not present exhaustive requirements, but only a statement that rubber FCM should be manufactured according to GMP by CoE.

Regarding sanctions, only Spain states that failure to comply with the law would imply sanctions, according to dedicated legislation that covers different types of infringements. Regarding declarations of compliance and supporting documents, only France, Italy and Romania provide more detailed information on documentation that has to be inserted into the declaration of compliance. Regarding support for enforcement, seven sources (Germany, Spain, France, Croatia, Italy, Austria and CoE) provide information on testing and migration methods, to different extents.

ETRMA has initiated the drafting of guidelines on traceability of materials and articles for food contact, in collaboration with the European Council, for rubber products which could contain lists of positive substances. The document has not been published to date.

Professional associations generally refer to ISO 9001 certification and to Regulations (EC) No 1935/2004 and (EC) No 2023/2006. With regard to the registration of business operators, IISRP reports that a registration scheme for producers/importers of FCMs exists in Denmark and is under preparation in Italy.

With respect to **what is used in practice**, the sectorial associations ETRMA, IISRP and WBT make reference to national provisions from France (Arrêté du 9.11.1994), Germany (BfR Rec. XXI) and Italy (DM 21.3.73), and to Regulation (EU) No 10/2011. ETRMA and WBT also cite Spain (RD 847/2011 (Article 4 for positive list and Article 7 for OML/SMLs, Annex 1 for QM)), whereas IISRP and WBT cite in addition the United States (FDA 21CFR 2600) and the Netherlands (Regeling 14.3.2014). The chemicals sector states that it refers to BfR XXI, FDA, the Dutch Warenwet (Chapter III) and the Italian DM 1973. The silicones sector states that it refers to BfR XXI and the Dutch Warenwet (for the positive list on silicone additives in rubber). IISRP also refers to the REACH regulation and to the SVHC list of banned substances, while WBT refers to Regulation (EC) No 1907/2006.

Overall, the main points can be summarised as follows.

- *Different definitions exist, which seems a major issue (at least two definitions, and differences in categorisation of materials).*
- *Classification in five categories (the Czech Republic, Germany, France, Croatia, Slovakia) or three (the Netherlands, CoE).*
- *Rubbers have lists of authorised substances developed by eight MSs.*
- *570-580 substances have been considered risk assessed (ESCO lists).*
- *1 028 substances are considered in the lists of authorised substances of different MSs.*
- *180 (18 %) substances are in lists of authorised substances common to two or more MSs and the Coe (or alternatively three or more Mss). 107 (60 %) of the 180 substances in common have different restrictions.*
- *The multiple references used by the sector (e.g. France, Germany, Italy, the Netherlands, Spain, the United States) are likely adding to burden.*
- *Relative lack of strong self-guidance: GMP guidelines for the sector may be under preparation but no sector-specific documents exist yet.*

Silicones

Measures are present in a number of EU MSs, with two main approaches derived from the measures used in Germany and France.

National measures are present in five countries (Croatia, France, Germany, Spain, Switzerland (Annex 18)). There is also a policy statement from the CoE. There are

similarities in the lists of authorised substances from different MSs. The list used in the Czech Republic contains elements of both the French arrêté and of BfR recommendation XV. The list of the Swiss ordinance mirrors that of the CoE. There is also some convergence on the nature of substances regulated in France.

In terms of definitions, silicones are silicone elastomers defined in both the German and French legislation as made exclusively by organopolysiloxanes.

The EFSA ESCO working group developed a list of substances for silicones. It contained 55 substances, considering as valid risk assessments only those from Germany, Spain and France. This list was updated where possible with restrictions present in measures from Germany, Spain, France, Switzerland and CoE. It is estimated that **336** substances are considered across EU countries and regulated for silicones intended to be in contact with foodstuffs across Europe. Out of these, **only 37 substances (11 %)** are considered in common to two or more MSs and the CoE and or Switzerland.

These substances were organised into different categories, based on the type of restriction and the degree of convergence of the restrictions (Annex 18).

- Agreement on absence of restrictions: 14 substances have no restrictions.
- Partial agreement: for carboxymethylcellulose (CAS 9000-11-7), three countries set no restriction, while only the fourth source (CoE) sets an SML.
- Absence of obvious agreement: 22 substances are regulated differently (with or without restriction, or with restrictions that are different). Examples include the following.

- *Acids (acetic, hydrochloric, phosphoric, sulphuric, sorbic), salts of acids (sulphuric).*
- *Hydroxides (potassium, sodium).*
- *Cellulose and derivatives (hydroxyethyl), formaldehyde, di-n-octyltin dilaurate/dimaleate, 1-dodecene.*
- *Oxides (iron, magnesium, aluminium, calcium, titanium, zinc) or inorganics such as carbon black/graphite.*

The distribution of substances regulated by three or more countries is illustrated in Figure 46, whereas Figure 47 shows the same substances reported as a percentage of the total number of substances that are regulated at European level, thus including the 299 substances that are regulated only in one or two countries (highlighted in grey).

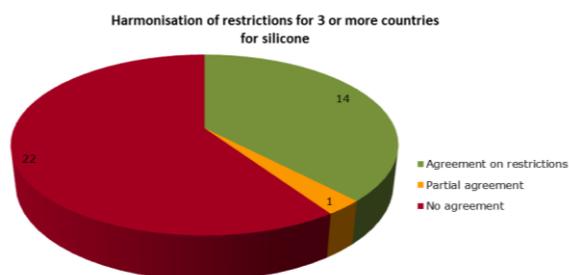


Figure 46: Extent of harmonisation for substances regulated in common by three or more MSs for silicones

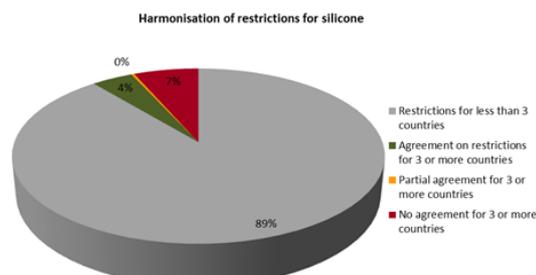


Figure 47: Substances are reported as a percentage of the total number of substances regulated at national level

No **standards** were found other than the European standard on the safety of toys ⁽¹⁹³⁾.

The FCM silicone sector has guidance on GMP ⁽¹⁹⁴⁾ that states that CES members' typical product ranges do not constitute "Materials or Articles" as they should be understood under the terms of Regulation 2023/2006/EC. Instead they are considered "Starting Materials", and thus fall outside of the scope of this regulation.

From the **standpoint of what is used in practice**, the main sources of regulatory

⁽¹⁹³⁾ EN 71 – Part 12: N-Nitrosamines and N-nitrosatable substances.

⁽¹⁹⁴⁾ CES – Good Manufacturing Practices for Organosilicon Materials Intended to Come into Contact with Food, 2009.

frameworks mentioned most often for silicones are BfR XV, DR 847/2011 and the French Arrêté 1992, followed by CoE and Warenwet III. FDA rule 21CFR 2600 was also mentioned, as was Swiss Ordinance 817.023.21 (in its Annex 5).

CES notes that in other MSs, such as the Czech Republic, Spain, Italy and the Netherlands, silicones are regulated together with natural and synthetic rubber. Other professional associations that replied to JRC questionnaires (CEFIC-FCA, FPE, Norden, WBT) cite BfR XV, French Arrêté 1992, DR 847/2011, Regulation (EU) No 10/2011 as amended, CoE ResAP (2005)2, FDA 21CFR 2600 and potentially the Netherlands (Warenwet III).

Regarding the requirements on documentation supporting the declaration of compliance applied by the sector for different end products/actors, CES stated that there are a number of applications in various sectors (e.g. paper and board, plastic, coatings, elastomers) where silicones are used as starting materials. In the case of silicone rubber the starting materials have to be cross-linked by the producer of the final article, and in case of the manufacture of coatings the silicone resins may also be co-polymerised with organic materials. Due to these highly diverse uses, the silicone industry could not supply a single recommendation for supporting documentation. CES noted that the transfer of information on requirements for compliance can include relevant and known decomposition products, information on use restrictions, etc.

Overall the main points can be summarised as follows.

- *Different definitions exist which seems a major issue (at least two definitions (FR, DE) and difference in categorisation of materials.*
- *Seven countries with positive lists (Croatia, the Czech Republic, France, Germany, Italy, Spain, Switzerland).*
- *CoE has addressed silicones in a policy statement.*
- *55 substances have been considered risk assessed (ECSO lists).*
- *336 substances are considered across different MSs and CoE.*
- *36 substances(18 %) considered by three countries or more (including CoE).*
- *No standard found.*
- *A dedicated sector-specific guideline exists for GMP and considers silicones as raw materials, which excludes them from the scope of Regulation (EC) No 2023/2006.*
- *Industry refers to Germany, France, the Netherlands, Spain, Switzerland, the United States and CoE.*

Multimaterials

There is a current scarcity of national approaches specifically targeting multimaterials. No specific remarks were made by MSs, and very few associations replied specifically for the usage of provisions for multimaterials. Generic statements included conversion/usage of individual materials (layers) beyond what can be used under Regulation (EU) No 10/2011. The overview table is included in Annex 19. France is the principal country that provides references for multimaterials in a national measure.

With regard to GMP, only FPE provided a reply on making use of the FPE Code for GMPs (e.g. flexible and fibre based) and of the Italian Cast project publication/guidance. The associations referred to the FPE template for the declaration of compliance and stated that for supporting documents the supplier food contact statements should include all layers and components, migration test/modelling results on the final article and/or other reasoning, such as worst-case calculations.

Other materials and articles

Kitchenware, cutlery, processing/vending/domestic equipment, etc. were considered within materials measures rather than as a stand-alone category.

3.5.4. Overview of substances

Across the different MSs in the EU for individual national measures and across different materials, a total of close to 8 000 substances were found in the context of this study.

These correspond to 1 323 for adhesives, 5 124 for printing inks, 387 for IERs, 1 721 for varnishes/coatings, 168 for cork/wood, 1 710 for paper and board, 1 028 for rubbers/elastomers and 336 for silicones. Waxes could not be estimated as the descriptions were too vague or referred to composite mixtures. Substances were found considered in more than one material (overlapping).

A comparison was made across all substances in all materials and an estimate was made of how many substances were regulated in four or more materials. This was done for organic substances and the list of materials included adhesives, printing inks, varnishes and coatings, IERs, cork, wood, paper and board, rubbers and silicones (maximum n = 9). The results are illustrated in Table 9.

Table 9: Number of substances considered across different materials

| No of materials in which substances found | Substance in common for that number of materials |
|---|--|
| 9 | 7 |
| 8 | 13 |
| 7 | 76 |
| 6 | 110 |
| 5 | 150 |
| 4 | 194 |
| sum 1 | 550 |
| 3 | 347 |
| 2 | 904 |
| 1 | 6227 |

The data indicates that overall the bulk of substances are used in one material only: out of 8 030 substances, 6 227 (78 %) are found only for one type of material, 904 (11 %) for two types of materials and a total of 897 (11 %) for three or more types of materials. It should be noted that of the 6 227 substances present only in one type of material, the large majority was for printing inks (61 %).

The potential inconsistencies between the limits set for the same substance in different materials regulated by a given MS were examined. A brief overview was carried out of substances regulated in most materials (e.g. eight or nine materials). In this case, the number of substances is limited (seven and 13 substances respectively), and they are, for a relevant portion, substances without restrictions on different materials for most MSs that consider them in their national measures. Based on the very limited set of data, MSs seem to regulate substances on average in two or three materials rather than all materials at once. For a given substance, the CoE similarly tends to regulate SMLs across materials. However, the data set cannot demonstrate that, for a given substance, an MS would tend to apply similar limits across different materials.

3.5.5. Horizontal aspect of compliance and enforcement: methods of analysis

The review in the preceding sections indicates that restrictions in the form of limits imposed on individual substances (or groups of substances) are used extensively.

Analytical methods

The approach described above implies that the critical step is the evaluation of the transfer of any given substance that becomes the object of a risk management measure at national level for non-harmonised materials, and at a later stage the grounds for the demonstration of compliance and the basis for enforcement. This entails a migration test, meaning the exposure of a (worst-case) finished product to a simulant under time-temperature conditions, but just as importantly the unequivocal identification and quantification of the substances regulated using methods of analysis with an acceptable uncertainty of the measurement around the limit imposed. This requires not only methods of analysis but also availability of substances to use as calibrants.

The OFFC regulation establishes a hierarchy of **methods** used for sampling and analysis

in applying official controls. First priority is given to methods laid down in Union legislation, followed by methods according to internationally established rules (CEN, national standards). In the area of FCMs, analytical methods are laid down in Union legislation for vinyl chloride from PVC and food, lead and cadmium leaching from ceramic ware, nitrosamines and nitrosable substances in rubber and food and rules for migration testing. Methods in the area of harmonised legislation for plastics have historically been standardised CEN methods covering migration testing procedures (series EN 1186) and the analysis of specific migrating substances (series EN 13130).

There are disproportionately few international standards (CEN, ISO) compared to the substances regulated. For example, there are only 28 analytical methods published by CEN for checking specific migration for plastics when the number of substances regulated cover close to 900 substances. At national level, examples for methods laid down in national legislation may be, for example, methods under §64 of the German food and feed code ⁽¹⁹⁵⁾. Other methods in the context of official controls (e.g. in-house control purposes) may be single-laboratory validated according to internationally accepted protocols (e.g. IUPAC harmonised guidelines). General criteria for the characterisation of methods of analysis exist. This situation highlights a significant issue of access to adequate methods of analysis in the form of internationally agreed standards.

An alternative source of access provided for under framework Regulation (EC) No 1935/2004 should in theory be that of petitioners' methods. Indeed its Article 19 stipulates that 'Applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002.' In addition, the following article, which refers to confidentiality, clearly states that the applicant or petitioner 'may indicate which information submitted under Articles 9(1), 10(2) and 12(2) is to be treated as confidential on the ground that its disclosure might significantly harm its competitive position.' However, it is envisaged that some information, such as the analytical method(s), 'shall not be considered confidential'. This means that for all substances petitioned to EFSA, analytical method descriptions (provided in an adequate format without confidential data) can and should become available for public use once a substance is permitted in the EU legislation.

Sensory analysis

The implementation of Article 3 implies means to evaluate whether a given FCM has or has not brought about an unacceptable change in the composition of the food or a deterioration in the organoleptic characteristics thereof. The standard definition of taint (ISO 1992) is a taste or odour foreign to the product resulting from internal deterioration in the food, and an off-flavour is an atypical odour or taste caused by contamination by a chemical foreign to the food. The main chemicals are usually volatile organics triggering an odour response even in low concentrations (in the order of less than µg/kg). Food packaging materials are frequent contributors to food taints and off-flavours ⁽¹⁹⁶⁾, which can occur for various reasons. Some examples are given in Annex 22.

Standards for taint transfer testing are available from an overall sensory testing standpoint. Some are also specifically aimed at food packaging materials (list available in Annex 22). The food packaging industry carries out regular taint and odour tests as part of their quality assurance programmes. These sensory tests usually involve a taint comparison using a test food (e.g. a triangle test). Yet, while sensory testing is a key parameter to identify taints, it does not provide unequivocal identification of chemical species causing the taint, which require instrumental methods.

⁽¹⁹⁵⁾ Lebensmittel- und Futtermittelgesetzbuch (§ 64 Amtliche Sammlung von Untersuchungsverfahren; Bekanntmachungen: official collection of analysis methods; Notices).

⁽¹⁹⁶⁾ Taints and off-flavours in food — B. Baigrie (ed), Woodhead Publishing Limited, England, CRC Press LLC, USA © 2003.

The implementation of Article 3 is often considered hindered by the lack of guidance on methodologies adequately covering the testing for compliance of this article. A workshop organised by the JRC in November 2011 ⁽¹⁹⁷⁾ noted that there is an interest in guidance particularly in the industrial context (and foods final products), as it is of great relevance to quality control and is often considered under GMP audits. Guidelines may exist at individual company levels rather than at the level of professional associations.

In terms of harmonisation for sensory tests on FCM, it was noted that some **MSs have in place enforcement** of sensory testing. The following countries already have approaches: Austria, the Czech Republic, Denmark, Estonia, France, Poland, Slovakia, Slovenia and Switzerland. The extent of approaches is different between different MSs. Some MSs have internal standards or follow ISO standards. For example, Switzerland has a panel of six for rudimentary tests, Austria has a standard operating protocol (SOP) and a mix of three standards and four people (only for screening), Slovakia uses a technical university for triangle tests, the Czech Republic has internal procedures using a panel of six to eight trained specialists and Slovakia provides its training. France has a 30-person panel accredited for wine. Denmark follows a Nordic Committee on Food Analysis (NMKL) method ⁽¹⁹⁸⁾. Poland has a national standard and a trained panel. Slovenia has no national standard but performs tests from time to time on imports or samples. Some kits (developed at the University of Dresden) also exist for the identification and description of a number of off-flavours specific to the field of FCMs, where calibration may be possible.

The workshop concluded that the criteria for official controls should include the reasoning for sensory testing for official controls, the basis (e.g. relevance of substances etc.) and the definition of the overarching scope (e.g. exposure assessment, SML, material type). It was recognised that it may not be possible to attain a structured control such as exists for chemical migration, but that harmonisation at least for action on imported goods would be advisable. Guidance could be useful for an area that is not regulated (e.g. silicones) as a tool for the rejection of unsafe or illegal imports. Industrial (FPE) stakeholder representatives agreed that it is a GMP point of systematic control for industry.

⁽¹⁹⁷⁾ <https://ec.europa.eu/jrc/en/event/workshop/sensory-science-food-contact-materials>

⁽¹⁹⁸⁾ Guideline for sensory analysis of food containers/packages, Procedure No 19, 2007 — updated 2015.

4. Indicators on compliance with general safety requirements for food

4.1. Introduction and objectives

While the European Commission ensures the implementation of legislation by MSs, MSs have the responsibility to enforce and control the implementation of EU and national legislation. In accordance with the framework regulation (Regulation (EC) No 1831/2003), MSs must carry out official controls in order to enforce compliance with that regulation in accordance with the relevant provisions of Union law relating to official food and feed controls. In addition to the specific conditions for controls of imports of polyamide and melamine kitchenware from China, MSs are required to carry out official controls regularly and with appropriate (voluntary) frequency that should be based on the level of assessed risk. Regulation (EC) No 853/2004 on official feed and food control (OFFC) stipulates that official controls should be carried out using appropriate methods and techniques, including routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples. MSs are also responsible for enforcing their own national legislation and must similarly monitor the fulfilment of the requirements of the legislation by the business operators. The OFFC regulation further requires appropriate training for the staff performing official controls, along with sanctions and measures including dissuasive penalties for non-compliance.

There is little information regarding guidance on indicators of the safety level of FCMs in impact assessments. The sources selected for use as indicators on the safety of FCMs in this study focuses on data related to audits and data related to compliance with the legislation in place by official controls, via the Rapid Alert System for Food and Feed ⁽¹⁹⁹⁾ (RASFF) and via direct queries, along with the presence of 'better training for safer foods' (BTSF) training courses and their impact, if any. This study found the search for data a very arduous task as there is a lack of data for effectiveness in itself and there is a lack of consistency and comparability of potential indicators of food safety in practice.

4.2. Materials and methods

One source of data considered consisted in the reports from the Health and Food Audits and Analysis office of DG Health and Food Safety (HFAA, ex-Food and Veterinary Office or FVO). The HFAA performs regular audits and inspections in the MSs to verify the implementation and effective enforcement of EU legislation on food safety, animal health, animal welfare, plant health and medical devices. In this context audits have been performed to verify the implementation and effective enforcement of EU legislation on FCMs and official feed and food controls. This study also considered the BTSF training courses and any potential link between HFAA audits and BTSF training courses as follow-ups and their impact.

Another source were the alerts and reports of the RASFF, which enables information concerning measures aimed at restricting the placing in circulation or withdrawal of food or feed, including FCMs from the market to be shared efficiently between the national food safety authorities of the EU-28, Iceland, Liechtenstein, Norway and Switzerland, the Commission, EFSA and the European Economic Area. However, it should be noted that the RASFF is not designed to check compliance vs non-compliance of legislation, but only to alert authorities' attention to non-compliances, since it does not report the total amount of samples that the control laboratories have taken. The non-compliances reported by the RASFF can be used as a rough index to check the relative importance of non-compliances between materials or the level of interest shown in certain controls for some materials or in testing by MSs' competent authorities.

⁽¹⁹⁹⁾ <https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1>

A third source was the data from MSs' competent authorities on monitoring. Questionnaires were sent that included a summary of a previous query done by DG Health and Food Safety in 2012. The information requested included not only data from official controls, but also information about enforcement campaigns, monitoring or surveillance work, research reports or other data that a given MS might have. In order to be able to make a comparison, the scope of the information covered all materials and articles, i.e. both those for which there are no harmonised EU rules and those for which EU harmonised rules exist, such as plastic and ceramic materials. The focus was on recent activity, but where possible included all years from 2005 onwards. Information included the type of work (e.g. official controls, enforcement campaigns, surveillance or monitoring, research, etc.), the type of materials or articles tested, the target substances, the number of samples, the type of documentary control, the number of non-compliant samples, the relevant measure(s) to check compliance, key findings, follow-up actions and potential links to reports/publications.

Finally, methods for testing were considered, both for analytical purposes (migration testing and quantification) and for sensory analysis. This was done reviewing as a first instance the presence of calibrants and methods for harmonised plastics as benchmarks and by reviewing standards in the literature. As this portion represents a horizontal issue (safety and burden), it was analysed as a stand-alone in the previous section.

4.3. Reports of issues based on HFAA (ex-FVO) audits

There were 23 reports of audits performed by the HFAA in 21 EU MSs between 2007-2010 with a focus on FCM. These are publicly available and were collected together; an overview is available in Annex 23. No specific audits were carried out on specific provisions for individual materials, thus the conclusions reported should be considered as of a general nature for all FCMs. The presence of national legislation on FCMs that are not harmonised at EU level was not always assessed, thus it would not be visible in the outcome of audits, even if the country may have provisions.

The information tabulated aimed to summarise the transposition of EU measures ⁽²⁰⁰⁾ into national law, the presence of national legislation and parameters of interest for this baseline study, including registration of food contact operators, declarations of compliance and supporting documents, details on GMP, bases for enforcement and for sanctions, certification/accreditation/quality systems, control/sampling systems, traceability and laboratory performance.

It should also be noted that data can only be considered as valid at the moment of issue of the report. Since then the situation in relation to non-conformities or the lack/insufficient implementation of EU provisions may have changed. The analysis of the data is considered as indicative only and not as a fully exhaustive source of information.

HFAA also performed two Audits in China and one in Hong Kong. The objective of the auditors was to verify if the official control systems on FCMs intended for export into the European Union were suitable to prevent migration of their constituents into food (e.g. primary aromatic amines and plasticisers from plastics, lead and cadmium from ceramic wares and formaldehyde from melamine kitchenware), according to Regulation (EC) No 1935/2004. These are also summarised in Annex 23.

From the data collected, it appears that all MSs had successfully transposed all EU FCM legislation (only the Czech Republic needed a small revision at the time of the audit) and that most of the EU MSs have certification/accreditation/quality systems in place. The

⁽²⁰⁰⁾ The regulatory framework of the audits pertinent to FCM sector included: Regulation (EC) No 178/2002; Regulation (EC) No 852/2004; Regulation (EC) No 882/2004; Regulation (EU) No 16/2011; Decision 2006/677/EC; Regulation (EC) No 1935/2004; Regulation (EC) No 1895/2005; Regulation (EC) No 2023/2006; Regulation (EC) No 372/2007; Regulation (EC) No 282/2008; Commission Regulation (EC) No 450/2009; Directive 80/766/EEC; Directive 81/432/EEC; Directive 93/11/, Directive 2002/72/EC; Directive 2007/42/EC; Directive 2011/8/EU; Directive 78/142/EEC; Directive 82/711/EEC; Directive 84/500/EEC; Directive 85/572/EEC.

table also highlighted that details on GMP and an efficient system of controls and sampling seem to have posed some issues in many countries over the years when the audits took place. The main issues highlighted by the auditors during their visits (pertinent to this study) are summarised in Annex 23. The HFAA audit programme has not included FCMs since 2011.

The data indicates that the main areas of issues have seemed to concentrate on the lack of (or insufficient) training, the lack or insufficient control systems, the lack of, insufficient or non-traceable documentation and/or declarations of compliance (Article 16 of Regulation (EC) No 1935/2004, Article 15 of Commission Regulation (EU) No 10/2011 and Article 2(a) of Council Directive 84/500/EEC), the lack of (or insufficient) GMP implementation and the lack of (or insufficient) validated methods. The issues regarding control systems analysed by the auditors pointed principally to a lack of coordination (e.g. between competent authorities and between competent authorities and control laboratories), to insufficient planning or an insufficient number of controls and to the lack of specific and functional procedures (e.g. on how to perform controls or how to access documentation). The lack of resources needed for controls (personnel for the inspections, analytical equipment, facilities, etc.) was also highlighted. It is also interesting to note one of the comments on the performance of controls in one MS, which stated: 'FCMs other than those subject to specific Union measures as foreseen in Art. 5 of Regulation (EC) No 1935/2004 are not part of official control', as it seemed to highlight the importance given by that MS to the presence of Union measures.

Regarding the audit performed in Hong Kong, it was stated by the Hong Kong Exporters Association that no FCMs manufactured in Hong Kong were exported to the EU (no written evidence was provided, however) and that the vast majority of FCMs manufactured in China and exported into the EU by Hong Kong traders were directly shipped from mainland China without actually passing through the territory of Hong Kong. It was therefore stated as a consequence that the Hong Kong authorities had no legal basis for control of FCMs manufactured in China, and that it was therefore not possible for the Hong Kong authorities to implement export controls. Regarding the audits performed in China in 2007 and 2009, the main issues highlighted were deficiencies regarding laboratory performance, the incomplete investigation of companies notified through the RASFF and the potential risk of non-compliant FCMs exported to the EU via Hong Kong. The report noted that 'as a result of the first audit the control system in place on FCMs destined for export to the EU has improved'.

4.4. Investments in better training for safer foods in FCMs

BTSF is an initiative of DG Health and Food Safety, managed by the Consumers, Health, Agriculture and Food Executive Agency (Chafea, formerly the Agency for Health and Consumers (EAHC)). It trains officials from EU MSs and non-EU countries involved in checking compliance with EU food and feed law, animal health and welfare rules and plant health rules. BTSF comprises training programmes on subjects related to its main areas of focus. For this reason a short review of the BTSF investments in FCMs was completed. The details can be found tabulated in Annex 23. Five sets of events have been organised on FCMs since 2007, totalling more than 17 sessions, including 15 on food contact and two on risk assessment, and attended by close to 550 participants overall. These courses were targeted both at competent authorities and at inspectors, with specific sessions also for laboratory staff. The topics indicated a recurrence of courses on GMP. It also highlighted that repeat sessions over the years were specifically targeted at the setting-up of national control plans on FCMs, the preparation by competent authorities of checklists for inspectors, the inspection of declarations of compliance and supporting documentation and the inspection of FCM premises, including sampling of FCMs. This indicates that these were areas of particular need. Thus, while these training courses were developed primarily for the EU harmonised legislation, they also should have provided benefits as models that can be used in non-harmonised sectors on safety requirements in general and aspects that have always been the most

critical for compliance, i.e. GMP and declarations of compliance. In addition a series of e-modules has been developed that are still free to access and should be exploited as much as possible.

4.5. Reports of non-compliance based on RASFF data

The RASFF system provides information on non-compliance data reported by the MSs. It should be noted that the role of the RASFF system is to represent a tool to ensure the cross-border flow of information to swiftly react when risks to public health are detected in the food chain. Although it does not give a full monitoring view, it can be a **relative** indicator for safety or it may be an indicator of the interest of different MSs in focusing on certain materials they deem of more particular interest and subject to testing.

An overview ⁽²⁰¹⁾ of the RASFF notifications was recently carried out by the NRL of Slovakia specifically for the period 2010-2015. The data indicate that the number of FCM notifications (1 378) is lower than that for feed (1 601), representing a small portion of the food alerts (n = 16 554) for the 5-year period, as shown in the Figure 48 below.

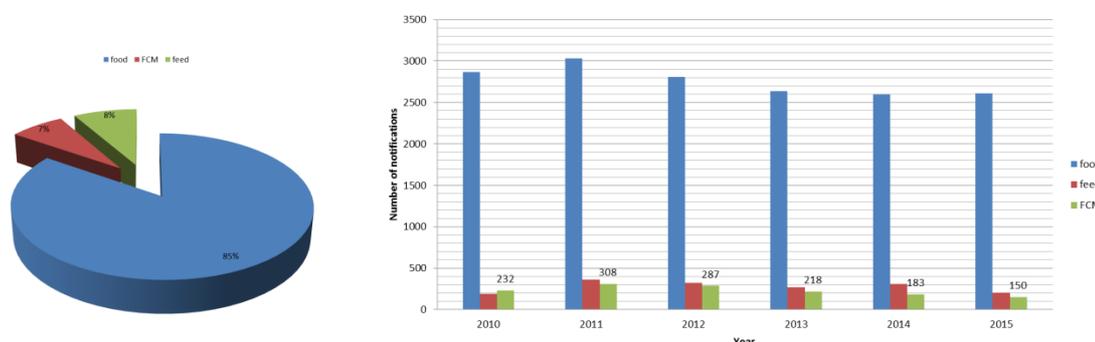


Figure 48: RASFF notifications in each category of product over 5 years, and on a year-by-year basis

On a year-by-year basis, the data shows that the number of notifications significantly increased from 2011 onwards, thus after the adoption and implementation of Regulation (EC) No 10/2011 (bisphenol A) and Regulation (EC) No 284/2011 (border control of melamine and polyamide kitchen utensils): this can be taken as an indicator of the more effective performance of official controls.

With respect to notifications by individual MSs, 13 MSs notified more alerts for FCMs than for feed, of which the most notable were Italy, Poland and Slovenia. In terms of risks, the study by the Slovak NRL classified the analysis of the RASFF notification by type of risk for the years 2010-2015, as shown in Figure 49 below.

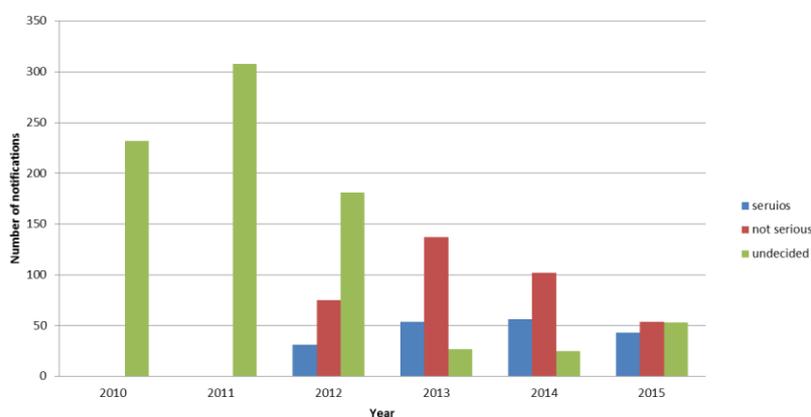


Figure 49: Analysis of RASFF notifications by type of risk

⁽²⁰¹⁾ M. Sycova, 'Analysis of RASFF notifications in the period 2010-2015', presentation to the EURL-FCM plenary of 06/2016.

The data indicates that some potentially carcinogenic substances have been reported in the categories 'non-serious' or 'undecided' ⁽²⁰²⁾. Underestimated classification indicates the need to improve the definition of the risk category.

The type of classification (i.e. news, border rejection, information or alert) is shown in Figure 50. The data indicate that the highest number of notifications was in border rejections (49 %), with the most common cases being primary aromatic amines (PAAs), mineral oils, photoinitiators, migration of formaldehyde and heavy metals. With regard to the type of control (Figure 51), the data indicates that 51 % of FCM controls were carried out at the border. Almost half (46 %) of the notifications were based on the performance of official controls in a particular MS (control of producers or control at retail stage). The study of the Slovak NRL thus concluded that border controls are an effective means to minimise issues of the safety of FCMs on the EU market.

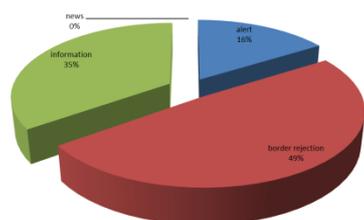


Figure 50: Analysis of RASFF notifications according to the type of classification

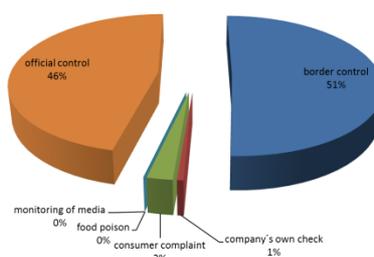


Figure 51: Analysis of RASFF notifications according to the type of control

In terms of reported non-compliance, the cumulative statistics from 2010 to 2015 were also compiled by the study of the Slovak NRL and reported in Figure 52. Overall it shows a predominance of heavy metals being tested for and found non-compliant with limits (elements). The materials subject to the controls were predominantly metals and alloys, and often specifically kitchen utensils. The main substances were heavy metals, formaldehyde, plasticisers, photoinitiators and epoxy compounds.

It should be noted that over the years 2010-2015, the vast majority of non-compliances were relative to imports from non-EU countries, in particular China (especially for PAAs, melamine from plastic kitchen utensils and heavy metals from metallic articles).

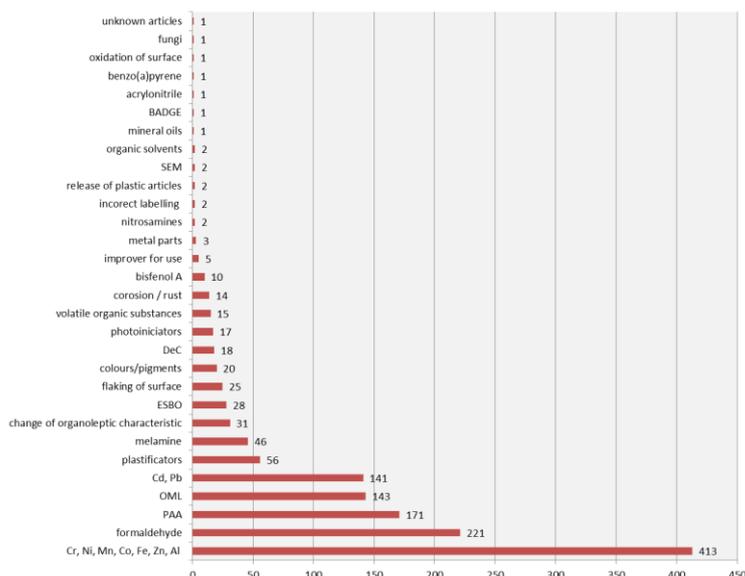


Figure 52: Analysis of RASFF notifications according the subject of the control

⁽²⁰²⁾ The national contact points for RASFF are responsible for the categorisation of notifications of the type of risk.

Most interestingly, the study also reported the results as a function of the type of legislation against which the notifications were reported (Figure 53).

| Legislative status | Number of notifications |
|---|-------------------------|
| Non-harmonized area | 450 |
| Regulation (EC) No. 10/2011 (plastic) | 680 |
| Directive 84/500/EEC (ceramics) | 141 |
| Framework Regulation (EC) No. 1935/2004 | 120 |
| Directive 93/11/EEC | 2 |
| Regulation (EC) 1895/2005 (epoxy derivatives) | 1 |

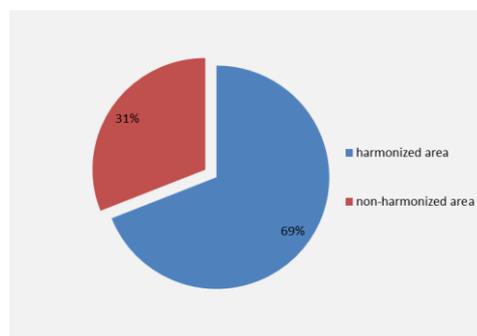


Figure 53: Analysis of RASFF notifications according to the legislative reference for the controls (number and percentage)

The study noted that, for the non-harmonised sector, few substances seem to be tested for and this they tend to appear recurrently in notifications (e.g. PAAs for paper, volatiles for silicones, photoinitiators for printing inks). In 2014, 66 % of the non-compliant plastic samples were due to migration of PAAs, formaldehyde or melamine above the limits, while 89 % of the non-compliant metallic samples were due to too much migration of specific metals, such as chromium, nickel, manganese and lead. It may indicate a growing interest by MSs in testing metals for kitchenware and corresponding import issues.

This data are, however, not indicative of the relative proportions of compliance vs non-compliance, so it was and should be taken with extreme caution.

4.6. Compliance statistics derived from Member States' official control data

Regulation (EC) No 882/2004 on OFFC specifies that control of the application of the rules within its scope applies also to materials and articles in contact with food, and can be implemented in terms of actions such as monitoring, surveillance, verification, auditing, inspection, sampling and analysis. Yet a hurdle not easily overcome in the area of FCM is that there are no systematic control plans for monitoring under Regulation (EC) No 882/2004 or other legislation. MSs focus control on materials and articles for which specific legislation is established at EU level or within the MSs.

Following the query from JRC, 20 MSs (Bulgaria, Denmark, Germany, Estonia, Ireland, Greece, Spain, Croatia, Cyprus, Luxembourg, Latvia, Hungary, the Netherlands, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden and the United Kingdom) sent information on the results of their official controls. The data available for the period 2005-2014 were heterogeneous. Campaigns could cover more than one material at once, which made it difficult to allocate the non-compliances to a given material. A campaign could also cover one material but group together several parameters so that allocation of non-compliance to a parameter became difficult. Data were compared when more than 1 000 samples were analysed by three or more MSs, since less data could not be considered a guarantee of any relevance or representativeness. The results are summarised in Table 10 below. MSs did not report on multimaterials.

Table 10: Review of monitoring, enforcement or national data

| Material | No of MSs | Which and what | Total No of samples | % non-compliant |
|--------------------|-----------|--|---------------------|-----------------|
| Printing inks | 6 | Mostly photoinitiators NB: It should be underlined that the results were very oriented over the time period following the ITX issue | 1 460 | 2.9 % |
| Varnishes/coatings | 6 | OM or metals or BPA or BPA and derivatives | 1 530 | 4 % |

| Material | No of MSs | Which and what | Total No of samples | % non-compliant |
|---------------|-----------|---|---------------------|--------------------------------|
| Ceramics | 19 | Metals/elements | 20 500 | 12 % |
| Glass | 6 | Metals/elements, OM, declaration of compliance | 6 850 | 12 % |
| Metals/alloys | 6 | Metals/elements | 10 300 | 14 % |
| Paper/board | 13 | Photoinitiators/benzophenone and derivatives, PAAs, formaldehyde, fluorinated substances, total organic fluorine, elements/metals, organoleptic test, plasticisers/phthalates, DIPN, BPA, inks, PCP, DIPN, bleeding, aqueous extract, preservatives, antioxidants, MCPD, colour/saliva fastness, labelling, sensory testing, organotin, MOSH-MOAH, brighteners, wet strength aids, inhibitors, anthraquinone, N-ethyltoluenesulfoneamide, microbiological analysis, phenols | 19 400 | 8 % |
| Plastics | 20* | Overall migration, specific migration, DOC, etc. (all topics) | 45 600 | 11 % |
| Rubbers | 3 | Nitrosamines and nitrosatable substances, OM, declaration of compliance, mercaptobenzothiazole, PAAs, extractable substances, labelling, volatile substances, sensory testing, microbiology, water-soluble latex proteins, release of colours | 2 200 | 10 % |
| Silicones | 5 | Sensory analysis, siloxanes, silicone oligomers, metals, volatile organic compounds, declaration of compliance, screening, organotin compounds, labelling, OM | 2 140 | 7 % |
| Wood | 3 | Volatile substances, tri-, tetra and PCP, formaldehyde, antimicrobial activity, labelling, release of colours, sensory analysis, glyoxal, preservatives, elements, short-chained phthalates, microbiology, pesticides, sensory testing, declaration of compliance, metals | 1 770 | 25 % (taint issue for sensory) |

Controls on were carried out only in one MS and only on 11 samples. The overall data showed that on average about 5 % of the samples for the parameters tested, i.e. migration results and documentation, are non-compliant. The data indicates low non-compliance at the early stage in the chain (3-4 % for coatings and varnishes). It also suggests that non-compliance is not significantly different between EU regulated and non-harmonised materials for the most part (in the range of 7-14 % for non-regulated vs c.11-12 % % for regulated plastics/ceramics). Interestingly the declaration of compliance checks showed a higher non-compliance of c.20 %.

4.7. Gaps in methods of analysis

As previously highlighted, the scarcity of standards (CEN/ISO) or methods in general in the area of non-harmonised materials is an impediment to demonstrating compliance and hinders official controls and industry alike. The main implications are not only for safety but also for burden, as this implies that industries must resort to external third-party laboratories for screening and quality control. The proprietary nature of methods developed by third-party entities is a source of commercial business and not conducive to sharing. The lack of access to methods for NRLs implies that greater efforts and human resources are spent on the development of methods potentially almost on an ad hoc basis.

5. Indicators on burden of measures and instruments

This study included an investigation on the impact, in this case of the application of national rules, on costs (administrative burdens, etc.). In this context, a dedicated questionnaire was developed in conjunction with DG Health and Food Safety to further tackle aspects of trade and burden towards the analysis of efficiency (also termed cost cost-effectiveness in the technical annex of this project). Factual elements were the primary criteria of interest (i.e. descriptors of a qualitative and quantitative nature).

Questions related to trade included the following aspects: composition/members of professional associations; proportion of the overall market in the sector represented by each association; approximate proportion of SMEs; proportion of production for FCMs vs non-food contact; actors up and down, if any. In order to develop descriptors to assess burden, questions were directed towards: (1) where the compliance work is done in the chain; (2) what measures industries/countries are using in the absence of EU harmonised legislation ⁽²⁰³⁾; (3) what standards are used, where relevant; (4) what tools are used for specific purposes (e.g. OM, SM, QM, GMP, registration, etc.); (5) whether tools are used for risk assessment; (6) evaluation of costs for demonstrating compliance in one country and/or in more than one country; and (7) any additional comments or data.

5.1. Costs to Member States

The costs and resources necessary for MSs to manage the national measures could not be obtained in a very detailed manner.

For many MSs there is no separate estimation of the yearly costs for implementation of EU FCM legislation and national legislation or risk assessment or of the official controls. The few data that was received from MSs are presented in Table 11.

Table 11: Estimation of the yearly costs for implementation of EU FCM legislation and national legislation or risk assessment or of the official controls (only MSs that provided data are shown — empty cells indicate an absence of data)

| MS | Resources for implementation of EU legislation | | Resources for implementation of national legislation | | Resources for risk assessment of national legislation | | | | Resources for official controls | | Share FCM in total food enforcement |
|----|--|---------|--|---------|---|---------|----------|--------|---------------------------------|----------|-------------------------------------|
| | FTE | EUR | FTE | EUR | FTE | EUR | EUR/appl | appl/y | FTE | EUR | |
| CY | 4 | | | | 0 | 0 | 0 | 0 | | | >4 % |
| DK | 2 | 150 000 | 0.5 | 37 500 | 1.5 | 15 000 | | | 2.7 | 200 000 | EUR 10 000 000 |
| DE | 1.5 | 175 000 | 1.5 | 175 000 | 2.5 | 240 000 | 5 330 | 45 | | | |
| FI | 1 | | 0 | 0 | | | 0 | 0 | 5 | 2000 000 | < 1 % |
| FR | 1.2 | 70 000 | 0.8 | 40 000 | | | | | 14 | 770 000 | |
| IE | | | 0 | 0 | | | | | | | |
| IT | < 2 | | < 2 | | | | | 5-10 | | | |
| LT | 0.75 | 5 082 | 1 | 6 776 | | | | | 28 | 316 000 | 2.7 % |
| LU | 0.25 | 15 000 | 0 | 0 | | | 0 | 0 | 0.1 | 21 000 | |
| NL | 0.3 | 35 000 | 0.7 | 85 000 | 0.3 | 45 000 | | | 6 | 800 000 | 0.5 % |
| PT | 1 | | 1 | | | | | | | | |
| RO | 4 | 2 000 | 4 | 2 000 | | | | | | | |
| SE | 1 | 118 000 | 0.15 | 17 700 | | | | | 0.2 | 23 600 | |
| UK | 0.75 | 30 000 | 0 | 0 | | | | | 3 | 359 000 | < 1 % |
| NO | 0.9 | 90 000 | 0.1 | 10 000 | | | | | 0.5 | 50 000 | |

It was not possible to obtain individual national data for the following.

- Administrative burden and costs for MSs to manage national legislation.
- Administrative burden and costs to manage risk assessment schemes.

The resources needed for implementation of legislation at MS level are given as follows.

⁽²⁰³⁾ Including EU Member States, Council of Europe, FDA, Japan, etc.

- EU legislation: 0.25-4 full-time employees (FTE) (14 MSs) or EUR 2 000-175 000 (eight MSs).
- National legislation: 0.1-1.5 FTEs (13 MSs) or EUR 2 000-175 000 (eight MSs).

Some MSs, i.e. Ireland, Luxembourg, Finland and United Kingdom, indicated no costs for implementation of specific national legislation since they do not have any. For risk assessment of national legislation only Denmark, Germany and the Netherlands gave input on costs, as 0.3-2.5 FTEs or EUR 15 000-240 000. Germany indicated that it has 45 applications per year at a cost of EUR 5 330 per application. Italy indicated 5-10 applications per year. The resources for official controls were in the range of 0.1-28 FTEs or EUR 21 000-2 000 000 (nine MSs). The share of costs for FCMs in the overall food safety area was in the range of 0.5-4 %.

5.2. Costs to industry

There was very little data on actual costs and administrative burden that could be collected over the several queries made in the context of this study. In particular, data are fairly scarce for the following.

- Costs for establishing and updating self-regulation.
- Burden and costs to comply with national measures, GMP and self-regulation.
- Burden and costs to comply with risk assessment schemes.

It was also not possible to obtain systematic data for each product category.

In addition, no information could be obtained, except from a qualitative and opinion polling standpoint, on drivers for the costs and burden and on the distribution of costs and burden in the supply chain.

5.2.1. Industry costs to administer guidance or self-regulation

Table 12 shows the costs for EU professional organisations to administer guidance or self-regulation. The notes indicate what work is included in the costs. Some professional organisations indicated that the contributions come from their members. Many costs could not be estimated by associations and are thus not known.

Table 12: Cost for EU professional organisations to administer guidance or self-regulation

| EU prof. org. | Human resources guidance/self-regulation | Human resources guidance/self-regulation |
|---------------|--|--|
| | FTE | EUR |
| FEICA | 1 | ? |
| APEAL | 1 | 100 000 |
| EMPAC | 12 | 500 000 |
| ECMA | 0.3 | 40 000 |
| FPE | 0.4 | 50 000 |
| EuPIA | 1.5 | 80 000 |

Professional associations also cite or provide a number of documents testifying to the administration of their guidance or self-regulation. These are shown in Annex 24 for the associations that gave feedback.

5.2.2. Industry costs for risk assessment

Generally, the costs for CEFIC-FCA members (chemical sector) to carry out risk assessment in support of establishing compliance with Article 3 of Regulation (EC) No 1935/2004 consists of internal costs supported by product stewardship departments within the companies, and also external consultancy costs where needed. FPE (plastics sector) interpreted costs for risk assessment as those for gaining authorisation for substances from official bodies. FPE members extend costs to their own internal risk assessments, for example for NIAS in finished materials and articles or for foreign body contamination of their materials and articles ('hygiene'), but these costs are impossible

to separate from costs for compliance. In 2012 ETRMA (rubber sector) estimated the risk assessment costs to be 6-10 % for elastomer/rubber in Spain and Italy and more than 25 % for Germany relative to the overall costs. The replies are summarised in Table 13.

Table 13: Risk assessment costs reported by various sectors (empty cells indicate an absence of data)

| Material | Subsector providing reply | EU professional organisation | Estimated relative costs for risk assessment | Estimated relative costs for risk assessment |
|------------------------------|---------------------------|------------------------------|--|--|
| | | | Turnover | Overall |
| | | | % | % |
| Adhesives | | FEICA | | < 2 |
| Metals and alloys | Steel | APEAL | | 2-5 |
| | Rigid packaging | EMPAC | < 2 | < 2 |
| Paper and board | Folded carton makers | ECMA | < 2 | |
| Plastics | Flexible packaging | FPE | | 0 |
| Printing inks | Inks | EuPIA | | 2-5 |
| Regenerated cellulose | | Cipcel | | 0 |
| Rubbers | Tyres and rubber | ETRMA | | 6-25+ |

5.2.3. Industry costs for application for an authorisation of a substance for EU or national legislation

The migration level of a particular substance from packaging to food will determine the set of toxicity tests to be submitted with an application. Hence the cost of an application may vary over a broad range. This is also true for both EU and national legislation. Table 14 shows the input received from the professional associations related to industry costs for application for an authorisation of a substance for EU or national legislation. The replies were quite scarce for the majority of sectors. Some associations downstream in the supply chain indicated that upstream suppliers of substances were responsible for authorisations.

Table 14: Industry costs for application for an authorisation of a substance for national legislation

| Material | EU prof. org. | Resources application of substance authorisation at national level | |
|----------------------|---------------|--|---------------------|
| | | Substance/y | EUR/y |
| Plastics | No data | No data | No data |
| Printing inks | EuPIA | 50 | 2 000 000/y |
| Rubbers | ETRMA | 3 | 4.5K (FR) |
| Waxes | EFW | Few | 500 000/application |

5.2.4. Overall costs to industry, perceived barriers to trade, burden

This section is a compilation of citations of the responses of industry on costs, additional burden and perceived barriers to trade. Most industries cannot provide their costs differentiated for each country.

Chemicals and intermediates

Chemicals and additives

CEFIC reported the generic **costs** according to the following characteristics.

- It is the main element for additive producers.
- The estimate is given for one petition (indicative).
- The estimate is valid for national-specific (non-harmonised) or EU-specific requirements.
- It is based on compliance with Article 3 of Regulation (EC) No 1935/2004 (and Article 19 of Regulation (EU) No 10/2011 for NLSs).

Estimates of costs per substance and per type of work were as follows.

- Costs for toxicity testing: EUR 150 000-2 000 000.
- Costs for migration testing: EUR 10 000-60 000.
- Costs for analytical testing: EUR 5 000-30 000.
- Costs for resources: EUR 10 000-100 000.

In these cases risk assessment is carried out under industry responsibility and is either performed internally by in-house experts or is outsourced to third parties recognised for their expertise. The estimation of costs depends on a variety of factors. In principle the cost estimations reported above could give an indication, but could also be substantially higher or lower depending on the specific substance, its use and its final application.

In terms of **burden and perceived barriers**, it was noted by CEFIC that due to national-specific legislation, industry have to submit their petitions in each MS, and that although MSs claim equal requirements based on the EFSA petition scheme, in practice requirements and criteria are different and this requires the suitable adaptation of the petition dossiers. In the ideal case, where the adaptation of the petition dossier from one country to another is minimal and no different testing is required, only resource costs are relevant. If different petitions have to be prepared for each country, the costs indicated above would need to be multiplied by the number of national-specific petitions required.

It was noted that while mutual recognition is a main element of functioning, its principle is not equally understood in the MSs. Access to national legislation only in a local language is another perceived barrier, requiring additional resources necessary to ensure compliance (and is especially relevant for non-EU partners). The burden cited also includes indirect costs (e.g. delayed market access) arising from sometimes lengthy authorisation processes.

CEFIC-FCA considered that, next to legal measures, safety may be certified on the basis of industry self-assessment in accordance with internationally recognised scientific principles on risk assessment and acceptance of approvals in other regions of the world that follow equivalent principles ensuring safe use (e.g. United States).

Adhesives

FEICA estimated the compliance **costs** to be less than 2 % relative to the overall costs, of which 25 % was spent on national legislation.

The following costs are specifically identified.

- Translation costs for national legislative documents.
- Different specific migration tests for the same substance but according to different national rules.
- General administration costs.
- External legal advice for different national regulations.
- In some cases even reformulation of the product is needed to comply with national legislation. This may have the consequence of a change of supplier.

In terms of **burden and perceived barriers to trade**, FEICA reported that the efforts and associated costs increased with the business size and expansion across the EU market, as multiple MSs implied more potential national measures to comply with and more staff effort (up to 4-5 times), and potentially the need for an external expert. It noted that customers ask more and more for global food contact status information, and that while large food companies develop internal standards that they apply globally, this can be too complex for smaller companies, which may thus become limited to their national market.

(Ion-exchange) resins

No comments/data on costs and barriers to trade were received from ERMA and SOIA.

Printing inks

EuPIA indicates that the **compliance costs** were estimated to be 6-10 % relative to the overall costs, of which 50 % is spent on national legislation. Additional costs were pointed out as coming from the REACH legislation (0.2 % of total sales). I&P Europe noted that costs were difficult to calculate and estimated the cost to be c.EUR 1 500-3 000 per formulation. Major costs and burden are based on voluntary and non-harmonised EU legislation.

With regard to **burden and perceived barriers to trade**, EuPIA noted that the burden is on the finished FCM rather than the printing ink itself. Printing ink manufacturers must provide relevant information to enable the manufacturers of the final FCM article to demonstrate the compliance of their product. The burden for the sector includes a lack of expertise in making risk assessments and consequent investment costs on GMP systems.

EuPIA noted that a patchwork of national laws results in unnecessary complexity of different lists of authorised substances in different countries.

- *For example, it was noted that the Swiss ordinance on food packaging inks has within its scope (and is restricted to) printing inks and varnishes applied to the non-food contact surface of food packaging. The latest draft of the future German ordinance also includes within its scope printing inks intended to come into direct contact with foodstuffs (printing on the food contact surface) and expands the scope to FCMs other than food packaging.*

EuPIA also underlined that the requirements on information exchange from one player in the supply chain to the next did not appear to be the same. This all results in multiple requirements to meet different demands for the same type of product. It highlighted that the movement of goods is very complex, as shown in the example below.

- *A food packaging ink is manufactured in one MS and sold to a converter in another MS, who prints and sells the printed packaging to a food packer in yet another MS. The packed food is then sold across Europe, and enforcement authorities in the various MSs undertake controls according to their national provisions. Food packed in printed packages is also imported from outside Europe into the EU.*

Regarding inks, FPE also noted that 'Globally acting companies insist on compliance with the Swiss legislation on printing inks no matter if materials are exported to Switzerland or not. Annex 6 of the Swiss ordinance is not comparable, for example, to the French positive list for inks. The German draft legislation differs in large parts of the positive list from the current Swiss list.'

Varnishes and coatings

FPE illustrated the burden from multiple testing with the example below.

- *The Italian legislation sets out a positive list for plastics that is also valid for lacquers. Migration testing is done in accordance with plastics regulation, but towards different limits (OML 8 mg/dm² vs 10 mg/dm² in Regulation (EU) No 10/2011). Yet the testing of lacquered aluminium with 3 % acetic acid is technically not feasible.*

No comments were received from CEPE.

Wax

EWf estimated compliance costs to be 2-5 % relative to the overall costs. EWf reported that most members refer to the BfR recommendations, the Dutch Warenwet and different paragraphs of FDA legislation in their declaration of compliance.

Materials: ceramics, glass, metals and alloys

Ceramics

No comments or data regarding costs and barriers to trade were received from Ceram-Unie or EEA.

Glass

No comments or data regarding costs and barriers to trade were received from GAE.

Metals and alloys

With respect to **cost** estimations, EMPAC estimated the compliance costs to be less than 2 % relative to both the turnover and the overall costs. 20 % was spent on national legislation. APEAL estimated the compliance costs to be 2-5 % relative to the overall costs. No data were received from EAA (aluminium), NI (nickel), Eurofer or Eurometaux, and FEC reported the absence of data in their possession. It noted that 'these costs are increasing very rapidly and could become higher than 0.5 %'.

In terms of **perceived barriers and burden**, EMPAC noted issues with mutual recognition, and FEC underlined repeat work and associated costs as a result of different compliance rules and certificates lacking harmonisation. No additional comments nor quantitative information were received on barriers to trade.

Materials: cork and wood, paper and board, rubber, silicone.

Paper and board

In terms of compliance **costs**, for the beverage carton industry, ACE reported the estimated compliance costs for more than one country (in Europe, or even including the United States) to be in the range of 0.5 % of companies' turnover. It pointed out that this was a very rough figure, which also depended on what to count as compliance costs. In the figure given for this study, it was considered to cover hygiene/quality management systems, laboratory facilities/staff, regulatory affairs managers and outsourced compliance evaluation or research work. ACE also mentioned additional costs such as REACH, CLP, PPWD, OHS, solvent emissions and GMP. These could not be quantified by the association. ACE underlined that the beverage carton industry operates on an international level, and that packaging material intermediates and articles will be used by multinational companies and require compliance work on an EU level. They concluded that, as a consequence, specific compliance with national legislation is the exception and cannot be singled out from the overall compliance costs.

The paper industry represented by CEPI reported that no European data were available and no company data could be made available due to anti-cartel rules. CEPI noted that companies simply did not provide services in all areas of the single market when the compliance costs for a low-cost commodity like packaging materials were prohibitive. It underlined that, even solely from a qualitative standpoint, the situation was estimated to be a loss for those manufacturing paper and board, as they had a de facto reduced market access, and for those buying paper and board as they could procure with reduced competition in supply. CEPI concluded it translated to higher costs to those using packaging and finally to consumers.

From the converters sector, CITPA did not provide direct feedback, but associations it represents did for the actors of carton makers (ECMA) and producers of corrugated board (FEFCO). ECMA noted that was difficult to judge the cost for one, two or more specific countries as the members deliver products for the entire food sector around Europe. It was estimated that the total costs for demonstrating compliance were estimated to be 2-5 % relative to the overall costs and 2-4 % related to turnover. It was noted however that this percentage did not cover the changes in raw material use and the required process changes. It was also underlined that to keep the compliance costs at a reasonable level it is essential to obtain serious information from the different suppliers and from the customers about the specific use of the product. It pointed out that without good formalised indications on the migratable substances and the concentrations that can be expected only a full screening approach is left, which can be infeasible or can add greatly to burden. With regard to corrugated board, FEFCO noted that the cost varies by country, company and customer and is difficult to quantify. IT

noted that there are direct (laboratory tests) and indirect (people, documentation, etc.) costs. FEFCO stated that additional costs were also found to be difficult to quantify, for example those on the hygiene requirements required by food laws, which for FCM suppliers also implies hygiene requirements for processes, equipment and safety.

In the context of the tissue paper and napkins sector, the association ETS reported that values for demonstrating compliance could not be provided due to a lack of member-specific information in this regard. It noted that compliance costs encompass provisions relating to the selection/changing of raw materials and the implementation of a quality, risk and hygiene management system in production process (GMP) along with product compliance, including product certificates from accredited laboratories. It noted that associated costs are expressed in personnel costs (operators, researchers, technicians, administrative staff to check compliance, ensure traceability and manage the quality assurance/risk management system) and consultant costs (product testing and certification, audit and certification of management systems). ETS highlighted that tissue paper and kitchen towels and napkins were multifunctional products not specifically intended for contact with foodstuffs, where the use as FCMs may be limited in frequency or time. Therefore they are covered today by specific CoE guidelines for tissue paper kitchen towels and napkins.

In terms of **burden and perceived barriers to trade**, the entire sector unanimously reported that the absence of an EU-specific measure for paper and board was a burden for the industry. For the paper sector, CEPI noted that, due to higher costs, companies, in particular SMEs, had reduced market access or did not have opportunities to access new markets. It also pointed out that many non-EU countries were starting to develop their own standards instead of taking one from the EU as a model, which impacted export possibilities for both FCM and packed food from Europe, thus translating to a loss to the European economy. CEPI and FEFCO (corrugated board) also stated that, in the absence of a sector-specific EU measure for paperboard, the supply chain was often requested by its customers to ensure compliance with the plastics regulation (Regulation (EU) No 10/2011), the requirements of which are often irrelevant for paper and board and hence are not (always) applicable. This aspect had a cascade effect as commercial laboratories are often forced to use plastic testing requirements for paper articles, leading to misleading results, which can cause misinterpretations that negatively impact the business. From a broader standpoint, it was felt that there is often a misconception that only harmonised materials are safe and that consequently paper and board might be thought unsafe. For the carton makers sector, ECMA confirmed that without clear legislation companies have to operate in a context of uncertainty where the principle of mutual recognition is not always respected and with the negative perception of being unregulated. ECMA also expressed concerns on public debates about specific concern on chemicals that can cause additional research and analysis, which can significantly increase the burden. From the standpoint of the converters, CITPA also noted that there are difficulties with mutual recognition in some countries, and that the unilateral requirement imposed by the rules of an MS could constitute an obstacle to trade.

Rubbers, elastomers, and silicones

With regard to **compliance costs**, the rubber sector, via its association ETRMA, reported that the cost for certifying a single product was least EUR 5 000, and this had to be multiplied for each country in which the product is commercialised. Additional costs for authorising a single substance were estimated to vary from few thousand euros to several hundred thousand euros. These compliance costs were estimated to be 6-10 % for elastomers or rubbers in Spain and Italy and more than 25 % for Germany, relative to the overall costs, of which 30 % was spent on national legislation. It was also extrapolated by ETRMA that, depending on the number of countries in which the product has to be certified, costs to demonstrate compliance could be up to 2 % of turnover. No data were received for synthetic rubbers (IISRP).

In terms of **burden**, it was underlined that the absence of common lists of authorised

substances implied a multiplication of the costs for assessing the same substance in different countries. The association WBT noted as an additional burden that the migration testing of thermoplastic elastomers (TPE) within the plastics regulation was an issue/concern and was considered as a factor excluding the development of more innovative materials. No comments were received from IIRSP. For the silicones sector, CEFIC-CES input was reported under its umbrella association CEFIC FCA.

Cork and wood

No feedback on costs and burden was received from C.E.Liège or CEI bois.

Burden issues stemming from lack of methods

The scarcity of standards (CEN ISO) and the lack of access to methods represent a burden, as this implies that industries must resort to external third-party laboratories for screening and quality control. It makes also sharing much more difficult since the proprietary nature of methods developed by third-party entities is a source of commercial business. It also means that NRLs spend added human resources on the development of methods almost on an ad-hoc basis.

The implementation of Article 3 is hindered by the lack of guidance on methodologies adequately covering the testing of compliance of this article. It is of relevance to quality control in the industry sectors since taints and off-flavours can be one the most common reasons for consumer rejection, resulting in loss of production and consequent financial loss to the company. Cases could result in subsequent legal action by food companies against the supplier of raw materials or packaging or processing materials and thus could also result in large compensation payments. Tainted food can also lead to a loss of consumer confidence in the product with long-term economic consequences on brand loyalty for the food company at the end of the chain.

Overview

Compliance costs

- *Costs were estimated to be 0-5 % of turnover, of which 20 % is spent on national legislation.*
- *Costs could be higher for smaller companies (up to 1 %).*
- *It is difficult to estimate the compliance costs for more than one country.*
- *Main costs also encompass regulatory affairs managers, regulatory information services/consultancy, analytical/migration tests for new developments, regular monitoring/customer requirements, analytical laboratories/staff, and development and project costs related to changes in raw materials or specifications due to regulatory changes.*

Burden and trade

Some recurring points on burden and perceived barriers can be summarised as follows.

- *Mutual recognition is a main element but its principle is not seen equally by the MSs.*
- *National legislation, written in different languages, tends to be ignored as though it is too difficult to find or understand.*
- *SMEs are penalised most by lack of access or understanding of national risk assessment or measures.*
- *Mutual recognition principles can be difficult to understand: when use of a substance is forbidden in one country, the importing of material containing this substance is difficult.*
- *Each actor (customer) may refer to its own national legislation: if selling to all EU MSs, the interpretation could mean to abide by multiple national rules if mutual recognition does not work in practice.*
- *Tendency for some countries to apply the plastics regulation to non-plastic material using their own requirements as though it were applicable to all materials or multimaterials.*
- *Industry self-regulation is lacking a framework of clear EU guidelines (e.g. for risk assessment methods and specification of information that should be passed up and down the supply chain).*

6. Key messages and conclusions

6.1. Industrial landscape

FCMs supply chains

The actors in the supply chain are organised material by material. FCMs include different sectors ranging from chemicals and intermediates to finished products. Chemicals and intermediates are at the beginning of several supply chains, including those for monomers, additives, starting substances, resins, adhesives, printing inks, varnishes/coatings and waxes. A second block includes sectors that supply inorganic materials, including ceramics and glass, enamels, and metals and alloys. A third segment of the supply chain can be considered as those sectors that supply organic materials, including paper and board, cellulose, cork, wood, rubber, elastomers and silicones, along with the plastics industry.

On the manufacturing side, supply chains in the EU are characterised by the presence of European associations (one or more) for each type of material. These are composed of members at the EU level and, in many cases, national federations at the national level with their own industrial members. Many companies are international in nature, and therefore the membership of European associations reflects the global trade, whereas the membership of national associations is more reflective of national manufacturers.

The supply chain can also be considered according to the position of each of the actors along the chain. As well as producers of starting substances and raw materials, actors include converters, producers of final materials and articles, distributors, importers and the users of the final materials and articles, including the food industry and, ultimately, consumers. Professional associations within a given sector are also organised into product categories, from intermediates (e.g. converters) to final actors (final packaging type). A simplified overview of this is given in Figure 54, with a more complex overview of the interaction of the various actors from different sectors (and by product category) given in the core of this report (Figure 2).

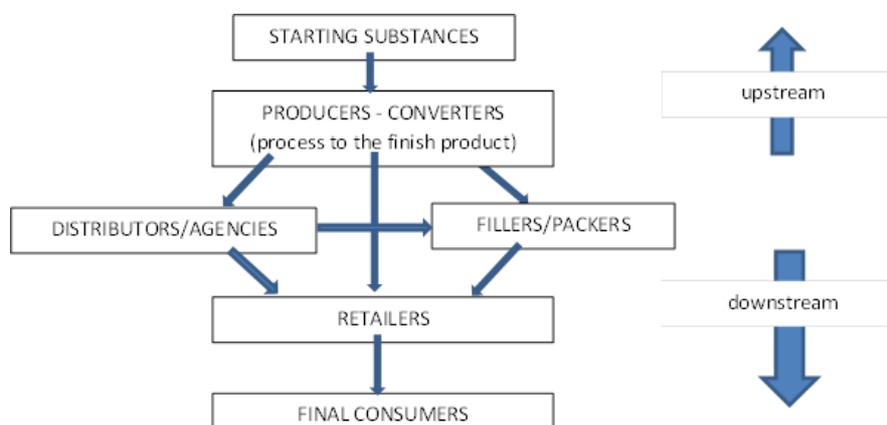


Figure 54: Simplified structure of the organisation of the FCM supply chain

Market shares

Volume and value of EU business operators in different supply chains

Concerning the value and volumes of the different supply chains specific to FCMs, it is difficult to place an overall figure on the market of the FCM industries in total, but the turnover seems to be in the range of EUR 100 billion per year. Figure 55 illustrates the distribution of annual manufacturing sales for each material sector, including general- and special-purpose machinery, based on the data available.

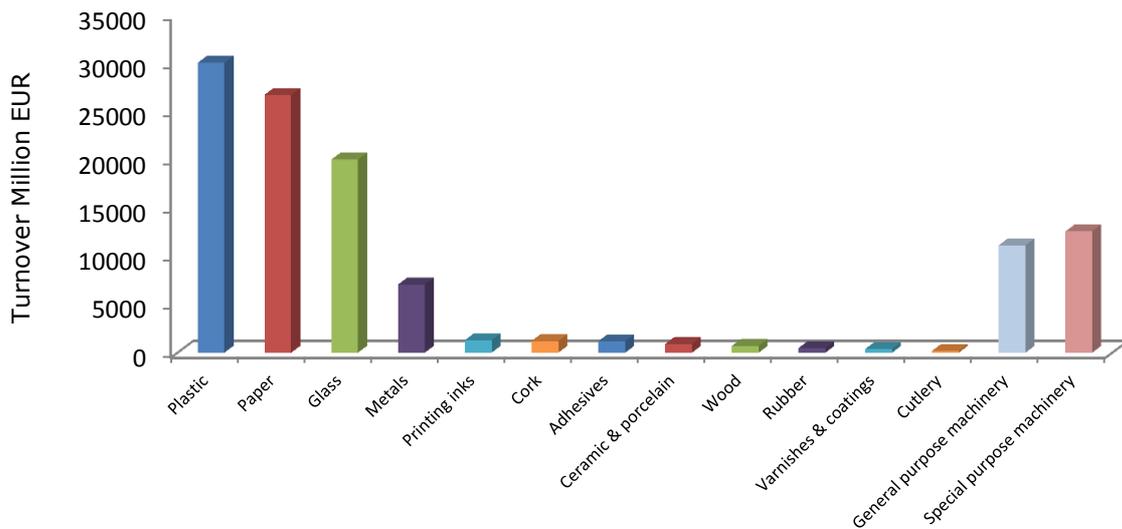


Figure 55: EU manufacturing sales per annum of different packaging materials, cutlery and FCM machinery

The data indicate that plastics is the largest sector with regard to the share of manufacturer sales, with a turnover of approximately EUR 30 billion, and that paper and board has a similarly significant turnover, in the range of EUR 26 billion. The glass sector is also significant (EUR 7 or 20 billion according to either Pira or GAE). Although considerably lower, metal and alloy packaging is relevant (EUR 7 billion). General- and special-purpose machinery also seem to be significant markets for FCMs and together may make up close to one quarter (in the range of EUR 11 billion each) of the overall FCM market. Sales for materials such as printing inks, adhesives, ceramics, and cork are in the EUR 1 billion range, and the sectors of wood, rubber, varnishes and coatings, and cutlery are worth less than EUR 1 billion.

In terms of volumes, data are disparate and thus relied on data from Euromonitor, which is available only for finished products sectors (glass, metals, multimaterials, paper) and is expressed in millions of units sold. Those values are more difficult to compare since materials of different natures may have quite different characteristics in volumes and weight. Trends over the past 10 years show a moderate increase for all sectors, except for glass, which exhibits a decrease.

The sales of the different materials also vary greatly from MS to MS, but with a trend for larger MSs to be significant suppliers of FCMs, including Germany, France and Italy. Spain, Poland and the United Kingdom also present high sales for many of the materials. An exception is cork where Portugal is the most relevant MS.

There are no further details on specifications for each market position aside from those provided by professional associations. The data are either not specific enough (Eurostat, Prodcem) or focus on end products (Euromonitor, Pira).

Volume and value of non-EU business operators in different supply chains

Very little data can be found on the share of EU MSs vs non-EU countries for FCMs in different sectors. Information was mainly gathered from the professional associations in relation to references to import/export. One main reason was that importers are not included in the membership (GAE). Glass exports from the outside the EU represent 8 % of the market. The influence on sales of non-EU imports is stated by FEC to be very relevant for the kitchenware sector. Further data are, however, needed in relation to this import/export aspect, and in particular the displacement of products of EU origin by products from non-EU countries, since RASSF notifications show that, for articles, the

majority of those found to be non-compliant are from non-EU countries.

Distribution of micro-, small and medium-sized enterprises in the different market positions

The distribution of micro-, small and medium-sized enterprises in the different market positions varies from material to material. Many sectors have a significant proportion of SMEs, even if they account for small proportions of the annual turnover.

For some materials, large manufacturers make up a significant proportion of sales. These include varnishes/coatings (95 %), printing inks (80 %) and glass (68 %). For other materials, the proportion is relatively equally split between small/medium-sized and large enterprises (e.g. metals and alloys, adhesives, ceramics/porcelain, rubber, machinery). In some cases the small and medium-sized companies represent a larger portion (e.g. paper, cork, wood and cutlery). Figure 56 shows the approximate distribution of enterprises based on manufacturing sales, rather than actual numbers. SMEs make up a much more significant proportion of the actual number of businesses. The distribution of SMEs tends to be significant for sectors such as adhesives, printing inks, cork, wood or ceramics.

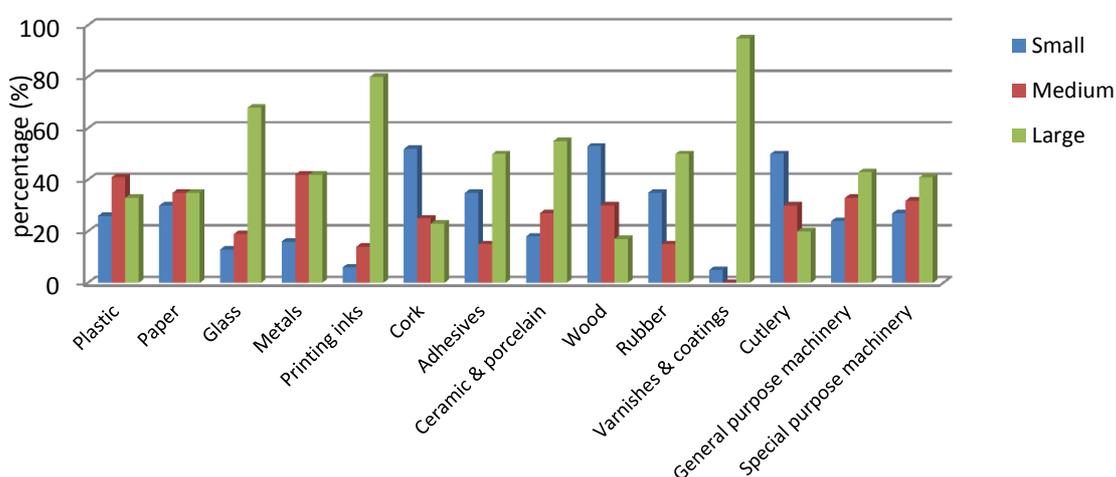


Figure 56: Distribution of different enterprises for various FCMs based on annual sales/revenue

6.2. Effectiveness of the current measures on safety

The objectives are to ensure that safe FCMs are placed on the EU market. This means the examination of risk assessments performed on FCMs, of the enforceability of the safety requirements of FCMs and of the self-control of manufacturers. This is presented in the next paragraphs in the form of questions.

Are the risk assessment schemes effective in ensuring compliance with the general safety requirements of the framework regulation?

The **risk assessment** processes that were developed under the Scientific Committee for Food and then taken up and expanded by EFSA have been most relevant. EFSA has a series of guidance documents that are available publicly and cover a large number of aspects for risk assessment (RA).

National context

Existence of risk assessment schemes

At MS level, the RA principles used at national level are, on the surface, fairly harmonised, and are mostly based on SCF and EFSA as reported in the ESCO report.

Twenty-five MSs have protocols in place, of which 10 have RA procedures dedicated to FCMs and conduct assessments, while 13 report either few or no assessments done, or a procedure for RA procedures from the food sector. Two MSs report that they have systems currently being developed. The rest did not reply, have no information or have no system in place. This distribution is presented as a percentage in Figure 57.

RA and risk management bodies may be separated or not at the national level and communication between them is not always systematic.

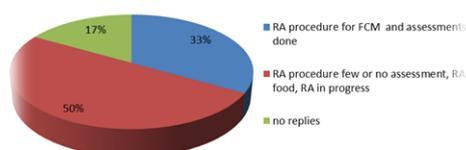


Figure 57: National risk assessment implementation in MSs

Access to national risk assessment schemes

In terms of access, the RA schemes at national level are not available publicly in their full details, the information in the context of this report relied on the information provided by the MSs or their RA institution but no supporting documents was available.

Content and convergence of risk assessment schemes

The basic concepts used in RA protocols at national level are in part stated to be based on the principles developed by EFSA. A relevant proportion of MSs (40 %) report that they use the EFSA note for guidance (or former SCF-FCM guidelines) for plastic FCMs, or a mix of EFSA or other references depending on the type of materials (for the non-harmonised ones). Yet there remains a disparity in relation to what MSs have developed in their own RA protocols for non-harmonised materials. In particular, additional specific requirements and potentially different templates (from those of EFSA) may be requested. A few MSs state that they have their own approach.

It is also unclear when a protocol exists at national level to what extent national protocols have been extensively tested on actual assessments.

One difficulty in this study was the lack of access to full descriptions of protocols for RA specific to sectors. It is consequently not clear whether these are in line with EFSA guidelines. The information collected is thus based on direct queries with MS and RA bodies. The main deviations identified in the context of this study are on the exposure assessment (Germany and the Netherlands), migration testing (Italy, the Netherlands and Switzerland) and toxicity data (France and the Netherlands). A few MSs refer specifically to using TTC (Germany, the Netherlands and Austria) or structural alerts (France).

The lack of access makes it impossible to quantify further the differences between RA schemes. However, it should be noted that EFSA has made efforts to bring the MSs' RA institutions under one unified network (the so-called FIP network), created to foster the sharing of information and the harmonisation of approaches for exposure assessment, including in non-harmonised areas. The work in the context of the ESCO report has given a valuable starting point for the correct status of substances with an existing traceable RA for various materials. The areas considered in the report were printing inks,

colorants, coatings, cork and wood, paper and board, rubber, and silicones. Areas not considered were adhesives, ion exchange resins, waxes, metals and alloys, glass and ceramics, beyond the EU legislation. The ESCO work highlighted that for non-EU harmonised materials the use of 3 000 substances at national level is regulated, while only 320 of these regulated substances are adequately risk assessed. This investigation updates the overview to a total of close to 8 000 substances present in national measures, norms, recommendations, or other guidance and scientific opinions.

The FIP network is a unique platform that could be further taken advantage of to share the specific protocols and to discuss and explore more common approaches for sector-specific RAs for non-harmonised materials as a follow-up to the ESCO work. It could investigate the potential need for changes either to the national guidance documents or to the EFSA guidelines in some cases (especially those noted by the European Parliament study on cocktail effects, sensitive population and mixtures). Particular aspects of interest for comparisons would be the fundamental or basic concepts used, the application of structural alerts, the application of thresholds of toxicological concern (TTC) and their respective compliance with the framework regulation.

Existence of hazard-, risk- and exposure-based tools

Both the EU (via RTD or national projects) and industry consortia have developed tools for RA with a specific focus on FCMs that represent relevant advances for hazard characterisation (Belgian-CoE FCM database), exposure assessment (FACET) and RA of NLSs (Matrix). FACET and Matrix are publicly free to use and have a stronger user base in industry sectors such as chemicals, inks and coatings, along with the plastic sector. Data are not yet fully available for the Belgian-CoE database due to its recent implementation for public use (free to MSs and fee-based for industry). Useful tools such as the FACET software however require significant expertise to be employed and exploited correctly and effectively, which is why training courses are organised internally by professional associations and are paramount.

Industry context

Existence and content of risk assessment schemes from the industry sectors

From an industry standpoint, when RA procedures are mentioned, guidance is available publicly or from the professional associations for individual sectors. It is not clear to what extent SMEs themselves can access or use them. The principles cited reflect those of EFSA. The main implementing tools used by the industry sectors as described above include the RA tool Matrix (for NLSs) and the exposure tool FACET.

Hurdles to risk assessment in the supply chain context

RA at industrial level is often hampered by the lack of transfer of safety-related information in the manufacturing chain for non-harmonised materials, whereas for plastics the exchange of safety-related information in the manufacturing chain is required via a declaration of compliance and subject to specific guidelines.

Another aspect is communication, where information on the composition and toxicological characterisation of substances and intermediates used and the use of materials is not communicated sufficiently throughout the production chain. It is likely that the business operators most affected in regard to ensuring the safety of their products are SMEs working in the intermediate production chain due to a lack of knowledge or resources to perform RA or a lack of weighing power to force suppliers to provide adequate information.

From an industry standpoint, stakeholders noted that MSs' requirements, even if based on EFSA petition principles, can be implemented in different formats and application templates for substance evaluation and authorisation. As the burden to perform adequate RA is on the business operators, they need to be aware of toxicological hazards (for the substances they use) and the final exposure of the consumer, which may not

always be the case, especially for smaller businesses.

Are the measures sufficiently detailed to demonstrate compliance with the general safety requirements? If not what are the gaps?

National measures or norms specific to FCMs not covered by EU legislation are found in 21 MSs, along with CoE and Norden. All materials have at least one MS with national provisions. In practice, national legislation does not always set out detailed requirements specific to each material. Some MSs rely solely on EU or other national measures (Ireland, Cyprus and Luxembourg). However, MSs that do not have material-specific measures still perform controls on non-harmonised materials.

From a **national regulatory standpoint**, some MSs only have general measures applicable to FCMs for overarching concepts of general safety requirements, such as GMP, registration of businesses and sanctions/enforcement.

- Around 10 MSs have provisions on the registration of business operators, with a registry set up and an application process described to a certain extent.
- Specific guidance and requirements on declarations of compliance and supporting documents appear in 13 MSs and three industry guidance documents, with France, Italy, the Netherlands, Sweden and Norden giving some details. Two guidance documents are also available from a joint group of professional associations representing different sectors of FCMs.
- Greater emphasis was found to be placed on certification systems in the context of GMP than in the context of controls responding to the need for authorisation of laboratories to perform compliance testing and details on requirements for testing laboratories. The most complete and recent at national level are those of Austria and Switzerland.
- With respect to the basis for enforcement, 15 MSs have provisions based on the criteria laid out in Regulation (EC) No 882/2004, ranging from limited to more extensive.
- Sanctions are also considered in national measures for the infringement of Regulation (EC) No 1935/2004. They are also considered for infringements of its implementation in Regulation (EC) No 2023/2006 on GMP. Sanctions include fines/penalties, imprisonment, confiscation of non-compliant goods (or rejection at borders, and/or bearing the cost of the destruction of goods), or closing down premises. They vary from country to country.
- Guidance on GMP is described at national level by 12 countries, but for FCMs as a whole rather than in material-specific requirements. At national/governmental level the most developed GMP guidelines are from Italy and Norden. Switzerland and the United Kingdom also have relevant documents.

From an **industry standpoint**, demonstration of the safety of materials to customers becomes more difficult when criteria for safety are not established. SMEs in particular are disadvantaged as they may not have the resources to set up their own safety criteria. This is an issue that is present within the EU for FCMs and becomes acutely relevant and notable for imports.

Are the instruments/measures available for one type of material complementary and consistent?

National measures for each type of material or sector

Presence of measures

Challenges posed by the multitude of national measures relate not only to their language but also the complex interrelationships between several (amended) rules or recommendations in each sector (material).

With respect to national measures that are specific to a given material, between three and 12 MSs (along with the CoE and Norden) have measures or norms, depending on the material or sector. This is shown in Figure 58. No MS regulates all materials, but 17 (along with the CoE and Norden) specifically regulate more than one non-harmonised material not otherwise regulated by EU legislation, as shown in Figure 59.

Some MSs may have only in total one measure on one material (e.g. Bulgaria on glass). The others rely on EU legislation and in principle on mutual recognition of rules in place in other MSs. Some of these remaining MSs, however, have provisions on the registration of business operators, sanctions, etc. and perform controls.

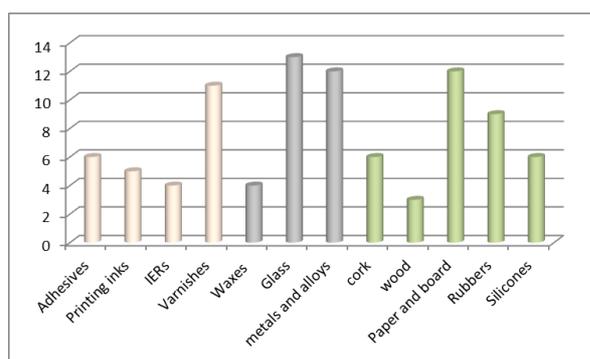


Figure 58: Number of MSs with measures per material

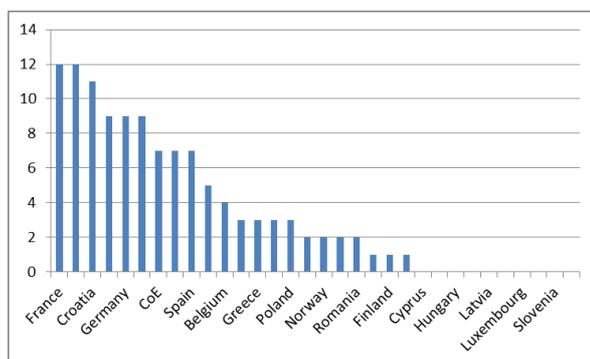


Figure 59: Number of sectors regulated by different MSs

Content of measures

There is a prevalence of measures based on lists of authorised substances, with the most common associated implementation tools being restrictions in the form of specific migration limits, compositional limits, quantity of materials and overall migration limits. Negative lists are more rarely used, except under the concept of lists of 'non-assessed' substances (at both CoE and MS level). However, these measures may differ from one another.

The presence of diverging or varying definitions is an issue for some materials, in particular for rubber/elastomers. The categorisation of fields of application can also be one source of differences between MSs.

From a material-specific standpoint, an overview presented in Table 15 shows for each sector how many MSs have specific national measures, how many substances are regulated (versus the risk-assessed ones of the ESCO lists) and how many are common to three or more MSs.

For individual materials, with respect to EU countries along with CoE and Norden, the materials most regulated⁽²⁰⁴⁾ across the EU at national level (more than 10 MSs) are metals and alloys, varnishes and coatings, and paper and board. Glass is also regulated in 12 MSs, often quite similarly to ceramics. Sectors regulated in six to 10 MSs include adhesives, rubber and silicones. The remaining sectors have measures in between three and five MSs (e.g. cork and wood, printing inks, ion exchange resins and waxes).

Combinations of materials are considered only in France, but self-regulation is available on the basis of guidelines developed jointly by different industrial sectors (e.g. plastics with paper and board).

⁽²⁰⁴⁾ NB: National measures may not be necessarily all be lists of authorised substances, but the majority are (e.g. Germany, Spain, Croatia, Italy, the Netherlands, Slovakia, Switzerland, CoE).

Table 15: Overview of comparison of contents of lists of authorised substances

| Material | MS with measures | MS with measures and no substances regulated | No substances regulated vs risk assessed* | Substances in common in > 3 MSs |
|-------------------|-----------------------|---|---|---------------------------------|
| Adhesives | 6 MSs | DE (77), ES (157), FR (3), HR (1 083), IT (17), NL (109) | 1323 / n/a | 9 (0.7 %) |
| Printing inks | 4 MSs + CoE | CH (5069), FR (43), NL (17), SK (15) + CoE (831) | 5 214 / 987 (19 %) | 34 (0.6 %) |
| IEERs | 3 MSs + CoE | ES (148), FR (6) NL (0) + CoE (253) | 387 / n/a | - |
| Varnishes | 10 MSs + CoE | DE (131), EL (576), ES (111), FR (58), HR (34), IT (2), NL (646), SK (16), CZ, BE-draft + CoE (576), | 1 721 / 456 (26 %) | 88 (5 %) |
| Waxes | 3 MSs | CH, DE, ES | undefined | |
| Ceramics | 9 MSs | AT, CZ, DE, DK, HR, NL NO, FI, PL | 16 / n/a | Barium Test for rim |
| Glass | 12 MSs + CoE | BE, BG, CH, CZ, DE, DK, FR, HR, IT, NL, NO, SK + CoE | 16 / n/a | Ban Hg Test for rim |
| Metals and alloys | 10 MSs + Norden + CoE | BE, CH, CZ, EL, FR, HR, IT, NL, SK + Norden + CoE | 15 SRLs / n/a | Norden CoE |
| Cork and wood | 5/3 +CoE | CZ (37), FR (13), HR (2), NL (80), SK (35) + CoE (70) | 168 / 60 (36 %) | 19 (11 %) |
| Paper and board | 10 MSs +Norden + CoE | BE (81), CZ (217), DE (324), FR (31), HR (35), IT (85), NL (314), SK (35), EL (plastics), [EE]+ CoE (1 110) | 1 710 / 565 (33 %) | 147 (9 %) |
| Rubbers | 8 MSs + CoE | CZ (111), DE (198), ES (149), FR (256), HR (54), IT (299), NL (237), SK (112) + CoE (705), | 1 028 / 580 (56 %) | 185 (18 %) |
| Silicones | 7 MSs +CoE | CH (127), DE (65), ES (150), FR (56), HR (19) + CoE (119) | 336 / 55 (16 %) | 37 (11 %) |

* 2012 ESCO lists.

Gaps and hurdles

Lack of common grounds on materials regulated by different MSs

Not all MSs regulate the same materials. Different MSs regulate different materials. There does not seem to be a correlation between the production or market share of certain materials and the presence of national measures.

Variations in type of restrictions

There is a prevalence of measures based on lists of authorised substances but not on lists of banned substances. There are similarities in measures from different MSs in relation to their implementation tools, such as specific migration limits (SMLs), compositional limits or quantity in materials (QMs), along with overall migration limits (OMLs). However, substances can be found regulated with an SML in one MS and a QM or compositional limit in another MS, which indicates an absence of convergence in the type of restriction chosen.

Lack of commonalities in the nature and restriction of substances by different MSs

The nature of authorised substances varies across MSs, which leads to cumulative lists across MSs that can span from 100 substances for some sectors to an average of 1 500 for the bulk of sectors, and up to a maximum of more than 5 000 for printing inks. There are also guidance and inventory lists from the CoE. Lists exist to a much lesser extent from European professional associations for industry.

The proportion of substances considered in common by three or more MSs (or two or more along with CoE or Norden) range from 0.5-5 % (adhesives, coatings, printing inks) to 10-18 % (cork, paper and board, rubber, silicones).

The variation in the content of lists of authorised substances is also reflected by MS lists and those developed by the CoE on the nature of substances considered. This seems to suggest that there is limited transposition of the CoE lists in practice by several ($n \geq 3$) MSs.

For the same type of restriction, a given substance considered in common by different MSs for the same material can have different numerical values in different MSs.

The limits set for the same substance by one MS can also vary in relation to different materials. MSs seem to regulate substances on average in two or three materials rather than all materials at once. For a given substance, the CoE tends to regulate SMLs across materials in a similar way. However, the data set cannot demonstrate that, for a given substance, an MS would tend to apply similar limits across different materials.

Finally there are also significant differences in the number of substances regulated and those that were considered risk assessed by the EFSA ESCO working group (between 15 % and 35 % have been risk assessed for the different materials).

Commonality between national legislation and industry guidelines

It was difficult to estimate the commonalities between national legislation and industry guidelines since they were generic in nature. Queries with stakeholders indicated that each sector had preferred national legislation references to follow. The feedback highlights that the references are often multiple (e.g. a negative list from Japan and positive lists from three or four countries, and most often also including one FDA reference).

Considerations on sector-specific aspects

Chemicals and intermediates

Sectors that are early in the chain (chemicals and intermediates), such as adhesives, varnishes and coatings, present a special need for improvement as they are then subjected to multiple uses and to multiple end products or materials/substrates. For these the number of actors from their formulation to their presence in the physical end products may be particularly complex. These sectors are also the worst with regard to the lack of commonalities on substances considered for restrictions across MSs (0.5-5 % common to three or more MSs), likely adding to the burden of multiple testing.

The following can be noted with regard to some specific points by sector.

- *Adhesives have a variety of end uses and cover a large number of substances (1 323), yet less than 1 % are commonly regulated by several MSs. The sector is also lacking in standards, although a large body of EU-funded research has been completed. It benefits from well-established industry guidelines that can be capitalised upon and convergence with national (Germany) and worldwide (FDA) rules.*
- *Printing inks have a strong predominance of one and soon to be two pieces of national legislation (Germany, Switzerland) that present similarities. This can be an incentive for harmonisation and to rally other MSs to study the commonalities. This is the sector with the largest number of substances (5 124), with less than 1 % common to more MSs than the two above. An examination of cost-benefit vs function, performance and sustainability may be indicated considering the particularly large number of substances in this sector in the context of the circular economy.*
- *Varnishes and coatings represent a vast number of substances (1 721) that are regulated across a large number of MSs (more than 10), but only 5 % of substances are commonly tackled by several MSs. The sector benefits from the presence of standards, and from sector-specific guidelines, and from convergence with the plastics regulation and national rules from Germany.*
- *Ion exchange resins have only a few national frameworks, but those that do exist are relevant to the field. The sector also suffers from a lack of industrial guidelines and thus it is not clear how the chain of compliance is ensured. However, no concerns have been reported.*
- *The waxes sector is one that is ill defined and without much investment in either sectorial guidelines or controls. The evaluation of the safety of the sector cannot be adequately addressed due to a lack of information, but the market size also seems to make it a minor concern compared to other sectors.*

'Inorganics' sectors

Sectors dealing with ceramics, metals and alloys, and glass are concerned in the first place with the release of elements. The examination of national legislation indicates that there are 15 to 20 principal elements, mostly heavy metals, that are the typical subject of restrictions and that the nature of elements considered in national measures is often coherent across sectors. What may be less coherent across sectors is the type of limits that are imposed (compositional or release) and their numerical values. In terms of

values, it is likely due to the evaluation of the tolerable daily intake (TDI), and thus of the exposure assessment itself if done differently by different MSs. As metals are of particular concern for food safety, not only positive lists but negative lists (bans) are of importance, for example on mercury or hexavalent chromium.

These sectors also have a relevant portion that are not materials for food packaging per se, but also for cutlery/kitchenware, appliances and food processing machinery. Therefore, for these sectors, the representativeness of the evaluation of use for exposure purposes and of the approach to testing to represent the worst case of intensive and/or repeated use is likely to be a particular issue. As the values and testing rely on exposure, this aspect will be very relevant for harmonisation. A distinction may be needed for articles such as machinery (food processing equipment) vs kitchenware/tableware vs materials as food packaging.

'Organics' sectors

These sectors include cork and wood, paper and board, and rubbers and silicones. They all have similar average of around 10-18 % of substances regulated in common across several MSs. Paper and board represents the largest block in terms of both the substances to consider (more than 1 000 for each) and their complexity in terms of composition, treatments, elements of the chain or end use. The next largest block is rubber.

- *Paper and board is characterised by a large number of substances across different MSs, with only 9 % regulated by several MSs. It benefits from the presence of standards, and from strong sectorial guidance. Joint associations have guidelines both on GMP and on compliance-recommending measures. Convergence is expressed by industry for measures from Germany, the Netherlands and the FDA.*
- *The rubber sector has a good deal of complexity in the chemical definitions of the materials covered. It represents a large number of substances, of which 18 % are considered in common by several MSs. Yet for 60 % of them the restrictions are different. It seems the sector has a noted lack of clear convergence of what national rules to use/prefer and also a certain lack of dedicated guidelines.*
- *The silicones sector for FCMs is quite contained and is characterised by fewer substances regulated across MSs, but faces two compositional definitions and a lack of standards, and only 18 % of the overall substances are considered by several MSs. The convergence across stakeholders on the use of common rules is fairly well defined by Germany and France, and the GMP/sector guidance in place is only quite general. Testing methods, in particular the choice of simulants, have been noted as being an issue.*
- *The cork and wood sectors are regulated by a limited number of MSs, and only 11 % of substances are considered in common by several MSs. The measures have predominantly been put in place by France for wood and the Netherlands for cork. Cork and wood have been considered together in the work of the EFSA ESCO group.*

Overall, across the different MSs in the EU in individual national measures and across different materials, a total of close to 8 000 substances have been found in the context of this study. These correspond to 1 323 for adhesives, 5 214 for printing inks, 387 for IERs, 1 721 for varnishes and coatings, 168 for cork, 1 710 for paper and board, 1 028 for rubbers and 336 for silicones. The number of waxes could not be estimated as the descriptions were too vague or related to composite mixtures. The bulk of this total represents one material only: 78 % are found only for one material (of which printing inks is the main one), 11 % for two types of materials and 11 % for three or more types of materials.

To what extent are the national measures enforced in the Member States? If there are difficulties, what are the difficulties?

In relation to **traceability and accountability**, the FCM supply chain is complex and lengthy.

Limitation of enforcement in the context of declarations of compliance

The system of declarations of compliance (DoCs) is a pillar of food safety, yet it must be

recognised that its implementation remains an issue for both harmonised and non-harmonised materials.

HFAA inspections in the past showed a lack of (or insufficient) training on controls, documentation and/or DoC and GMP implementation. MSs' official controls still show that non-compliance of the DoC is higher (20 %) than non-compliances for most materials (in the range of 11-14 %). Improvements needed for DoCs and supporting documents have also been consistently highlighted as an issue as feedback to the BTSF training courses.

Limited detailed requirements and guidance on national measures

In the context of non-harmonised materials, only a limited number MSs have detailed requirements on DoCs and supporting documents. Requirements may vary in practice (specific information and template) from MS to MS for the DoC. In addition the definition of supporting documents may vary and their acceptance may fluctuate from MS to MS.

This disparity in the supporting documents accompanying the DoC is also noted in the attachments to notifications or alerts in the RASFF system.

There is a lack of quality criteria and standardised specifications for both DoCs and supporting documents. To compound this issue, the requirements themselves can be different from MS to MS (positive lists, SMLs, QMs, compositional requirements), and the test methods or basis of enforcement may be different or unclear in different MSs.

Absence of linkage between quality documentation and sanctions

Authorities find it arduous to financially penalise substandard compliance work. In the absence of European coordination it is difficult to apply sanctions to a business operator on the basis of an infringement related to the quality of the documentation provided.

Effective enforcement is reported to suffer especially when compliance work is either inadequate or missing, but the product is stated still to be within the limits, making its compliance status legally sensitive.

Lack of monitoring or control plans for the sector

The FCMs sector does not have mandatory control plans, leaving MSs the freedom to decide the type of products to test for compliance. This may in theory provide a greater ability to cover more sectors and products, but in practice MSs may also select the same type of FCMs year after year, and those may be different from MS to MS. Often the number of samples is also limited. MSs tend to focus controls on materials and articles for which specific legislation is established at EU level or within the MS.

The data in this study highlighted that only a few MSs supplied larger sets of compliance data. These data were often aggregated so specific conclusions could not always be made. The efficacy of measures is thus difficult to evaluate by the ad hoc collection of data.

More consistent data production and collection is advised in order to evaluate the impact of national measures more systematically.

Potentially inconsistent drivers for monitoring

The safety issues that have appeared in the media or in alerts over the years (inks/ITX in 2005, 4-methylbenzophenone in 2009, mineral oils) often point to either quality assurance issues, communication issues across the chain or issues related to recycling.

In terms of improvements, better sharing of practices for monitoring, the development of guidelines for monitoring or approaches to flexible but established and shared control plans and more convergence on campaigns for official controls would be beneficial for improving the situation on safety/burden for non-harmonised materials.

A number of national regulatory frameworks exist as generic statements, without further specific measures, which means that those MSs often that they consider a case-by-case

approach in the absence of their own material-specific measures. This may be perceived as a lack of transparency for the stakeholders on the receiving end of a non-compliance. Finally, sanctions are also different across MSs and thus may be an issue for mutual recognition as a deterrent to preserve the highest food safety standards.

Limitations of the RASFF system as a tool to assess safety issues in a monitoring context

The RASFF system is a major achievement in the monitoring of food safety. Yet the system is not a correct indicator of food safety as a whole as it illustrates only non-compliance rather than the proportion of non-compliant vs compliant products.

It is difficult to establish whether safety issues highlighted via the RASFF system in terms of types of materials analysed (and non-compliances) are a reflection or indication of issues or simply a result of MS orientation for given types of materials for controls (in the absence of control plans).

Overall the percentage of non-compliance from data that MSs provide on their monitoring and checks for non-harmonised materials is not much different from that of plastics, and are both around 11 %. This therefore indicates that, in terms of indicators of safety, the current numbers do not point to drastically different statistics for non-harmonised materials compared to materials harmonised at the EU level.

Limitation of enforceability from lack of methods and standards

The approach as lists of authorised substances and using restrictions (in the form of limits) requires compliance checks. These checks can be assessed effectively only when parameters, criteria or performance are available from a practical testing guidance standpoint in order to give benchmarks. Then the assessment of compliance can be more easily made and agreed from one MS to another.

There are few or no standards for some sectors. The ceramics, glass, metals and alloys, varnishes and coatings, cork, rubber, and paper and board sectors have some standards that provide a minimum base for testing. However, there are few or no standards for adhesives, wood and silicones (aside from nitrosatable substances), and very few standards for inks aside from those from France. For varnishes and coatings, standards exist but are often associated with their substrate (on metals, on paper and board). The development seems ad hoc rather than organised in a structured manner. Standards for rubber exist but seem a little heterogeneous at the EU level. Testing conditions for materials differ between MSs. There are also few methods targeting sensory testing.

The lack of official or agreed methods exacerbates the difficulties for industries to show compliance. It also makes enforceability more difficult for official controls. The lack of a common approach to testing (including methods) can have a negative impact on mutual recognition and the establishment of cost-effective testing for food safety. Examples include testing for the limits of metals for steel for coffee machines (Italy and Finland), or how the uncertainty of measurement is defined and considered for compliance. The absence of criteria in turn affects the controls for given materials and the reporting in the RASFF on the part of the control authorities.

Points of reflection

A recent report ⁽²⁰⁵⁾ stressed that the importance of standardisation in stimulating and enabling competitiveness in Europe is at the heart of European policy, and was highlighted in a number of European Commission communication documents and flagship initiatives ⁽²⁰⁶⁾. The latest communication stressed the importance of standards

⁽²⁰⁵⁾ JRC foresight study — how standards facilitate new production systems in the context of EU innovation and competitiveness in 2025, F. Scapolo, P. Churchill, V. Viaud, M. Antal, H. Cordova, P. de Smedt, 2014EUR 27096 ISBN 978-92-79-45414-1.

⁽²⁰⁶⁾ European Commission: COM(2008) 133, COM(2010) 2020, COM(2010) 546, COM(2010) 614,

as a policy tool supporting different European policies towards EU competitiveness in the global market and to meet the requirements of both industry and public authorities.

The report underlined a need for the acceleration of standardisation in the European Standardisation System (ESS), by anticipating the need for standards using horizon scanning and foresight techniques, and setting up forums in Europe for discussions between the scientific and standardisation communities.

The report also highlighted that this acceleration should be implemented carefully, as the quality of the outputs, the respect of the consensus principle of standardisation and the need to involve a broader scope of stakeholders, in particular experts from SMEs and consumers, need to be taken into consideration.

It also proposed to group the standards dealing with health and safety, security and privacy, accessibility and environmental protection issues into a single category — ‘de-risking’ standards — since, in terms of innovation and competitiveness, the main benefit of all these standards is to reduce the risks related to the acceptance, uptake and dissemination of the proposed innovative solutions. The report pointed to three areas of priorities for developing standards as being standards for integration, for environmental sustainability and for quality and performance.

More integrated standards could well support a value chain such as FCMs, which has a tendency to be disaggregated while its products are more integrated. Standards could be function based rather than sector based. The development of performance-based standards was indicated as being key to ensuring the required quality of materials, products and services and the performance of processes and technologies. Some are traditionally covered by standardisation activities.

To what extent do Member States enforce good manufacturing practice? If there are difficulties, what are they?

With respect to **GMP**, FCMs must be manufactured in compliance with GMP in accordance with Regulation (EC) No 2023/2006, which requires manufacturers to operate documented quality assurance systems and quality control systems. Quality assurance covers the selection of starting materials and control of manufacturing operations to ensure a safe final material. Yet this overarching framework is general and its implementation requires both specificities for the different sectors from the standpoint of MSs and self-regulation standards or guidelines from professional associations.

Current situation

While significant steps have been taken with a relevant presence of industrial guidance (²⁰⁷) in most sectors, there are only few MSs that have comprehensive guidelines on GMP. It was also noted that even fewer have expanded from generic GMP descriptions to sector-specific GMP that may better target the inherent issues and specifics of each type of materials and each level of actors in the chain (e.g. beginning-intermediates-finished products).

Existing guidelines across MSs can be complex or may have deviations between them, or may not cover all aspects equally. Only one guide contains different chapters addressing each type of materials (Italy).

Insufficient implementation of GMP was noted in past audits by the HFAA (ex-FVO) on national enforcement of FCM legislation. National authorities may have limited resources and knowledge to fulfil this task. It is not clear whether this situation has improved.

COM(2011) 21, COM(2011) 311. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation.

(²⁰⁷) GMP at sectorial level is considered again in a latter section.

Initiatives of the Commission via the BTSF programme have aimed at improvements via training courses on GMP and DoC. These actions have been relevant investments into providing support to competent authorities and official controls, including GMP inspections. However, in the absence of new audits on FCMs by HFAA post-2011 it is not possible to judge whether these initiatives have had a long-lasting impact.

Some countries have started to establish guidance or checklists at national level on how to assess the compliance of GMP systems, in particular Norden and Italy (and the United Kingdom in its former guidance). The presence of relevant work indicates that the situation can present avenues for improvement.

Gaps and hurdles

From the official control side, the hurdles noted show that it is difficult for authorities to integrate the controls (DoC and GMP) into their structure as they may not fit into either inspections or the laboratory. It is reported by MSs that local inspection is not adequate for checking compliance work for FCMs with a supply chain spread throughout the world. However, it is found to be useful for the quality control of manufacturing and hygiene.

From the industry side, industrial GMP guidance documents are established to varying extents in the different sectors. Existing industry GMP guides do not always cover all aspects set out in legislation. It is not clear in practice whether each one matches the guidance established at national level (since there is little such guidance and it may already diverge) or how complementary it can be to MS requirements to ensure food safety.

The industry-drafted guidelines present the advantage of being developed by each sector and for the specificities of the sector, which is not the case for most MS guidelines. They also exploit each sector's own knowledge for implementation criteria.

It cannot be evaluated whether the presence of and free access to guidelines also benefits local SMEs since most guidelines are in English. There was no information on training courses, use or feedback on the GMP guidelines from various actors in the chains in different sectors. This may be something to explore further as a route for improvement, especially in the context of SMEs. It also could not be evaluated whether all distribution chains are composed entirely of certified companies, which should be a fundamental part of a traceability system.

To what extent is compliance with the national laws of another MS accepted by MSs?

Convergence at national (MS) level on what to use in practice

Queries addressed to stakeholders indicated that MSs do not declare specific reference to other MS rules in the absence of national legislation. Rather they seem to proceed on a case-by-case basis. Statements on convergence more often come from MSs with no legislation (Luxembourg, Slovenia). Only a few statements give a specific reference (such as BfR, CoE, the Netherlands). In specific cases a clearer trend is observed, such as Switzerland for inks, Germany for paper and board or both France and Germany for silicones.

Industry sectors refer to national legislation of EU countries, which highlighted that multiple references are often taken (e.g. three or four MSs and most often one FDA reference). In some cases standards (ISO, CEN, national) are also referred to. This may mean that more documentation and tests are needed to prove compliance, and lead to increased burden.

Convergence of practice between business operators

The professional associations of each sector have an advisory role with regard to their members and to the sector. Guidelines developed in a given sector sometimes

specifically cite references to national or supranational legislation. The convergence corresponds to the main countries with the most legislation, except for the Czech Republic, France, Croatia and Slovakia, which are less often taken as a common basis even although they have a large number of materials covered. The most common MSs taken as references are Germany, Spain, Italy, the Netherlands and Switzerland, along with CoE or Norden at supranational level. In addition, the harmonised sector of plastics is often taken as a reference. The inputs received across the different materials are summarised in Table 16. Bold or red type means that multiple different sectors have given the same reference(s).

Table 16: Overview of convergence with MS national measures by industrial sector

| Material | Regulation (EU) No 10/2011 | BfR Rec | NL | IT DM73 | CH 817 | ES 847 | FDA 21 CFR | CoE | Other |
|-------------------|----------------------------|------------------------------|---------------|---------|----------|--------|---------------|-----|-----------------------|
| Adhesives | x | XXVII | | (x) | | (x) | 175/177 | | ECMA |
| Printing inks | x | | | | X | | x | x | EuPIA |
| Varnishes | x | XIV mostly | NL X | (x) | x | (x) | 175 | x | x |
| Waxes | x | XXV | NL II + X | | x | x | 175 | | |
| Metals and alloys | | | | | | | 178 | (x) | EN 601/602 |
| Cork and wood | | | NL IX | | | | | x | C.E.Liège |
| Paper and board | | XXXVI , XXXIV, XIV | NL II | x | | | 176 | x | Joint industry |
| Rubbers | x | XXI | NL III | x | | (x) | X 2600 | | FR |
| Silicones | x | XV | (NL III) | | (x) | (x) | | x | FR |

For IERs, ceramics and glass no clear references were made.

It is not clear whether small and micro-enterprises are aware of national legislation and self-regulation. The hurdles faced are that the information and advice must pass from the European association to national associations and to their members. Depending on the sector, the coverage of EU or national associations does not necessarily include the majority of SMEs.

Implementation of the mutual recognition principle

A report in 2015 conducted an evaluation of mutual recognition of goods⁽²⁰⁸⁾. It highlighted several points that are also applicable to the current context of FCMS.

The effectiveness of the current regulatory framework cannot be demonstrated in the absence of better monitoring of the implementation of the mutual recognition principle. It seems that it falls to national contact points to do so, but there is no information or traceability available on consistent follow-up with competent authorities and coordinating actions. There is also a significant lack of information on the extent of any incorrect application of the mutual recognition principle, particularly for SMEs. Indicators are needed from companies (particularly SMEs) on costs and indicators of burden related to the incorrect application of the mutual recognition principle in the context of the current situation for non-harmonised FCMS.

In the context of the situation of mutual recognition, there is a definite need for a mechanism of (1) demonstration of 'lawful marketing' for economic operators and (2) support for clear requirements for all sectors regarding unified requirements for DoCs, supporting documents and sanctions for failure. This would enable economic operators to demonstrate more easily the adequacy/compliance of trading products they market (and previously marketed in their home MS) and to ease the administrative burdens for product contact points and economic operators. The report suggested the development of either a manual or an encyclopaedia format based on currently existing guidelines for the demonstration of lawful marketing.

⁽²⁰⁸⁾ Evaluation of the application of the mutual recognition principle in the field of goods — ENTR/172/PP/2012/FC — Lot 4.

The disparities between different pieces of national legislation and the lack of potential transposition from one MS to another or from CoE to MSs imply that individual national measures may have a silo effect. This in turn requires better exchange and dialogue between competent authorities. There are platforms such as the DG Health and Food Safety working group, the EFSA FIP network and the network of NRLs, each acting in their own field. However, there could and possibly should be a group dedicated to convergences and/or mutual recognition, either under the Commission working group or at the level of a network of national contact points that could interact with the working group of MS competent authorities (or via the Internal Market Information System). This group could also deal with the language issue in relation to different pieces of national legislation.

Awareness-raising campaigns aimed at companies, regional and national authorities and business associations could possibly be developed by using the EEN as a platform or by means of a format similar to BTSF aimed at stakeholders using the train-the-trainers principle.

For unified requirements on adequate documentation and traceability, this could be in the form of either guidance or standards (performance/quality based standards).

Are the self-regulation initiatives consistent with national laws? If not, on which aspects?

From an **industry standpoint**, forms of self-regulation are described to varying extents in all sectors for individual materials, either as stand-alones or integrated into documents such as codes of practice, traceability, hygiene or those dedicated to GMP.

Guidelines on GMP range from highly detailed documents corresponding to relevant additions to Regulation (EC) No 2023/2006 to descriptions remaining generic in nature. Sectors with strong guidance include adhesives, inks and coatings, and paper and board in the form of multisectorial joint guidance with the sectors of flexible plastics and chemicals. Sectors with a single guidance document include those of metals and alloys, cork and silicones. Sectors with an absence of sector-specific guidance include ion exchange resins, waxes, ceramics, glass and rubber. For combinations of materials a guideline on GMP developed by the plastic sector also includes fibre-based packaging (fibres/foil and treatments applied such as inks, varnishes, adhesives or metallising).

While most guidelines present aspects related to certification systems on raw materials, QA and QC, it was not possible to obtain data on to what extent they are applied in practice other than the statements provided by the professional associations, which do not fully represent the extent to which SMEs are able to implement those systems. Options for reaching such data (e.g. via initiatives potentially with the EEN platform) would be needed.

Some sectors have developed dedicated guidelines on DoCs and supporting documents, with checklists available for a few (sectors early in the chain, paper and board). Guidelines may also include lists of substances authorised or banned (negative lists) that are found to be relevant to the sector. These are taken from relevant national measures not only from the EU but also often from outside the EU (e.g. Japan, United States). Lists are mainly given in the form of inventories or negative lists in industry guidance.

Sectorial guidelines sometimes mention national measures or CoE resolutions and thus seem fairly consistent with national laws. They seem to focus particularly on where gaps are present in the context of national measures (i.e. DoCs, GMP, codes of practice, etc.). Several guidelines, especially on GMP and compliance, are developed by more than one professional association and more than one sector, which makes them accepted and cited by different sectors. This indicates that business operators may reach a greater awareness of sectorial guidance and a greater acceptance through these self-regulation documents.

In addition, a cross-sectorial group from 18 professional associations representing different sectors has recently been formed to develop guidelines on migration testing appropriate for each association's products for non-plastic FCMs. Each sector is also assessing the applicability or not of the plastics regulation migration testing guidelines for their own sector. While the chapters are developed individually by each sector, the group meets regularly to discuss progress and share their issues on experimental testing of various materials. The group has given reports at several conferences and the majority of the associations' guidelines are/will be available on their website. This work has enabled different FCM sectors to identify common or cross-cutting issues in testing, and has also provided a better forum to tackle testing of multimaterial FCMs. This approach based on multiple associations acting together in consortia is also an indicator of an important step forwards in ensuring the acceptability of such new self-regulation for business operators in different sectors or by different actors in FCM supply chains.

Burden of the current measures on safety

The study included indicators on administrative burdens both for administrations and industries. A requirement of this study was to focus on data ⁽²⁰⁹⁾.

Do the national measures pose a real or perceived barrier to trade? To whom? Why?

Perceived barriers

In areas where no specific harmonised Union legislation exists, different interpretations of general rules by MSs and industry may lead to legal uncertainty. There is sometimes a lack of correspondence in lists of authorised substances (e.g. substances that lack unequivocal references or are referenced as a mixture of multiple chemicals or potential different composition).

A multitude of national rules, binding nature, multiple languages

Generally speaking, one major hurdle is that the relationships between national rules can be obscure. It is also not clear for many national documents what constitutes a legal basis and what is a document of a potentially legal nature but is not mandatory. It is also a source of confusion to have national measures consisting of a multitude of individual pieces of legislation sometimes relating to one substance, with cross referencing of other legal documents that becomes so complex that only a legal expert could decipher the field of applicability of some implementation approaches. For example, the time this study spent on obtaining legislation, reading it, obtaining translations from DG Translation, comparing the translations to the original documents, updating the ESCO lists and comparing them to lists of substances authorised in the broadest sense resulted in a 2-year effort.

Multiple national requirements and mutual recognition or self-regulation

Stakeholders indicated that the principle of mutual recognition can be difficult to understand and thus may not be fully applied by some countries. The associated hurdles for the enterprises are closely related to the requests from different MSs that several national requirements be met or tests carried out, even though the mutual recognition principle should apply, and that this result in an added burden. In addition, while industry seeks to find convergences with select pieces of national legislation agreeable to mutual recognition, it often has to account for the duality of EU/United States markets for compliance. Under these sets of variables, industry is vocal in favouring the 'one market one legislation' approach.

⁽²⁰⁹⁾ Rather than opinion, which was done in 2012 and has recently also been compiled under the European Parliament inquiry.

Stakeholders also indicated that industry self-regulation has limitations, as it must be carried out within a framework of clear EU guidelines covering RA and information rules in the supply chain. They feel that SMEs are particularly penalised as they do not have extensive networking systems or leverage on their suppliers for 'best-in-class' supporting documentation, DoCs and communication channels.

Growing relevance of non-EU legislation in a global market for non-harmonised materials

Customers of actors in various chains ask more and more for global food contact status information so that they can use the products they buy in different markets. Large food companies develop internal standards that they apply globally. The application of these standards is difficult if global players insist on complying with non-EU national legislation and if EU national legislation is not coherent. This is also too complex for smaller companies and they are thus often limited to their respective national markets.

More and more FCMs and raw materials are imported from non-EU countries. Questions from industry operators situated in non-EU countries indicate that the absence of specific harmonised EU requirements is at best misunderstood and at worst taken as lesser requirements to demonstrate the safety of FCMs. Many non-EU countries can also start developing their own standards instead of integrating one from the EU. This fact could impact the export possibilities for both FCMs and packed food from Europe.

Aspects of burden

In the absence of mutually agreed or harmonised criteria for safety, the burden of demonstration of safety of FCMs to different customers is greatly increased.

Burden from multiple testing or method development

Differences in lists of authorised substances and in restrictions or multiple different requirements lead to multiple direct costs for (re)testing, which can run from a few hundred euros to tens of thousands, depending on the product, and a longer time frame that may impact trade.

Stakeholders report that various commercial laboratories are applying multiple testing requirements, adding costs. National measures often cite the plastics regulation, which leads laboratories to also apply the testing approach for plastics to other materials, leading to misleading results.

Public debates about specific concerns on chemicals (e.g. migration, consumer health, substances of animal origin, mineral oil) also cause additional research and analysis, which can significantly increase the burden.

The lack of methods causes NRLs to invest efforts and human resources in the development of methods almost on an ad hoc basis. The lack of framework or guidance on sensory testing may also be an issue, although to a lesser extent, as it can be part of GMP from an industrial standpoint

Burden from higher expertise needed

Divergent rules also make it almost a necessity to seek sources of external legal advice on different national regulations, leading to added costs. Stakeholders report that in some cases even the reformulation of a product is needed to comply with national legislation, and may have the consequence of a change of supplier.

Indirect costs may stem from delayed market access due to lengthy evaluation/authorisation processes in comparison with other national/international processes vs the FCM sectors.

The scarcity of standards and testing methods has an impact on burden, as this implies that industries must resort to external third-party laboratories for screening and quality control. The proprietary nature of methods developed by third-party entities is a source of commercial business and hinders the sharing of analytical advances.

Burden associated to greater emphasis on certification system

The lack of harmonised limits and the existence of potentially divergent national rules also lead to the increasing implementation of certification and accreditation systems at the industrial level. This in turn generates additional costs and administrative burden for industry. SMEs in particular are disadvantaged (by a lack of resources).

Burden from court cases due to the failure of mutual recognition

Stakeholders report that the potential burden imposed on companies resulting from the incorrect application of the mutual recognition principle is not proportionate, with court cases being costly and lengthy. In some cases, professional associations have indicated that it limits the entry of companies into some markets. The costs and administrative burdens have particularly severe effects on SMEs, which are much less able than larger companies to counteract requirements from MS authorities that are not in accordance with the mutual recognition principle. SMEs are thus much more likely to simply have to comply with all requirements or abstain from entering the market.

Conclusions

Overall the entire sector of FCM suffers to a certain extent from the current situation, which exhibits a lack of harmonisation of materials listed under the framework regulation and is the object of issues relating to mutual recognition.

DoCs and supporting documents have long been identified as flawed, but this is not specific to non-harmonised materials. The flaw in the system is identified as a lack of communication and provision of adequate portfolios of documents, from the DoC to well-defined criteria and quality-checked supporting documents, with accompanying sanctions. It may be a side effect of an implementation of GMP that there may still be silos between actors in a chain or between actors interacting across various sectors. This indicates a need for either guidance or standards.

There is wealth of assessments from different MSs covering the various sectors that is a key basis for use. In general, there is at least one MS with extensive coverage of a given sector. This means that there is no sector that suffers from a complete gap. The measures are based on a given material or a specific parameter (material associated with an end use, such as rubbers, or a treatment, such as coated paper). Few measures exist specifically for combinations of materials. This, however, does not seem a particular issue as multimaterials seem to be treated both by industry and by controls as the sum of their layers/components.

Existing national measures are not always sufficiently detailed, in particular from the standpoint of general requirements common to all FCMs. Examples include lack of specificity for requirements and quality assurance in relation to DoCs and supporting documents, certification where applicable, the basis for enforcement and sanctions. In the absence of agreed incentives and requirements, MSs can face hurdles in demonstrating a lack of safety and practical difficulties for the enforcement and removal of products in their own markets.

With regard to GMP, generic guidance from MSs is also seldom very detailed from an implementation standpoint, and is rarely material specific. The HSFAA and BTSF actions clearly indicated that GMP was endemic to the FCMs sector. As recent training has focused on these aspects, further conclusions on whether the BTSF training courses have had an impact would provide added value. From the industry side, GMP is a well-developed activity of professional associations in the form of guidelines. It is not clear whether these guidelines are used in practice by the members at national and local levels all the way down to SMEs. Further indicators not existing at this stage would be needed.

In terms of material-specific aspects, the main hurdles are access to relevant legislation and disparities in both the nature of substances considered and in the numerical

restrictions imposed. These factors are the main impediments to mutual recognition. A particular point regarding the practical implementation is the lack of access to or availability of testing methods and analytical determination and quantification for substances on which restrictions are based.

With regard to the FCMs sector, performance standards could be a way to approach the quality assurance and communication in the chain as a whole, with sections specific to sectors. It could in particular tackle the aspect of DoCs, supporting documents, certification, sanctions highlighted as gaps and GMP where needed. This could be one way to explore ways to ensure that accountability is clearer at every step and for all materials across each manufacturing process.

This investigation was initiated as a study to establish a baseline for the European Commission's DG Health and Food Safety to assess the food safety aspects and burden of the current situation, including the benefits and the administrative burdens and costs of the existing situation for businesses. The work suffered from the lack of strong indicators providing clear-cut answers on food safety (in particular effectiveness) and on specific burden in the context of mutual recognition.

However, due to the nature of the JRC, the baseline was also developed to become a base reference for anyone seeking information on requirements and tools on FCMs. The compilation of national references, their translation into English and the current compilation of master lists of substances should provide stakeholders, including SMEs, and official controls with a stronger base for access to relevant information and comparisons.

7. References

- *In the present section all references present in the text are reported, in their full format, with links to the official free sources, where possible (choosing the English version, where available). Also all the documents that have been used in the analysis and elaboration of the report have been added, even if they are not explicitly cited in the text.*
- *It has to be noted that for an easier identification of the entries, an identification code has been added to all the entries, indicating the source. Thus, all documents coming from MSs have been named starting with the abbreviation of the MS name (full name for non-EU countries or associations of countries), all standards have been named starting with 'STRD' (adding the type of standard and/or the country of provenience, where the case), all documents coming from industries or industry associations have been named starting with 'IND' and then adding the materials(s) they refer to and the association(s), where the case, all documents coming from literature search have been named starting with 'LIT', all documents coming from the Council of Europe have been named starting with 'CoE', all documents from different EU sources have been named starting with EU (and adding the additional source, such as EFSA, HFAA, and so on, where the case).*

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STRD — DE — DIN 5080:1978-03 — Haushalt-Konservengläser und -Konservenflaschen; Gummi-Dichtringe (Einkochringe) (Preserving jars and bottles for domestic purposes; rubber seal rings)

STRD — DE — DIN 7750:1979-01 — Flaschenscheiben aus Gummi für Bügel- und Hebelverschlüsse (Rubber sealing rings for lever stoppers of bottles)

STRD — DE — DIN 51032:1986-02: Keramik, Glas, Glaskeramik, Email; Grenzwerte für die Abgabe von Blei und Cadmium aus Bedarfsgegenständen

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STRD — DE — DIN-18865-5:2003-05 — Equipment for commercial kitchens — Food distribution equipment — Part 5: Tray slides

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List of abbreviations and definitions

| | |
|-------------|---|
| 3-MCPD | 3-monochloropropane-1,2-diol or 3-chloropropane-1,2-diol |
| ACE | Alliance for Beverage Cartons and the Environment |
| ADI | acceptable daily intake |
| AENOR | Asociación Española de Normalización y Certificación |
| AFNOR | Association Française de Normalisation |
| AFSSA | Agence Française de Sécurité Sanitaire des Aliments (FR) |
| ALARA | as low as reasonably achievable (safety principle) |
| ANSES | Agence Nationale de Sécurité Sanitaire de l'Alimentation |
| Anvisa | Agencia Nacional de Vigilancia Sanitaria |
| AOAC | American Official Chemists' Association |
| APCOR | Associação Portuguesa de Cortica |
| APEAL | Association of European Producers of Steel for Packaging |
| APFE | European Glass Fibre Producers Association: now GlassFibreEurope |
| APs | Aids to polymerisation |
| As | arsenic |
| AS | Australian Standard |
| ASTM | American Society for Testing and Materials |
| AT | Austria |
| B | boron |
| Ba | barium |
| BADGE | bisphenol A diglycidyl ether |
| BE | Belgium |
| BedGstV | Bedarfsgegenständeverordnung |
| BfR | Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung) |
| BG | Bulgaria |
| BGBI | Bundesgesetzblatt für die Republik Österreich (AT) |
| BOCCRF | Bulletin Officiel de la Concurrence, de la Consommation et de la Répression des Fraudes |
| BPA | Bisphenol A |
| BTSF | Better Training for Safer Foods |
| C.E.Liège | Confederation Européenne de Liege |
| CAA | Código Alimentario Argentino (Argentina) |
| CAS | Chemical Abstract Service (e.g. CAS registration number of a component) |
| CBI | Centre for Promotion of Imports from developing countries |
| Cd | cadmium |
| Ce | cerium |
| CECED | European Committee of Domestic Equipment Manufacturers |
| CEFIC | European Chemical Industry Council |
| CEFIC-FCA | CEFIC Food Contact Additives subgroup |
| CEI-Bois | European Confederation of Woodworking Industries |
| CEN | European Committee for Standardisation (Comite Europeen de Normalisation) |
| CEPE | European Council of Paint, Printing Ink and Artists' colours Industry |
| CEPI | Confederation of European Paper Industries |
| Cerame-Unie | European Ceramic Industry Association |
| CES | Centre European des Silicones — sector of CEFIC |
| CETIE | Centre Technique International de l'Emboutillage et du Conditionnement |
| CFIA | Canadian Food Inspection Agency |
| CFR | Code of Federal Regulations, the US laws |
| Cipcel | Comité International de la Pellicule Cellulosique |
| CIRFS | European Man-Made Fibres Association |
| CITPA | International Confederation of Paper and Board Converters |
| Clanak | article (HR) |
| CMR | Carcinogenic, mutagenic, reprotoxic (CMR) substances |
| Co | cobalt |
| CoE | Council of Europe |

| | |
|---------|--|
| CONAL | National Committee of Food (Argentina) |
| COSME | EU programme for the competitiveness of enterprises and small and medium-sized enterprises |
| CPIV | Comité Permanent des Industries du Verre now Glass Alliance Europe |
| CPME | Committee of PET Manufactures in Europe |
| CPSC | US Consumer Product Safety Commission |
| CPSIA | US Consumer Product Safety Improvement Act |
| Cr | chromium |
| Cr6 | hexavalent chromium |
| CSHPF | Conseil supérieur d'hygiène publique de France |
| CU | Customs Union (CU), includes Russia, Kazakhstan and Belarus |
| CY | Cyprus |
| CZ | Czech Republic |
| DCP | 1,3-DCP:1,3-dichloropropane-2-ol |
| DE | Germany |
| DEAB | N,N-diethylaminobenzaldehyde |
| DEHP | Bis(2-ethylhexyl) phthalate |
| DFI | Dipartimento federale dell'interno (ordinanza, CH) |
| DGCCRF | Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes |
| DGT | European Commission — Directorate-General for Translation |
| DIN | German Institute for Standardization |
| DIPN | 2,6-Diisopropyl-naphthalene (2,6-DIPN) |
| DIY | Do it yourself |
| DK | Denmark |
| DM | Decreto Ministeriale (IT) |
| DoC | Declaration of Compliance |
| Dodatak | addition, addendum (HR) |
| DPR | Decreto del presidente della Repubblica |
| DSS | Department of Science Service of Thailand |
| DVS | Die Verbindungs Spezialisten |
| EAA | European Aluminium Association |
| EASME | Executive Agency for Small and Medium-sized Enterprises |
| EB | electron beam |
| EC | European Commission |
| ECHA | European Chemical Agency |
| ECMA | European Carton Makers Association |
| EDANA | International Association serving the nonwovens and related industries |
| EE | Estonia |
| EEA | European Economic Area (28 EU Member States + Iceland, Liechtenstein and Norway) |
| EEA | European Enamel Authority |
| EEN | Enterprise Europe Network |
| EFBW | European Federation of Bottled Waters, member of FoodDrinkEurope |
| EFSA | European Food Safety Authority |
| EFTA | European Free Trade Association (Iceland, Norway, Switzerland, Liechtenstein). |
| EL | Greece |
| EMPAC | Metal Packaging Manufacturers Association |
| EPFMA | European Polyvinyl Film Manufacturer Association |
| ERMA | European Resin Manufacturers Association |
| ES | Spain |
| ESCO | EFSA Scientific Cooperation |
| ETRMA | European Tyre and Rubber Manufacturers Association |
| ETS | European Tissue Symposium |
| EU | European Union |
| EuCIA | European Composites Industry Association |
| EuPC | European Plastics Converters |
| EuPIA | European Printing Ink Association — sector of CEPE |
| EuPR | European Plastics Recyclers |

| | |
|-----------------|---|
| Euratex | European Apparel and Textile Organisation |
| EURL | European Union Reference Laboratory |
| EURO INOX | European market development association for stainless steel |
| Eurometaux | European Association of Metals |
| Europen | European Organisation for Packaging and the Environment |
| Eurostat | statistical office of the European Union situated in Luxembourg |
| EVA | European Vending Association |
| EWf | European Wax Federation |
| F | fluorine |
| FACET | Flavourings, Additives, FCMs Exposure Tool |
| FCM | food contact materials |
| FCN | food contact notification (FDA) |
| FCS | food contact substances |
| FDA | Food and Drug Administration |
| FEC | Federation of the European Cutlery, Flatware, Holloware & Cookware Industries |
| Fedemco | Spanish Federation of Wooden Crates and their Components |
| FEFCO | European Federation of Corrugated Board Manufacturers |
| Fefpeb | European Federation of Wooden Pallet and Packaging Manufacturers |
| FEICA | The Association of the European Adhesives and Sealants Industry |
| FEVE | The European Container Glass Association |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FI | Finland |
| FIG | FACET Industry Group |
| FoodDrinkEurope | Association of the food and drink industries of the EU |
| FoodExI | EFSA's food classification and description system (version 1) |
| FP | final product, the FCM as it will come into contact with food. |
| FP7-SME | framework programme to support research for the benefit of SMEs |
| FPE | Flexible Packaging Europe |
| FPME | Food Processing Machinery Europe |
| FR | France |
| FSSA | Food Safety and Standards Act — India |
| FSSAI | Food Safety and Standards Authority of India |
| FTE | Full Time Employee |
| FVO | Food and Veterinary Office |
| GAE | Glass Alliance Europe (used to be CPIV) |
| GB | Chinese standard |
| GMC | Grupo Mercado Común (Mercosur) |
| GMP | good manufacturing practices |
| GRAS | generally recognised as safe (FDA) |
| GSO | Gulf States Ordinance |
| HACCP | hazard analysis critical control point |
| HFAA | health and food audit analysis |
| Hg | mercury |
| HPFB | Health Products and Food Branch (Canada) |
| HR | Croatia |
| HU | Hungary |
| I&P Europe | Imaging and Printing Association |
| IE | Ireland |
| IER | ion exchange resins |
| IISRP | International Institute of Synthetic Rubber Producers European Section |
| INSG | International Nickel Study Group |
| IPBC | 3-iodo-2-propynyl butylcarbamate (fungicide) |
| ISO | International Organisation for Standardisation |
| IT | Italy |
| ITX | isopropylthioxanthone |
| IUPAC | International Union of Pure and Applied Chemistry |
| Jhospa | Japan Hygienic Olefin and Styrene Plastic Association |

| | |
|------------------|--|
| JRC | Joint Research Centre |
| LCA | life cycle analysis |
| LC-MS | liquid chromatography-mass spectrometry |
| LFGB | Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (DE) |
| Li | lithium |
| LT | Lithuania |
| LU | Luxembourg |
| LV | Latvia |
| MAST | Icelandic Food and Veterinary Authority |
| Mg | magnesium |
| MHLW | Ministry of Health, Labour, and Welfare (Japan) |
| MPC | maximum permissible average daily concentrations of pollutants, in mg/m ³ |
| MPCw | maximum permissible concentrations of chemicals in potable water |
| MS | Member State |
| MT | Malta |
| NF | norme française (French standard by Association Française de Normalisation — AFNOR) |
| NGO | non-governmental organisation |
| NHFPC | National Health and Family Planning Commission (China). |
| Ni | nickel |
| NIAS | non-intentionally added substances |
| Nickel Institute | European Nickel Industry Association |
| NL | Netherlands |
| NLS | non-listed substances |
| NMKL | Nordic Committee on Food Analysis |
| Norden | geographical and cultural region in northern Europe and the North Atlantic |
| NRL | national reference laboratory |
| OECD | Organisation for Economic Cooperation and Development |
| OFFC | official feed and food control |
| OJ | <i>Official Journal of the European Union</i> |
| OM | overall migration |
| OML | overall migration limit |
| P&B | paper and board |
| PAA | primary aromatic amine |
| Pack2Go | European convenience packaging association |
| PAHs | primary aromatic hydrocarbons |
| Pb | lead |
| PC | polycarbonate |
| PCB | polychlorinated biphenyl |
| PCP | pentachlorophenol |
| PE | polyethylene |
| PET | polyethylene terephthalate |
| PL | Poland |
| PM/REF | the old name for the EU reference number of a component |
| PN | Polska Norma (PL) |
| PP | polypropylene |
| PPA | polymer production aids |
| PQM | permissible quantities of the migration |
| PRO Europe | Packaging Recovery Organisation Europe |
| Prodcom | Prodcom provides statistics on the production of manufactured goods |
| PS | polystyrene |
| PT | Portugal |
| PU | polyurethanes |
| PVC | polyvinyl chloride |
| PVdC | polyvinylidene chloride |
| QA | quality assurance |
| QC | quality control |
| QM, QM(T) | quantity in material, total quantity in material |

| | |
|-------------|---|
| QMA, QMA(T) | quantity in material expressed per unit surface in contact or total |
| QSAR | quantitative structure activity relationship |
| RA | risk assessment |
| RASFF | Rapid Alert System for Food and Feed |
| Rb | rubidium |
| RC | regenerated cellulose |
| REACH | registration, evaluation, authorisation and restriction of chemicals |
| ResAP | Resolution of the Council of Europe |
| RO | Romania |
| S/V | surface-to-volume ratio (e.g. 6 dm ² is expected to come into contact with 1 kg) |
| Sb | antimony |
| SCF | Scientific Committee for Food (now the EFSA) |
| SD | standard deviation |
| Se | selenium |
| SE | Sweden |
| SI | Slovenia |
| SK | Slovakia |
| SLRs | specific limits of release |
| SME | small or medium-sized enterprise |
| SML, SML(T) | specific migration limit |
| SNCA | National Food Inspection System (Argentina) |
| SOIA | synthetic organic ion exchangers and adsorbents |
| Sr | strontium |
| TD | tolerable dose |
| Tenax® | porous polymer adsorbent matrix (Poly(2,6-diphenyl-p-phenylene oxide) (PPPO) |
| TISI | Thai Industrial Standards Institute |
| TMDDO | 2,4,7,9-Tetramethyl-5-decyne-4,7-diol |
| ToR | threshold of regulation |
| TS | technical specification (CEN) |
| TTC | threshold of toxicological concern |
| Ueapme | Union Européenne de l'Artisan et des Petites et Moyennes Entreprises |
| UK | United Kingdom |
| UV | ultraviolet |
| WBT | World Association of Manufacturers of Bottles and Teats |
| Zn | zinc |
| Zr | zirconium |

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Annexes



Annex 1. Information on supply chains

This annex represents additional information that could not be integrated into the core of the text, in relation more specifically to some particular aspects of the organisation of the supply chain. It includes information retrieved from JRC desk research on technical guidance documents from industry associations (overall guidance, other documents).

Note: the text of this Annex contains direct excerpts from the industry guidelines and documents analysed, as well as excerpts of the replies from the professional associations

Adhesives

Applying to adhesives the classification used for plastics, as described in the "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain", the following actors are identified in the supply chain.

a) A "substance manufacturer" is any operator, who manufactures or produces a chemical substance or starting material, and is the supplier of monomers, polymers, resins, paraffin, oils, additives, etc.

b) A "manufacturer of intermediate materials" is any operator who uses the chemical substances, or mixtures of them, or starting materials, and processes them into the intermediate products. This is an adhesive producer (mainly chemical mixtures, sometimes producing own polymers or supplying 2 component systems, where reaction takes place on user side).

c) A "manufacturer of final materials and articles" is any operator who uses chemical substances or starting materials to manufacture final materials or articles – e.g. user of the adhesives in order to produce final materials or articles, mainly the food packaging industry, but also converters, if adhesives are used to close the (filled) packaging.

d) A "user of food contact materials and articles" is any operator or person who puts food or food ingredients/intermediates in contact with a final material or article. This includes the food industry and their ingredient suppliers, retailers with an additional role of user, and food vendors (catering, restaurants, canteens, baker/butcher stores and other food outlets).

e) – f) Definitions under e-f (distributors, importers, retailers respectively) for the adhesive industry are considered in the same way as for plastics.

Printing inks

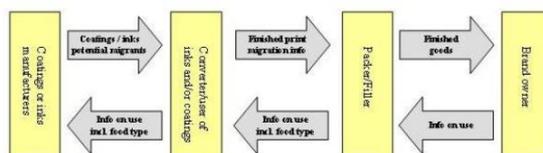
EuPIA Guideline on Printing Inks indicates that printing inks are chemical mixtures, prepared combining different chemicals (this operation can be done also by the converter). The actors in the supply chain for printing inks are the same as described in the "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain". The chain can be summarised as follows:

- Suppliers of starting substances (comparable to the level a – "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011) that can be colorants (pigments, dyes), binders, solvents, and additives.
- Manufacturer (comparable to the level c – "manufacturer of final materials and articles").
- Users, retailers and distributors, comparable to level d - "user of food contact materials and articles", level e - "distributors", level f - "importer" or level g – "retailer".

From I&P Europe, information received indicated that digital inks and toners are chemical mixtures whereby the major part of ingredients/raw material is also related to chemical mixtures and not to chemical substances (both supplied by "a" and "b" manufactures). The supply chain is relatively short, but to get reliable information from the chemical supplier – in addition to mandatory MSDS information – is often quite complicated based on confidentiality reasons. By-product information, biocide information and NIAS information in general are not easy to collect, however they are an essential part of the GMP. Often a specific migration test (voluntarily done by formulators) will disclose the presence of such material and basis of improvement of FCM.

Substance manufacturer is not necessarily only the manufacturer of a starting substance, but also the manufacturer of a raw material (mixture of substances). The substance manufacturer provides the building blocks from which an ink or a coating is made. Printing ink manufacturers use a wide range of raw materials/substances in various combinations to create printing inks or coatings – the combinations of raw materials/substances are many and varied due to bespoke optimization required in design and use of these formulated products which are required to successfully print, dry, cure and adhere to the plethora of substrates used in FCM and withstand the broad range of application conditions demanded of such inks, substrates and the resulting FCM's. Such demanding conditions may include exposure to temperatures from -20°C to +240°C, containment and preservation of fatty, sugar-based, dried or aqueous foodstuffs, as well as the physical demands required of the packaging such as abrasion resistance, friction properties, lightfastness and specific colour specifications. The converter purchases and utilizes substrates, printing inks/coatings and other intermediate materials and forming equipment to produce food contact materials and articles, for a range of end customers (retailers and brand owners). A suitable flow of information must be secured along the entire supply chain of raw material supplier, converter, packer/filler and food producer/brand owner so that the packaging can be designed for compliance. A typical information flow process for coatings/printing inks:

Information flow along the supply chain



Food packaging inks are manufactured from combinations of colorants, binders, solvents and additives. In the manufacture of printing ink raw materials, an excess of 5,500 different chemical substances are used by the raw materials supply industry. Printing inks are usually supplied to printers as press-ready products, formulated specifically to meet the technical requirements of the specific printing process, substrate, packaging type and processing properties.

Varnishes and coatings

Limited information was found on varnishes on the guidance documents (e.g. code of practice) of CEPE association.

A basic supply chain can be drawn as follows:

- Suppliers of starting substances (comparable to the level a – "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011), that can be resins (synthetic or natural), crosslinking agents or crosslinking resins, additives (such as waxes, pigments, lubricants, flow aids and defoamers), organic solvents.
- Suppliers of raw materials (comparable to level b – "manufacturer of intermediate materials") that can be polymers, or pre-polymers, or crosslinking pre-polymers.
- Manufacturer, comparable to the level c – "manufacturer of final materials and articles".
- Users, retailers and distributors, comparable to level d - "user of food contact materials and articles", level e - "distributors", level f - "importer" or level g – "retailer".

Waxes

A supply chain for waxes, could be described as:

- First level: suppliers of starting substances (comparable to the level a – "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011) that can be manufacturers of paraffin waxes (including synthetic paraffin waxes and microcrystalline waxes), natural waxes and polymeric waxes.
- Second level: manufacturers of intermediate materials that are any operator who uses the chemical substances or their mixtures, or starting materials, and processes them into the intermediate products. This includes the manufacturing of wax blends, composed of waxes themselves, with the addition of specific additives, as well as blends of waxes with other ingredients, including polymers and resins. These blends are supplied to manufacturers of

intermediate materials (adhesives, printing inks, coatings) as well as to manufacturer of final materials and articles.

- Third level: manufacturers of final materials and articles that are operators who use chemical substances or starting materials to manufacture final materials or articles.
- Fourth level: users, retailers and distributors, comparable to level d - "user of food contact materials and articles", level e - "distributors", level of - "importer" or level g - "retailer"

Ceramics

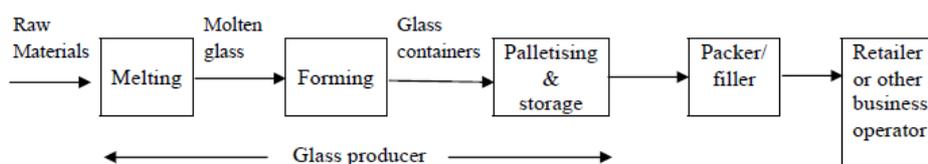
As far as tableware is concerned, the majority of members (national associations) represent manufacturers of tableware and kitchenware, as well as ornamental ware. Sectors covered by the EU Framework Regulation (incl. ceramic tableware) would fall only under Chapter 1 of the Cosmetic Product Safety Report as the obligations for the economic operators are already covered by the EU Framework Regulation). The professional association does not have industrial guidelines. As to whether a parallel could be drawn between the organisation of the supply chains of plastics and ceramics remains a question which would require time and resources to be answered.

Glass

The "Guidelines for the glass industry Registration, Evaluation, Authorisation and Restriction of Chemicals, REACH" contains a division of the actors in: suppliers, manufacturers and importers. It also contains the description, according to Article 3 of REACH, of actors as:

- "Recipient of a substance or a mixture: a downstream user or a distributor being supplied with a substance or a mixture." Comparable to the level b - "manufacturer of intermediate materials" - described in the Union Guidance on Regulation (EU) No 10/2011. Glass Source is based on the REACH Regulation, where raw materials used to produce glass are considered as intermediates. For consistency, the sector suggests indicating "manufacturer of a substance" instead of "intermediate materials". Glass manufacturers are producers of an article and not recipients of an article.
- "Producer of an article: any natural or legal person who makes or assembles an article within the Community." Comparable to the level c - "manufacturer of final materials and articles" - described in the Union Guidance on Regulation (EU) No 10/2011.
- "Downstream user: any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) of REACH shall be regarded as a downstream user".

The traceability of materials used in the production of glass packaging containers cannot be precisely defined for two reasons. Firstly, raw materials must be stored in large quantities before they are used, so that a definite identification of the individual deliveries or suppliers (if there is more than one supplier for the same raw material) is not possible from information relating to the glass containers produced. This is especially true for the recycled cullet that is, depending on the glass colour and the production site, often the main raw material in the glass melt. Secondly, glass melting furnaces are continuously operated facilities in which raw materials are introduced on one side, while molten glass is removed on the other side and formed into a product after a thermo-chemical melting process has taken place. This process, in which partial mixing occurs, is another factor inhibiting a definite traceability of the starting materials used to make particular glass containers.



(Industrial guidelines on traceability of materials and articles for food contact, 2006)

Metal for food and drinks

The following associations represent suppliers of raw materials used for food contact paint/lacquers:

- PlasticsEurope
- EPRA - European Phenolic Resins Association

The following associations represent incoming materials used for metal packaging:

- APEAL — Association of European Producers of Steel for Packaging
- EAA — European Aluminium Association
- CEPE — Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art (European Confederation of Paints, Printing Inks and Artists Colours Manufacturers)
- Rubber — No European Association identified; information provided by an individual company

The following associations represent metal packaging manufacturers:

- EAA — European Aluminium Association (e.g. trays)
- FPE — Flexible Packaging Europe, - covered in the Plastic Appendix Guide- (e.g. aluminium foil lids and laminates).
- SEFEL — European Secretariat of Manufacturers of Light Metal Packaging (e.g. cans, closures, aerosols, etc.)

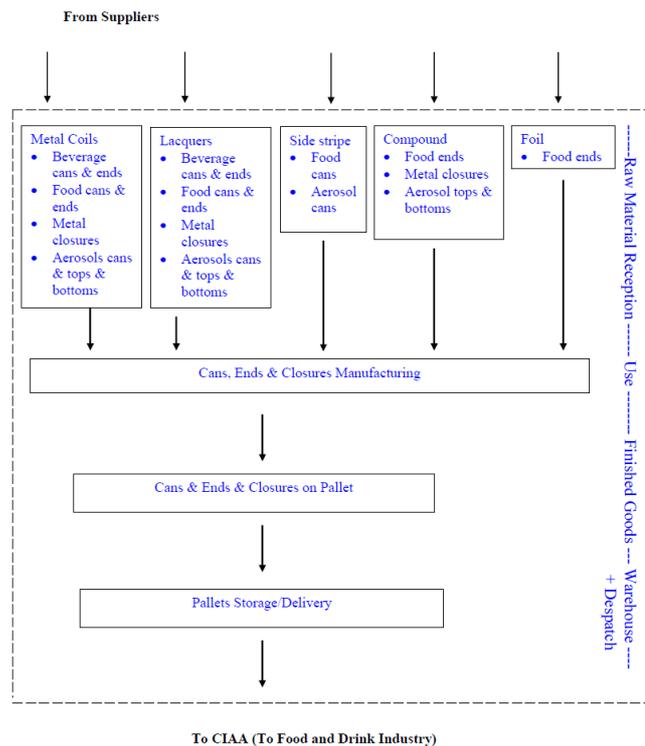
(Industrial guidelines on traceability of materials and articles for food contact, 2006)

For metals supply chain a general source of information is a document prepared by a joint work of most of the FCM industry associations titled "Industrial guidelines on traceability of materials and articles for food contact". According to it the supply chain can be described as follows:

- Suppliers of starting substances (comparable to the level a – "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011) that can be: chromium, chromium oxide for coating steel, lubricant, chemicals for aluminium (trays, beverage can lid stock, rigid containers and semi-rigid containers, cans, flexible packaging, household foil, chemicals for producing resins for lacquers and coatings or chemicals to prepare sealing compounds for primary packaging (pails, drums, plastic bags) and secondary packaging (pallets, wraps, films).
- Suppliers of raw materials (comparable to level b – "manufacturer of intermediate materials") that comprise: steel for packaging (metal coils, side stripe), aluminium for packaging (metal coils, side stripe, foil), lacquers/coatings for packaging.
- Packaging manufacturer (comparable to the level c – "manufacturer of final materials and articles"), for the following types of finished products: beverage cans and ends (that use metal coils), lacquers for food cans and ends (that use metal coils), lacquers for metal closures (that use metal coils, lacquers, compounds), aerosols cans (that use metal coils, lacquers, side stripe, compounds).
- Users, retailers and distributors, comparable to level d - "user of food contact materials and articles", level e - "distributors", level f - "importer" or level g – "retailer".

Moreover, for metals and alloys also two material specific documents titled "Guide to good manufacturing and hygiene practices for metal packaging in contact with food, Edition 1: May 2009" and "Code for good manufacturing practices for the European aluminium industry: Good Manufacturing Practice for aluminium alloy semi and end products intended to come into contact with foodstuffs (version updated on April 2012 that supersedes previous version of 2008)" are available.

According to these two sources the first level of the supply chain (comparable to the level a – "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011) groups the following categories:



- Producers of plastic (film or granulate), for coil coated steel (with organic coatings) produced into sheets. Producers of lacquer and varnishes for coil, sheet, drums and 2 or 3 piece cans, closures for bottles and jars, aerosols, open end/peelable ends.
- Producers of can end sealants

The second level of the supply chain (comparable to the level b – "manufacturer of intermediate materials"- described in the Union Guidance on Regulation (EU) No 10/2011) groups the following categories:

- Producers of laminated foil
- Producers of coil steel or aluminium uncoated
- Producers of coil coated by organic coatings

The end products producers (comparable to the level c – "manufacturer of final materials and articles"- described in the Union Guidance on Regulation (EU) No 10/2011) are the producers of: cans (2 piece drawn and wall ironed, 3 pieces, drums and ends), closures of bottles and jars, pail components, easy open ends, peelable ends etc.

Other actors are the process lubricants producers (comparable to the level a –"substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011).

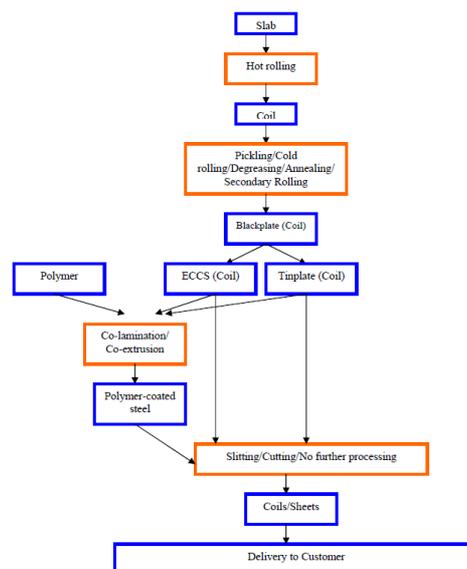
Production of Steel packaging

From molten steel, steel slabs are produced which are further processed into coils or cut into sheets and, in most instances, delivered directly to the can manufacturing industry. After pickling, the coil is cold rolled to almost final gauging. The cold-rolled strip is cleaned (degreased) and sent to the annealing process (batch or continuous) which will restore its mechanical properties. After annealing, the coil goes through the secondary rolling where its mechanical properties and geometry are fine-tuned.

The coil is then electrolytically coated with a layer of tin (tinplate) or chromium (ECCS/TFS). The supplier of tin ingots provides documents which contain supplier identification and lot number, and certification of purity. The lot is analysed in order to check conformance with the declared composition. (Industrial guidelines on traceability of materials and articles for food contact, 2006)

After plating, the ECCS coil is lacquered either in the steel mill (rarely) or by another company (the general rule). The lacquer supplier provides written information including supplier identification, lot number and product information. Lacquers are generally delivered in drums.

Tinplate or ECCS/TFS can be additionally coated with a polymer. The polymer is often delivered in big bags with indication of lot number, manufacturing date, identification of supplier and nature of the polymer. Traceability is ensured by internal documentation.

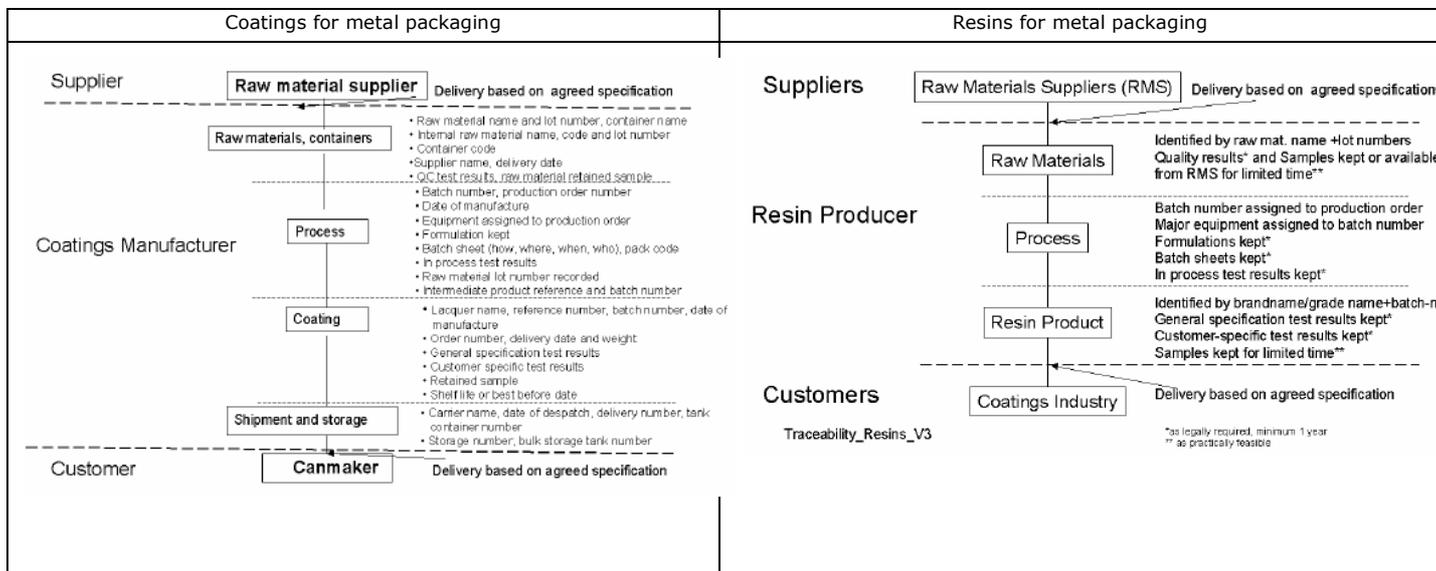
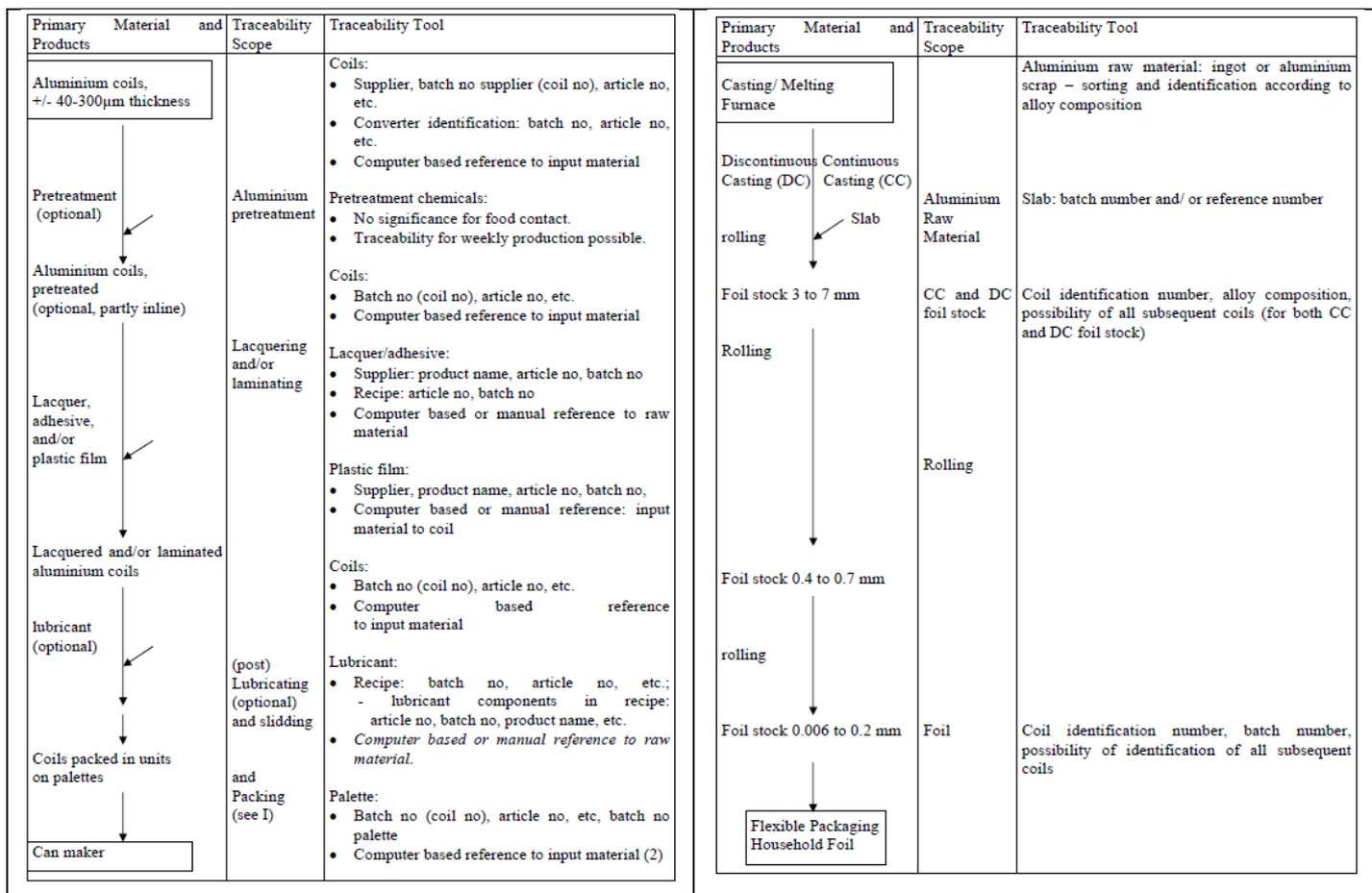


The European standards EN10202 and EN10205 specify requirements for steel for packaging products. Steel for packaging consist of single and double reduced low carbon mild steel electrolytically coated with either tin (tinplate) or chromium/chromium oxide (ECCS/TFS).

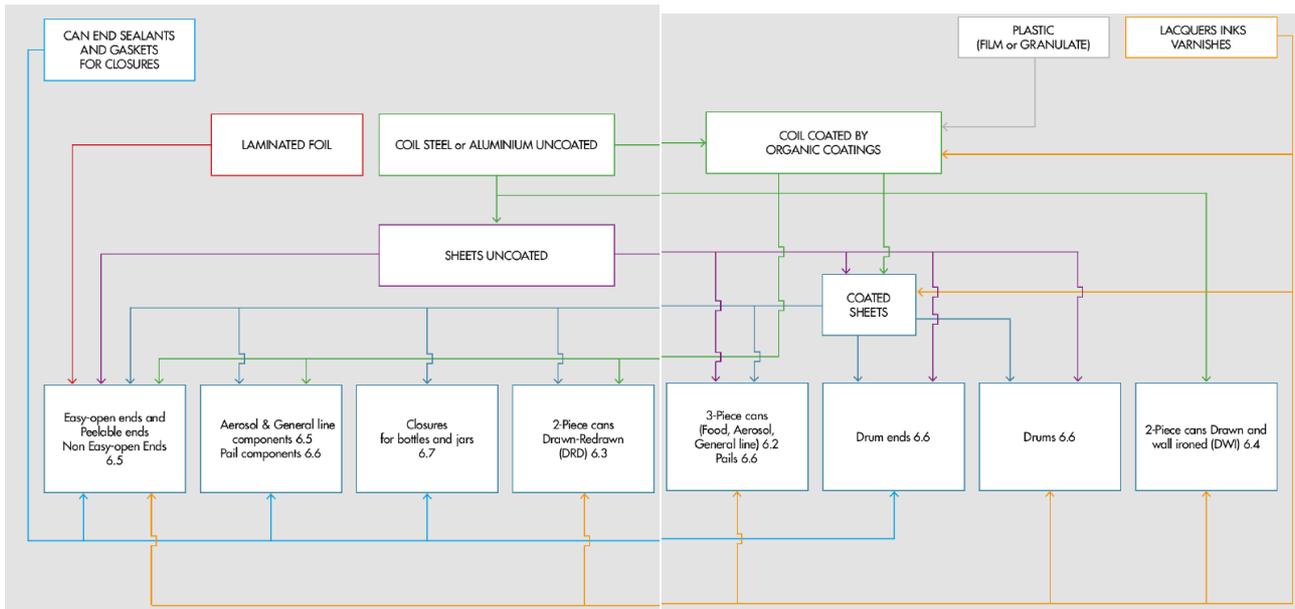
Aluminium for packaging

The information on the supply chain are shown below (excerpts of "Industrial guidelines on traceability of materials and articles for food contact, 2006)

| Casting and rolling of aluminium | | | Production of aluminium trays | | |
|--|--|---|--|--|---|
| Primary Material and Products | Traceability Scope | Traceability Tool | Primary Material and Products | Traceability Scope | Traceability Tool |
| <p>Melting oven / Casting aluminium</p> <p>↓</p> <p>Ingots</p> <p>↓</p> <p>Aluminium coils, about 3-7 mm thickness</p> <p>↓</p> <p>Aluminium coils, about 0.4-0.7 mm thickness</p> <p>↓</p> <p>Aluminium coils, about 0.006-0.3 mm thickness</p> <p>↓</p> <p>I) Bare aluminium trays, II) Beverage can lid stock, rigid containers and semi-rigid containers</p> | <p>Warm rolling and cold rolling</p> <p>Rolling</p> <p>Rolling</p> | <p>Ingot:</p> <ul style="list-style-type: none"> • Batch number (no.), bar code, alloying constituents, etc. • Reference no. with bar code for identification of cast and all subsequent aluminium coils. • Alloy composition registered - cast analysis on request. <p>Coils:</p> <ul style="list-style-type: none"> • Coil no., batch no., bar code, etc. • Reference no. with bar code for identification of cast, and all subsequent aluminium coils. • Computer based reference to cast. <p>Coils:</p> <ul style="list-style-type: none"> • Coil no., batch no., bar code, etc. • Computer based reference to input material and cast. (1) <p>Coils:</p> <ul style="list-style-type: none"> • Product no., article no., coil no (batch no)/bar code, etc. • Computer based reference to input material in the rolling program. | <p>Aluminium coils, +/-40-300µm thickness</p> <p>↓</p> <p>Lubricant</p> <p>↓</p> <p>Aluminium coils, lubricated</p> <p>↓</p> <p>Aluminium trays in packed units</p> <p>↓</p> <p>Packed units on palettes</p> <p>↓</p> <p>Trade</p> | <p>Lubricating and slitting</p> <p>Stamping and forming</p> <p>Packing</p> | <p>Coils:</p> <ul style="list-style-type: none"> • Product no, article no, coil no (batch no) bar code, etc. • Computer based reference to input coil <p>Lubricant:</p> <ul style="list-style-type: none"> • Recipe: batch no, article no, etc.; - lubricant components in recipe: article no, batch no, product name, etc. • <i>Computer based or manual reference to raw material.</i> <p>Coils:</p> <ul style="list-style-type: none"> • Product no, article no, coil no (batch no) with bar code, etc. • Computer based reference to input material. <p>Tray units:</p> <ul style="list-style-type: none"> • Product no, batch no, bar code, etc. • Computer based reference to input material <p>Palettes:</p> <ul style="list-style-type: none"> • Product no, batch no, bar code, etc. • Computer based reference to input material (2) |
| Production of lid stock for beverage cans and rigid or semi-rigid containers | | | Production of aluminium foil | | |

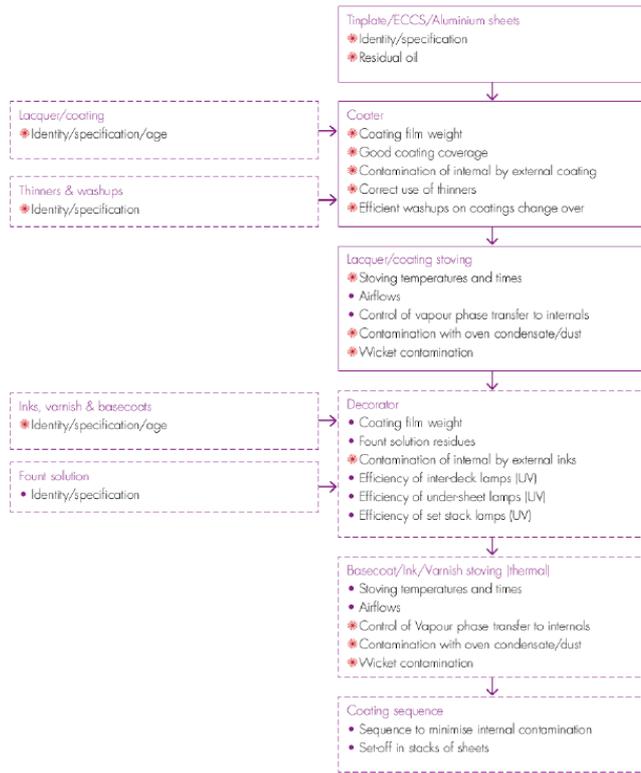


Raw material sources (Chapter 3 of EMPAC GMP document)

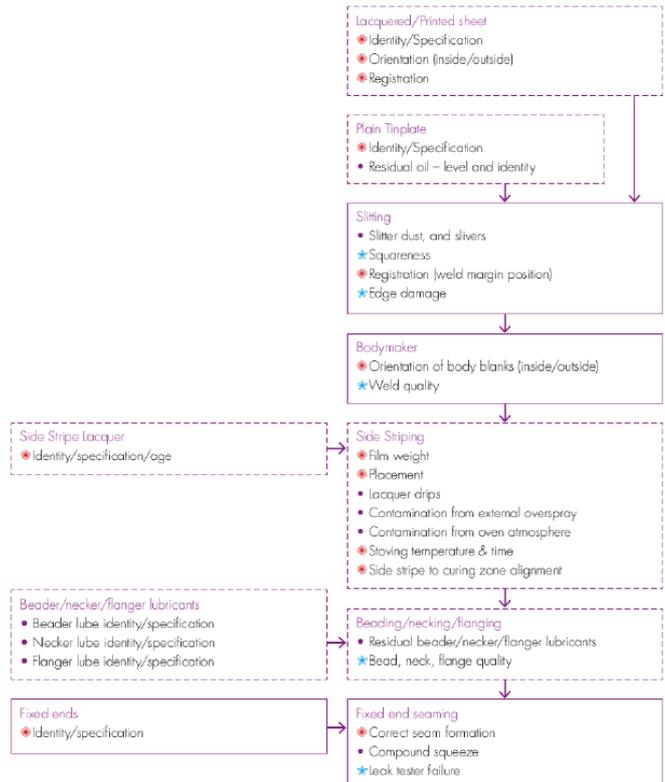


(Industrial guidelines on traceability of materials and articles for food contact, 2006)

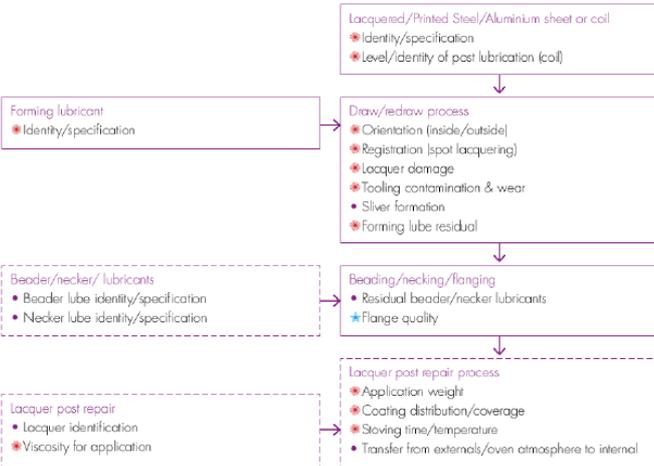
Sheet coating and printing



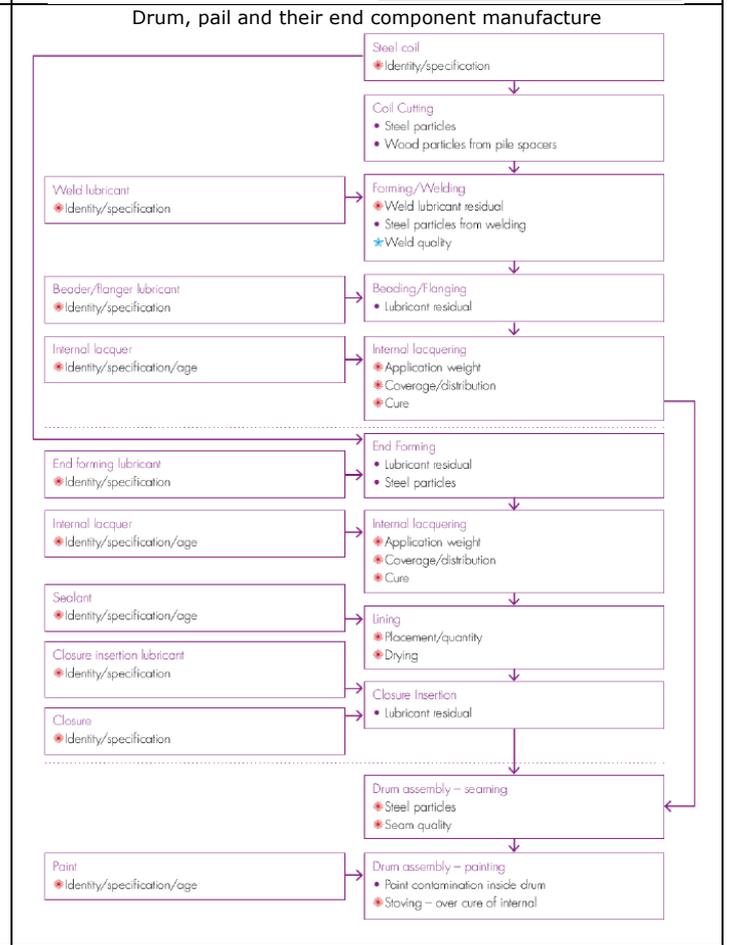
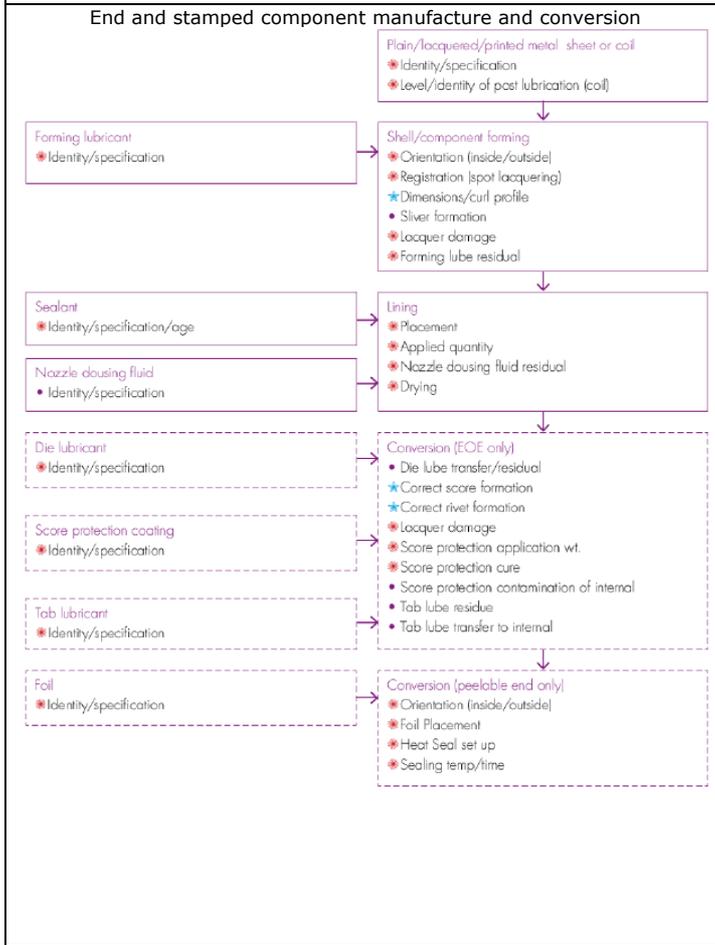
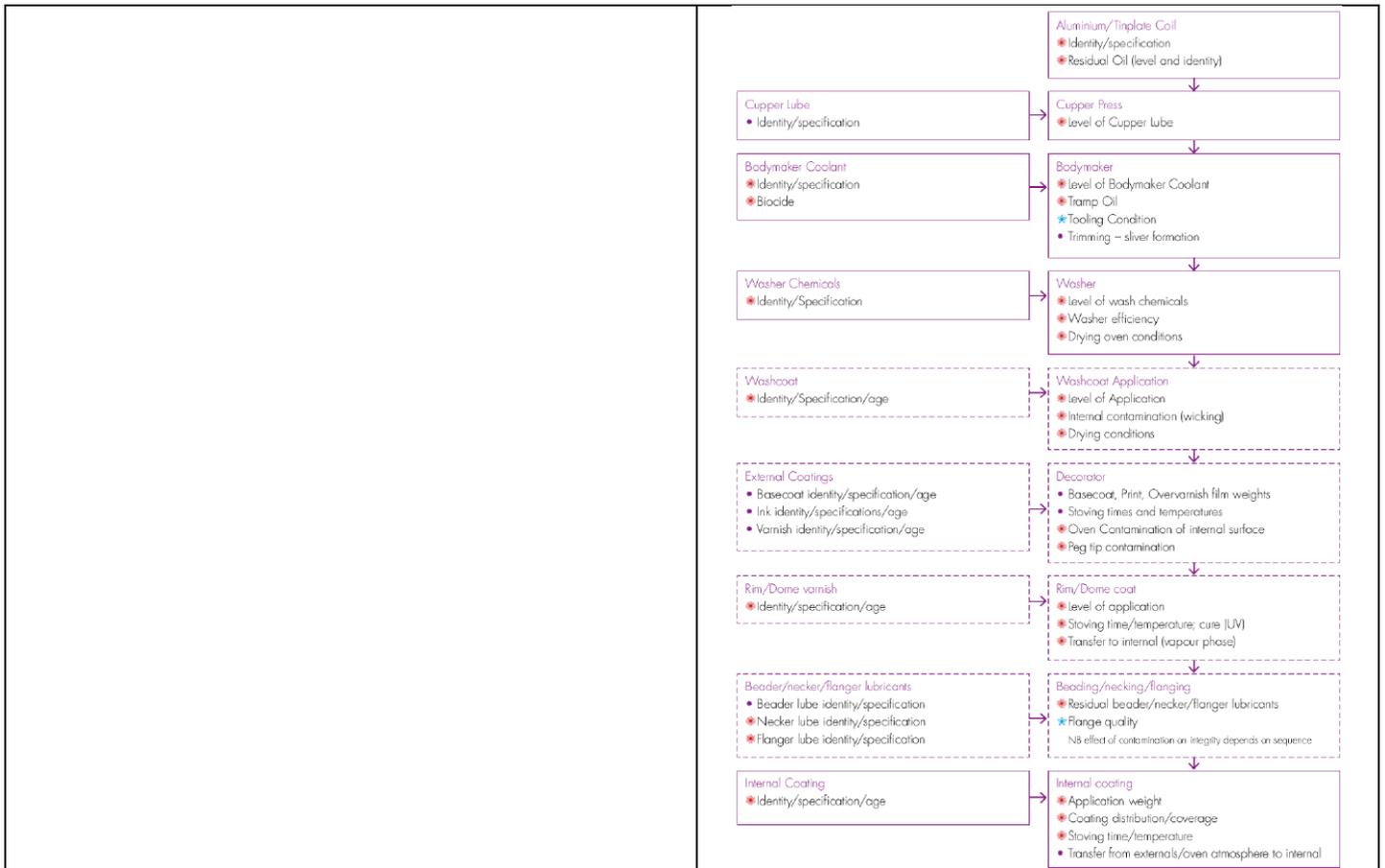
3-piece can manufacturing



Drawn/Redrawn (DRD) 2-piece can body manufacture

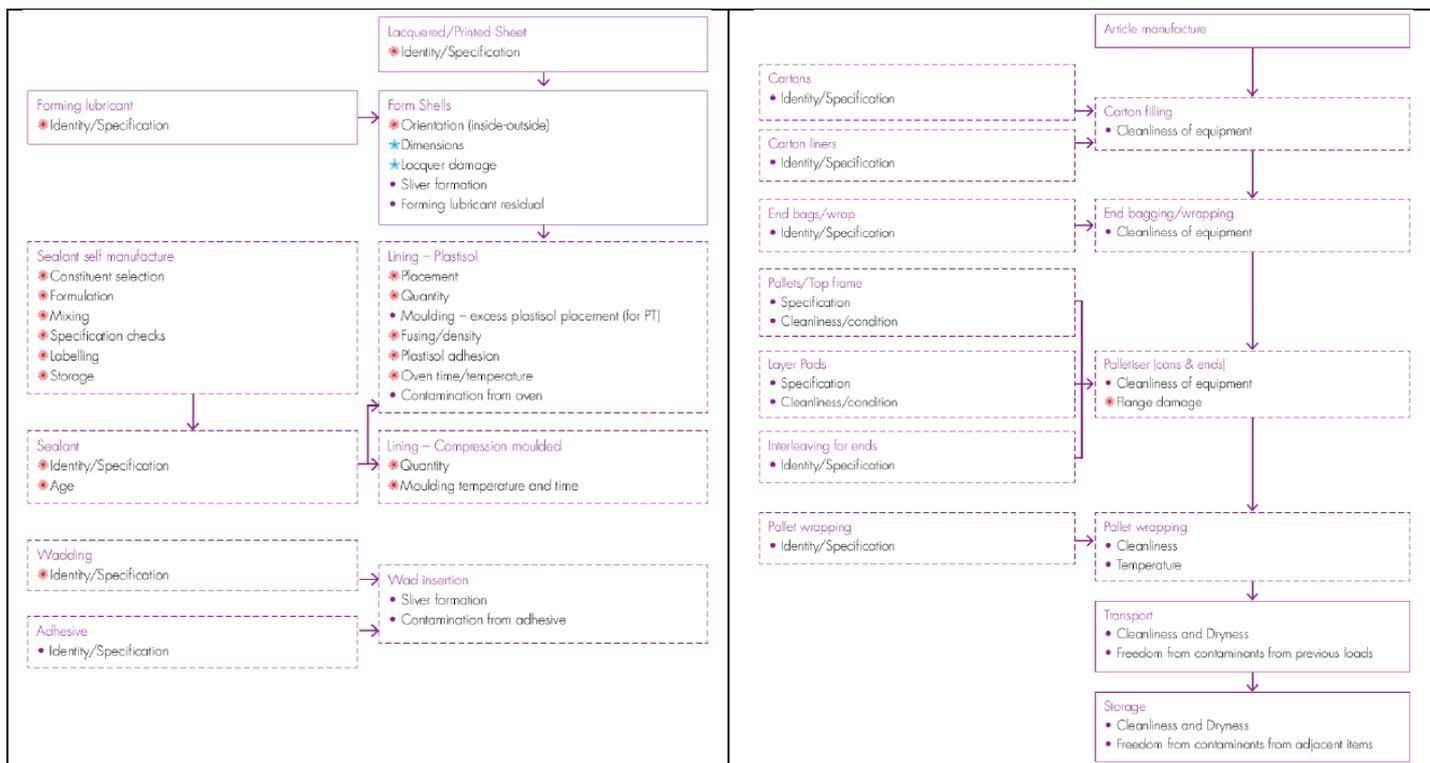


Drawn and wall-ironed (DWI) 2-piece can body manufacture



Closure manufacture

Secondary packaging, warehousing and transport



(Industrial guidelines on traceability of materials and articles for food contact, 2006)

Cork

The information source for cork is the document from Celiege (in FR) "Code international des pratiques bouchonnières - Version 6.03" that was sent by DG Health and Food Safety in 2012. However, it is not very relevant for what regards information on the supply chain and actors.

Some information is only available on the production steps and is summarised as follows:

- Preparation: Transformation of raw cork in starting material that can be used by industry. Comparable to the level a – "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011.
- Manufacturing: Processing of the starting material into a semi-processed product (slices or corks). Comparable to the level b – "manufacturer of intermediate materials" - described in the Union Guidance on Regulation (EU) No 10/2011.
- Semi-finishing: Transformation of semi-processed product in semi-finished products. The semi-finishing activities are washing, sealing and coating. Comparable to the level b – "manufacturer of intermediate materials"- described in the Union Guidance on Regulation (EU) No 10/2011, or to the level c – "manufacturer of final materials and articles".
- Finishing: Transformation of a semi-finished cork into a cork ready for use. Comparable to the level c – "manufacturer of final materials and articles"- described in the Union Guidance on Regulation (EU) No 10/2011.

Note: all these activities could be done by the same producer ("manufacturer of final materials and articles")

Activities of preparing the raw material for the production of cork stoppers are:

Activity 1: Preparation/ Treatment of cork

- CORK DELIVERY / RECEPTION. To guarantee the traceability of raw cork, and ensure that the wedges, burnt cork or cork with yellow stain, amongst other defects that make it unsuitable for cork stopper production, have been segregated.
- STORAGE OF CORK PLANKS. Period during which the planks are stored outside waiting to be submitted to the first boiling. Stabilization of the raw material (cork bark).
- First boiling. Immersion of planks in clean boiling water to clean the cork bark, to extract water-soluble substances, to increase the thickness and to improve cork flexibility and elasticity.
- Post-boiling stabilisation. Period between boiling and selection of the cork planks to flatten planks, to allow the cork bark to rest sufficiently until it reaches an adequate consistency and it has an homogeneous moisture content that will allow for trimming (cutting the planks into strips).
- Selection of cork planks. Ranking the cork that is destined for the cork stoppers sector according to thickness and quality [visual aspect]; separation of all cork with defects and that is unsuitable to be used in the manufacture of stoppers/discs. To grade cork depending on its use, eliminating the cork that is unsuitable.
- Storage of cork planks. Phase following the selection of the cork planks and that occurs prior to transport and/or processing. Maintain the physical and sanitary characteristics of cork after its transformation.
- Constitution of bales. To group the treated cork planks, according to thickness and visual classification. Constitution of units for transport and commercialization.
- STORAGE OF CORK BARK FOR GRINDING. The processing phase that is previous to the grinding process. To preserve and ensure the stability of the raw material that will be used in the manufacture of granulate for the cork stopper industry.
- MANAGEMENT OF CORK THAT IS UNSUITABLE FOR THE MANUFACTURE OF STOPPERS/DISCS. The treatment of cork that is unsuitable for the manufacture of cork stoppers/discs and that is detected during the preparation process. To eliminate the risks of contamination, in order to guarantee cork that is suitable for the manufacture of stoppers/discs.
- TRANSPORT OF PLANKS / BALES OR GROUND CORK. Transportation of cork planks, or bales of cork, or ground cork to the transformation location. To ensure that the cork planks, bales or ground cork is protected from any contamination as well as preserve its stability.

Activity 2 – manufacture of granulated cork for the cork stopper industry

- Reception/entry control of cork for grinding. Proceedings to be put in practice by the manufacturer regarding the reception of cork for grinding, to guarantee the quality of the cork for granulation.
- Storage of cork for grinding. Period of time between the reception of cork and the grinding process. To keep the cork destined for grinding in the best conditions, in order to avoid any alteration to its characteristics.
- Grinding/trituration. First operation that breaks up cork bark into smaller pieces. Obtain small pieces of cork that will be used for the next operation.
- Granulation. Fragmentation of the cork that comes from the grinding operation. To obtain fragments of cork (cork granules) that will be subsequently graded according to their granule size (between 0.25 and 8.0 mm).
- Densimetric separation. Separation of granules according to bulk density. To obtain specific granules for the manufacture of different types of stoppers.
- Drying of the granules. Operation process whereby the moisture content of the granules is reduced. Ensure the correct moisture content is established for the operation which follows.
- Storage of cork granulate. Conservation period of cork granules for future use. To keep the granulated cork in the best conditions for future use, avoiding alteration to its characteristics.
- Transport of granulated cork. Loading and transport of granulates from the manufacturing location. To deliver granulates to the manufacturers of cork bodies/ rods / stoppers.

Activity 3 – Manufacture of natural cork discs

Activity 4 – Manufacture of natural cork stoppers and cork bodies for bar-top stoppers

Activity 5 – Manufacture of multi-piece natural cork stoppers

Activity 6 -Manufacture of cork rods, bodies and agglomerated cork stoppers for still wines, sparkling wines, spirits, beer and cider

Activity 7 -Manufacture of stoppers/agglomerated treated cork granule bodies for still wines, sparkling wines, spirits, beer and cider

Activity 8 -Manufacture of agglomerated cork stoppers with natural cork discs for still wines, sparkling wines, gaseous wines, spirits, beer and cider.

Activity 9 -Manufacture of agglomerated cork stoppers with natural cork discs for effervescent wines

SEMI-FINISHING CORK STOPPER ACTIVITIES

Activity 10 -Washing and drying

Activity 11 –Colmation of cork stoppers

Activity 12 –Coloured coating

FINISHING OF STOPPERS THAT ARE FULLY INSERTED INTO THE BOTTLENECK AND OF BAR-TOP CORKS

Activity 13 -Gluing of the capsules (for bar-top stoppers)

Activity 14 –Marking and surface treatment of stoppers that are fully inserted into the bottleneck and of bar-top stoppers

FINISHING PROCESS OF STOPPERS FOR EFFERVESCENT WINES

Activity 15 –Marking and surface treatment of stoppers for sparkling, effervescent and gaseous wines, beer and cider.

of the Cork Industry's processing activities:

| DESCRIPTION OF SPECIALITY | ACTIVITY | Activity Nr. |
|---|---|----------------|
| PREPARATION (treatment) of the raw material destined for the production of stoppers | Treatment of the cork | 1 |
| | Manufacture of granulate | 2 |
| MANUFACTURE of stoppers or discs | Discs | 3 |
| | Natural cork stoppers | 4 |
| | Multipiece cork stoppers | 5 |
| | Agglomerated cork stoppers | 6 |
| | Agglomerated cork stoppers from treated granulate | 7 |
| | Agglomerated cork stoppers with discs | 8 |
| | Stoppers for effervescent wines | 9 |
| | SEMI-FINISHING of stoppers | Washing/Drying |
| | Colmation | 11 |
| | Coloured Coating | 12 |
| FINISHING of stoppers that are totally inserted into the bottleneck and capsulated/bar-top stoppers | Gluing of tops | 13 |
| | Marking and Surface Treatment | 14 |
| FINISHING of stoppers for effervescent wines | Marking and Surface Treatment | 15 |

Paper and Board

As for metals, an information source for paper & board (not material specific) is the document "Industrial guidelines on traceability of materials and articles for food contact" prepared by a joint work of most of the FCM industry associations". From such document the supply chain can be summarised as follows:

- Suppliers of starting substances that can be pulp, chemicals, pigments, sizing agents, mineral fillers, adhesives, starch.
- Suppliers of paper materials: it comprises operators performing the following paper production actions (see also CEPI GMP document September 2010 - page 13): stock preparation (pulping, cleaning, thickening, beating/refining, mixing, dosing), paper fabrication (sheet formation, pressing, drying, on-line surface treating including pigment coating), paper finishing (calendering, slitting, cutting, packing).
- Suppliers of paper materials: it comprises operators performing the following operations: application of off-line surface treatments lamination (with films made of plastic materials, metal – mainly aluminium foils, paper materials) made through: extrusion: plastic films (e.g. for cartons for liquid foods); bonding (use of adhesives): plastic films, metal foils, papers; other off-line surface treatments (e.g. for greasy foods); corrugating (for corrugated boxes).
- Suppliers of paper articles: it comprises operators performing the following operations: printing and/or varnishing, die cutting and creasing, folding and glueing packer/filler, comparable to level d - "user of food contact materials and articles".
- Users, retailers and distributors, comparable to level d - "user of food contact materials and articles", level e - "distributors", level f - "importer" or level g - "retailer".

Another source of information, specific for paper and board, is the document titled "Good manufacturing Practice for the Manufacture of Paper and Board for Food Contact (version: Issue 1 - September 2010)", issued by CEPI. The document provides information on the supply chain and it reports also in this case that the processing chain is extremely complex, involving thousands of steps. From the information reported it is thus only possible to draw a general scheme for the supply chain:

- Suppliers of starting substances (comparable to the level a - "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011) that can be wood pulp, chemicals, pigments, adhesives.
- Suppliers of raw materials (comparable to level b - "manufacturer of intermediate materials") that provide the paper material (it can include recyclers).
- Manufacturer, (comparable to the level c - "manufacturer of final materials and articles"), performing the following operations: coating, labelling, cutting, manufacturing.
- Packer/filler, comparable to level d - "user of food contact materials and articles".
- Users, retailers and distributors, comparable to level d - "user of food contact materials and articles", level e - "distributors", level f - "importer" or level g - "retailer".

The document issued by FEFCO titled "European Database for Corrugated Board Life Cycle Studies" (2012) is a third material specific source of information for paper and board. In the document there is a description of the production system for corrugated board and some information on the suppliers of raw materials. Thus the supply chain could be extrapolated as follows.

- Suppliers of starting substances (comparable to the level a - "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011) that can be chemicals, starch, process additives, pigments, adhesives, caustic soda, borax, modified starch and wet strength agents.
- Suppliers of raw materials (comparable to level b - "manufacturer of intermediate materials") that provide the paper material (it can include recyclers).
- Manufacturer (comparable to the level c - "manufacturer of final materials and articles").

Paper and board products (materials) need further conversion into articles before being able to be used for food contact applications and the processing chain might be extremely complex, as "there are literally thousands of different ways in which paper may be processed before use". The distinction between the different actors is not easy to put into a general scheme, as many operations can be done by the same operator or by many different ones. Nevertheless, it is possible to clearly identify all the actors of the chain on a case by case basis. Comparison with roles as classified in the Regulation 10/2011 is not fully working for all the paper and board supply chain.

For practical reasons basically all packaging grade paper and board are made to the food contact standards as it reduces the risk of accidental non-compliant supply and in a continuous process industry (24/7 production) it is less problematic than working batch-wise. So this means that changes in FCM regulation has not only influence on the fraction of paper and board used for food contact but on the whole production volume for packaging.

Production steps

Raw materials warehouse: Raw materials (pulp, selected recovered paper, auxiliary substances, charging and adjuvant substances) getting to the paper mill are checked to verify if corresponding to accompanying documents, do not result damaged even partially, and were packed following supplier request. Once in the mill, raw materials are identified per grade and stored in the raw material warehouse, while quantities data and location of storage site are registered. Unsuitable material is properly identified and stored in a specific area left at this purpose. Raw material ready for production is then taken out and sent to the mixing (mixture) division in accordance with quantity and quality required for specific productive grade.

Mixing (Mixture) department: Fibrous raw materials are duly treated to make them suitable to be used and then mixed amongst themselves and with auxiliary and charging substances on the basis of proportion pointed out in the "formula". Pulps and/or recovered paper are firstly sent to the kneader (or pulper) where pulp fibres are crumbled and suspended into water. Then, fibres are sent to refiners where, through friction, raising of fibrils of pulp surface is obtained, so to allow fibres to increase capacity of binding precisely when forming the sheet. When using recovered paper, refining is not always necessary but, in this case, the mixture passes one or more cleaning (purge) phases, to remove impurities through proceedings mainly mechanical (filters and centrifugal purgers). Water suspension of fibres is therefore added with auxiliary substances in right proportions, such as mass adhesive and colouring agents, retentives and charging substances, necessary to mould the mixture ready for forthcoming preparation of paper sheet with required characteristics.

Deinking: For some grades of recycled and recovered papers, one more step (deinking) is necessary, where, due to the action of surface-actives, a removal of inks is obtained. To the surface-actives action bleaching action of oxidant agents can follow. So managed fibre is ready to be used for the preparation of the mixture.

Paper Machine: the mixture duly diluted is sent to the afflux case, which takes care of spreading it out with homogeneousness on a band continuously moving (wire section) in which fibres lay down and join while water drains in the below area. Then, the sheet is taken to a further and deep dehydration through pressing between calenders in rotation (moist press) just before being dried in the dry end, composed by a number of high temperature calenders in which paper sheet passes by accompanied by two felts. When coming out the dry end, uninterrupted sheet is rolled up on a cylinder (pope), forming the paper reel.

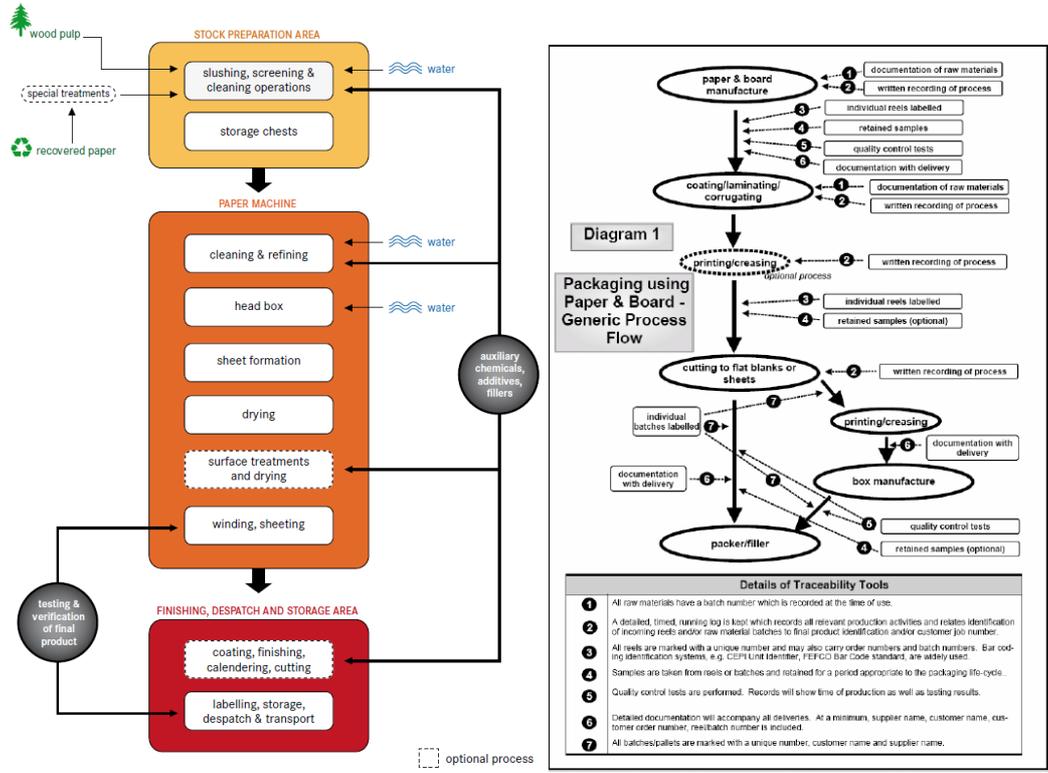
Surface gluing: for some paper grades paper machine is equipped with a further phase called "size press", in which the already formed sheet undergoes a surface gluing treatment to increase its characteristics of mechanical strength and rigidity.

Patina cooking and coating: some grades of paper are exposed to a further coating treatment, that can take place in the same paper machine (coating on line) or afterwards (coating out of line). Coating is a surface treatment, on the paper sheet (bearing) one or more layers of pigments are laid down, on one or both sides, so to allow a better aspect and printability. Patina is prepared in its specific cooking, a water dispersal of mineral pigments, ligand and auxiliary substances mixed in right proportions.

Finish and setting up: reels such as they come out from paper machine can be directly addressed to the finished products warehouse or undergo to further production. With calendaring, sheet is to suffer a strong pressure amongst a series of coupling cylinders (one in iron is rigid, the other one is made out of flexible material) so paper can be smoothed and made lighter and homogeneous to the surface. Embossing, instead, impresses a surface deformation to the sheet to make specific relief drawing possible. With the respool, paper ribbon is wrapped up again on board tubes and, in case, cut in small reels ("bobinette"). Such lower reels can be finally cut in sheets for the delivery to customer. Reels, small reels (bobinette) or sheets, as for customer request, are finally wrapped-up, labelled, sometimes palletized ready to be sent to the finished products warehouse ready to be delivered to customer.

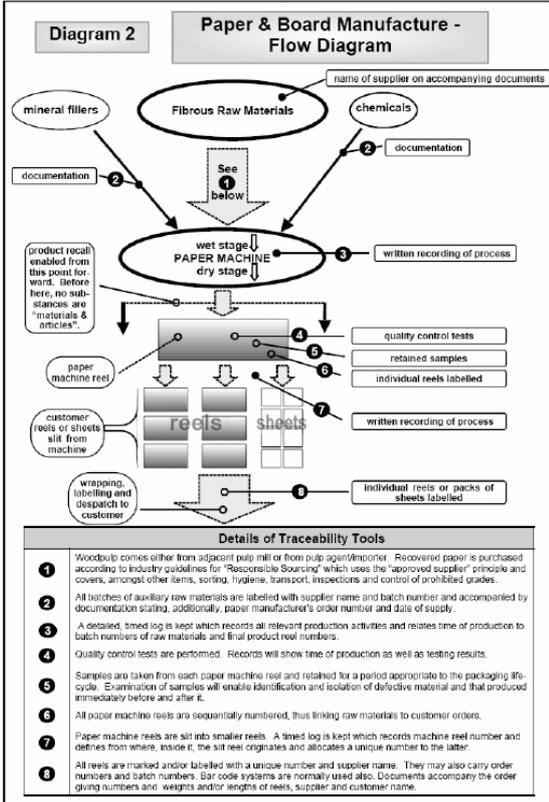
Finished products warehouse, delivery: the finished product, duly labelled, is stored in the finished products warehouse. Data on quantity and location of stored material are registered. Material which does not meet is duly identified and stored in a place previously decided. Finished product ready for the delivery is taken out the finished products warehouse as requested in the delivery plan and loaded on means of transport, accompanied by necessary documentation.

Overall paper and board producing process

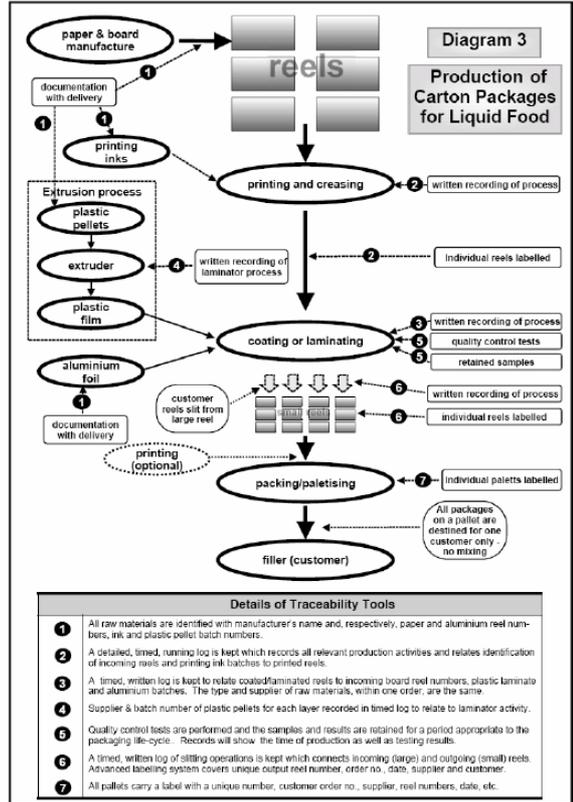


(Industrial guidelines on traceability of materials and articles for food contact, 2006)

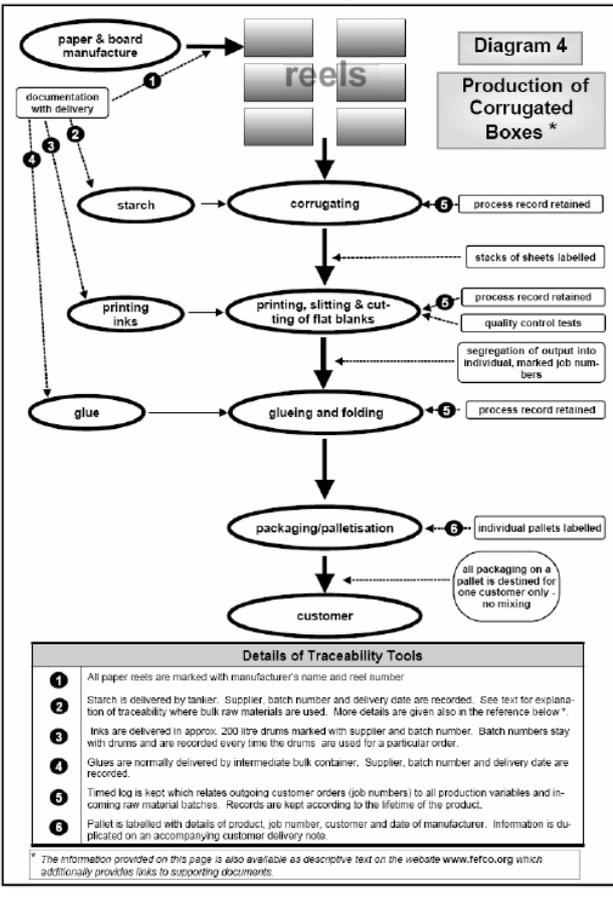
Paper and board producing process



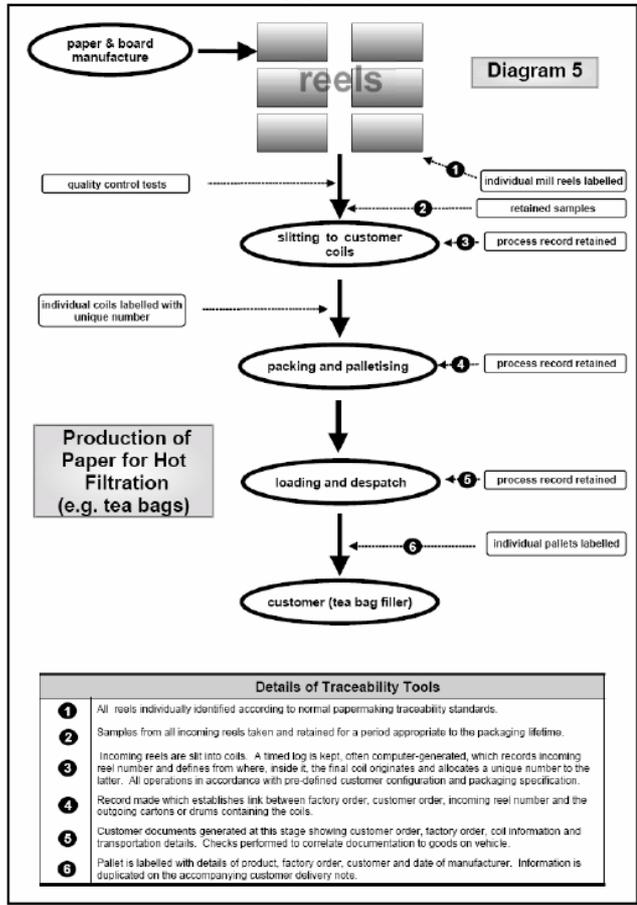
Production of cartons for liquid foods

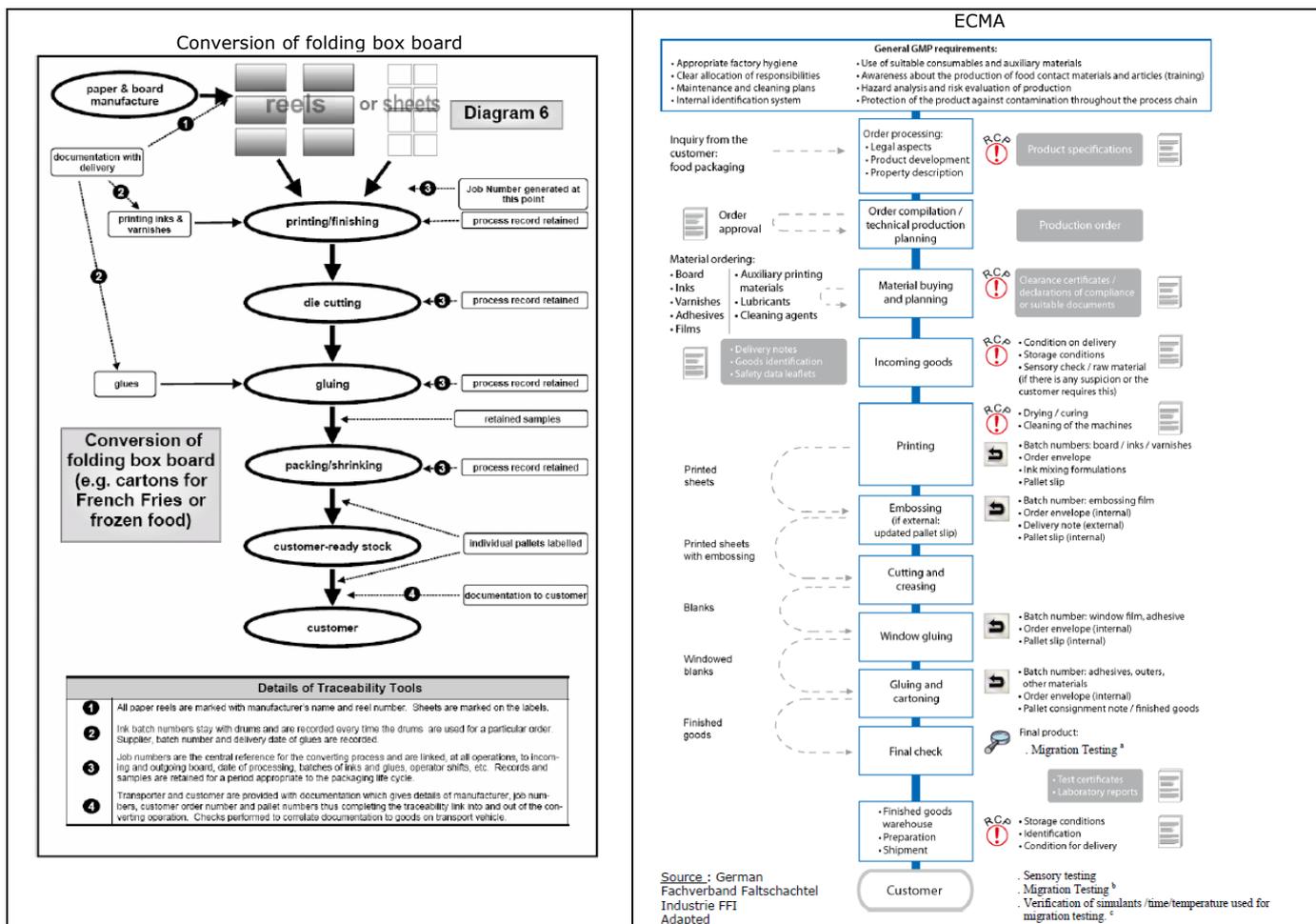


Production of corrugated boxes



Production of paper for hot filtration





(Industrial guidelines on traceability of materials and articles for food contact, 2006)

Tissue paper (kitchen towels and napkins)

Tissue paper products are made from light weight, dry creped and some non-creped paper. Typical products are toilet paper, kitchen towels, handkerchiefs, facials, napkins, hand towels, and wipes. These products can be made of one or several plies, each ply of one or several layers, prepared as sheets or rolls, folded or unfolded, embossed or unembossed, with or without lamination, printed or unprinted and possibly finished by post treatment, e.g. lotion application.

Kitchen towels and napkins are manufactured from cellulose-based natural fibres from bleached and unbleached fibre material, including recycled fibre materials. In addition, they may contain functional additives and synthetic fibres. Kitchen towels and napkins may be printed, and also printed surfaces may come into contact with foodstuffs.

Kitchen towels and napkins have specific technical characteristics and perform specific functions that differentiate them from paper and board packaging materials and other paper products. They are multi-purpose products that have a broad cleaning and absorption function and are not primarily intended for food contact. However, sometimes they are put into contact with foodstuffs by the final users.

The limited and short-term use in food contact means that consumer exposure is very low.

In contrast with food packaging materials, kitchen towels and napkins are not primarily designed for food contact. Consumer studies have shown that the main use of tissue products is for hygiene and cleaning, and that use in contact with foodstuffs is limited. For instance, it is estimated that only 27% of buyers of kitchen towels regularly use them in contact with food and that on average less than one kitchen towel (or about 1.2 gr.) is used in food contact per day per person. In addition, kitchen towels and napkins are soft and exhibit a lack of structural resistance. Once they absorb a liquid they lose their properties and cannot be reused. Consumer studies confirm that, in case of food related use, the

predominant function is to absorb moisture or fat and that food contact is typically limited to a few seconds. Use over 15 minutes is rare.

In addition, the manufacturing processes used are designed to reduce the amount of impurities and contaminants, and the high level of purity of the products has been confirmed. Migration studies have also demonstrated the low migration profile of kitchen towels and napkins.

Production stages (CoE Policy statement concerning tissue paper kitchen towels and napkins Version 1 –22.09.2004)

| STAGES | POSSIBLE HAZARDS | SUGGESTED MEANS OF PREVENTION |
|---|---|--|
| NON FIBROUS ADDITIVES | | |
| a) Selection prior to purchase | Contamination from a chemical source, due to the use of raw materials whose safety has not been determined. | Reference to Section 5.2. of these Guidelines. |
| b) Transport (delivery to factory) | Contamination from a chemical and/or microbiological source, linked with absence of cleanliness (truck, tank, etc.). | Reference to the specifications of both transporter and supplier. |
| PULPING | | |
| | Error about raw materials which may lead to the introduction of inadequate raw materials into the pulper. | Manufacturing specifications. |
| | Contamination of the pulp from micro-organisms brought by pests. | Maintenance of cleanliness of premises (pest control, etc.). |
| | Contamination from a chemical source, linked with production shift (from non-food to food products). | Manufacturing specifications, grade shift procedure. |
| DEINKING, PREPARATION AND INTRODUCTION OF ADDITIVES | | |
| | Inadequacy of physical characteristics and/or possible contamination from a chemical source, linked with concentration error or overdose of hazardous products. | Compliance with procedures. Records. |
| | Contamination from micro-organisms as a consequence of microbiological growth of a preparation. | Compliance with procedures. Cleaning of preparation chests. Storage conditions (e.g. temperature). Preventive treatment with biocides. |
| REFINING, CLEANING, DILUTING, SHEET FORMATION | | |
| | Contamination from a microbiological source, linked with absence of cleanliness (chests, circuits). | Appropriate cleaning and/or anti-microbial treatment. |
| | Contamination from a chemical source, from cleaning agents of clothing. | If a chemical is not suitable for food contact, segregation of cleaning water from other parts of machine is needed. |
| PROCESS WATER TREATMENT | | |
| | Proliferation of micro-organisms in process water. | Appropriate anti-slime treatment. |
| | Accumulation of dissolved and/or colloidal material. | Process water clarification, e.g. by flotation. |
| DRYING, CREPING, CALENDERING, WINDING, DOUBLING, CUTTING | | |
| | Soiling due to condensation or to premises dust fallout onto the reel. | Appropriate maintenance and cleanliness of premises. |
| TREATMENT WITH CHEMICAL ADDITIVES | | |
| | Inadequacy of physical characteristics and/or possible contamination from chemical components as a consequence of a quantity of deposit, possibly out of regulatory tolerance, or out of specification. | Compliance with procedures. |
| | Contamination from micro-organisms, linked with microbiological growth of a preparation. | Compliance with procedures. Cleaning of preparation chests. Storage conditions (e.g. temperature). Preventive treatment with biocides. |
| MOTHER REEL HANDLING | | |
| | Soiling due to condensation or to premises dust fallout onto the reel. | Appropriate maintenance and cleanliness of premises. |
| | Contamination from a chemical and/or microbiological source due to the lack of cleanliness of pallets or inappropriate treatment of the wood. | |

| STAGES | POSSIBLE HAZARDS | SUGGESTED MEANS OF PREVENTION |
|------------------------------------|--|---|
| FIBROUS RAW MATERIALS | | |
| a) Selection prior to purchase | Contamination from a chemical and/or microbiological source, due to the use of raw materials whose safety has not been determined. | Reference to Section 5.1. of these Guidelines. |
| b) Transport (delivery to factory) | Contamination from a chemical and/or microbiological source, linked with absence of cleanliness (truck, etc.). | Reference to the specifications of both transporter and supplier. |
| c) Reception, storage, handling | Contamination from a chemical and/or microbiological source at the moment of storage, as a consequence of mixing up grades suitable for food-contact with unsuitable ones. | Separate areas (where relevant), compliance with procedures (quality assurance). |
| PRODUCTION AREAS | | |
| | Contamination from a chemical source, linked with leakage or residues from cleaning agents. | Restricted stored amount of hazardous cleaning products, or of their residues in production areas. Compliance with procedures. |
| | Possible contamination from a microbiological source linked with humidity, temperature, and absence of cleanliness of premises. | Cleaning and sanitation. |
| CONVERTING AREAS | | |
| | Contamination from a chemical source, linked with leakage or residues from cleaning agents. | Restricted stored amount of hazardous cleaning products, or of their residues, in production areas. Compliance with procedures. |
| | Possible contamination from a microbiological source linked with humidity, temperature, and absence of cleanliness of premises (animals and undesirable insects). | Cleaning and sanitation (UV insect control lamps and rodent control). |

| STAGES | POSSIBLE HAZARDS | SUGGESTED MEANS OF PREVENTION |
|---|---|--|
| IN-PROCESS CONTROL AND QUALITY CONTROL OF FINISHED PRODUCTS | Inadequacy of physical characteristics and/or chemical characteristics possibly out of the regulatory tolerance. | Compliance with procedures, process control, down-grading and identification of products which are out of specification, records. Clear and precise identification of samples for laboratory analysis. |
| LABELLING | Error of identification of paper or batch mix-up leading to the use of a paper unsuitable for the required utilisation. | Compliance with procedures. |
| STORAGE OF FINISHED PRODUCTS | Degradation of the physical or chemical characteristics of paper due to bad storage conditions (humidity, temperature) or to excessive storage duration. | Implementation of appropriate conditioning. Compliance with procedures. Preventive maintenance programme. Maintenance of cleanliness of premises (appropriate cleaning, pest control). |
| | Contamination from micro-biological source, linked with absence of cleanliness within storage areas. | Compliance with procedures. Maintenance of cleanliness of premises (appropriate cleaning, pest control). |
| SHIPPING | Paper identification error, batch mix-up, bad condition of loading and of means of transport, leading to using a paper unsuitable for the required utilisation. | Implementation of specifications regarding transport. |
| | Contamination from a micro-biological source, linked with bad conditions and absence of cleanliness of means of transport. | Compliance with procedures. |
| | Contamination from a chemical source through polluting products from previous transport. | Implementation of specifications regarding transport. Requirement for non-transportation of chemicals and odorous products in the vehicles used. Compliance with procedures. |

Wood

Also for wood a non material specific source of basic information on the supply chain is the document titled "Industrial guidelines on traceability of materials and articles for food contact". Only the production process of wood crates is described in the document, and only in its manufacturing steps, so the supply chain can be only schematically extrapolated as follow:

- Suppliers of starting substances (comparable to the level a – "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011) such as chemicals, inks.
- Suppliers of raw materials (comparable to level b – "manufacturer of intermediate materials"), such as sawmills providing plywood, sawn wood or peeled poplar.
- Manufacturer, (comparable to the level c – "manufacturer of final materials and articles").
- Users, retailers and distributors, comparable to level d - "user of food contact materials and articles", level e - "distributors", level f - "importer" or level g – "retailer".

Wooden crates

Wooden crates for fruit and vegetables are made mainly of poplar. Member States regulations allow the use of other wood species like pine, beech and eucalyptus. The systemic analysis of crate production is as follows:

Trees cropped => Logs delivered to the factory => De-barking => Cutting into sections => Peeling (or sawing) to produce laths => Plywood production => Peeling into veneers of same dimensions => Gluing and assembling in warming press => Cutting => Component production: heads (width), sides (length) and bottoms => Laths printed (sides and/or heads) if requested by the customer => Assembly of heads and sides (framing) => Assembly of the bottom to the frame (bottoming).

Poplar logs are debarked and cut into pieces of 1 meter long (approx.). Then, each piece goes to a peeling machine, producing long slices of poplar (1 mm thick) which are cut into slices. The slices are transferred to a machine where they are warmed, glued and pressed to form plywood. This plywood may be cut to meet the customer's specification.

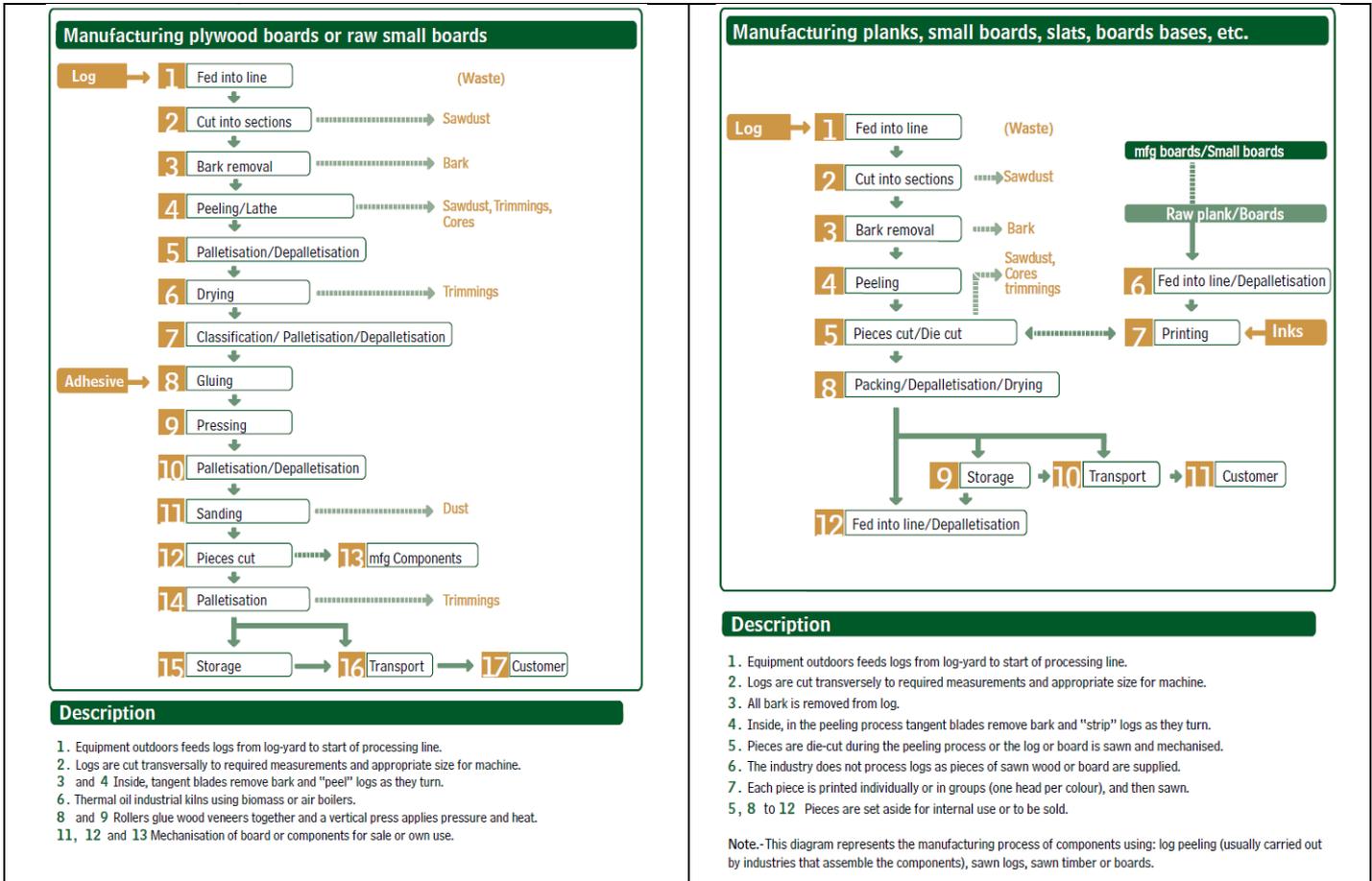
Dependant on Member State regulations and the properties of the wood species wooden crate factories may or may not carry out the whole range of production processes:

Integrated factories cover the whole range of production process.

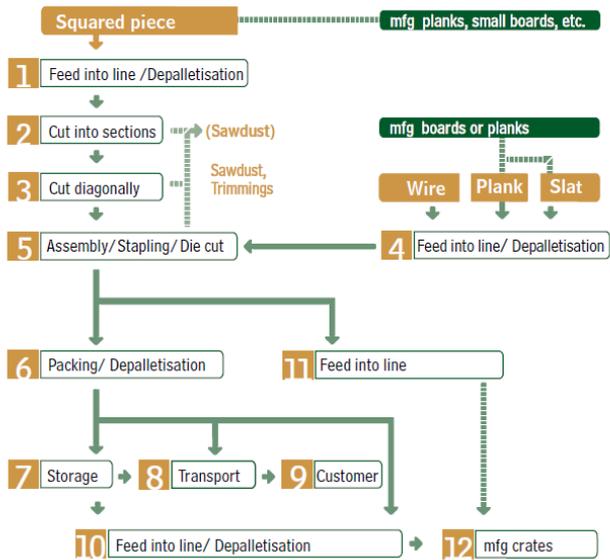
Component producers manufacture heads and/or bottoms and/or sides.

Assemblers buy components and assemble them.

Sawn slices and plywood are generally bought from sawmills and plywood producers. However, wooden crate factories (mainly in Spain, but also in South America, Chile and in Eastern Europe) may produce their own plywood and/or sawn wood. Once the crate has been assembled, it is sent to the filler. Detailed processes are depicted in the next flowcharts.



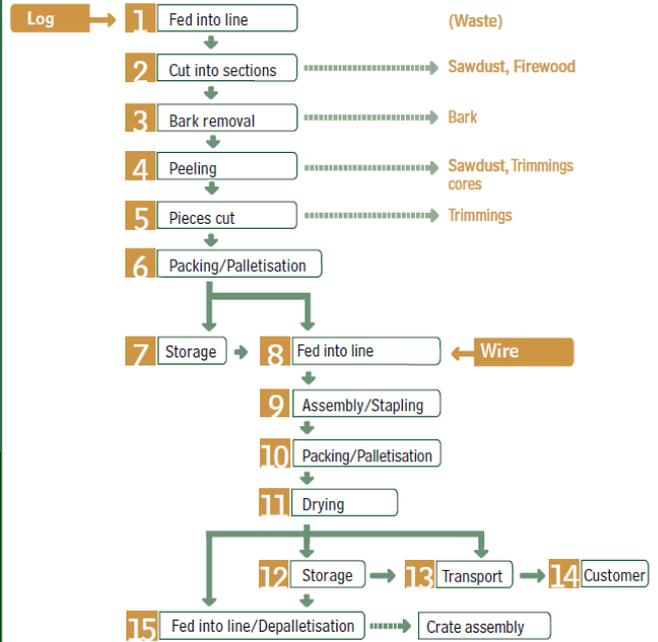
Manufacturing heads



Description

1. Currently a manual process.
2. Determines height of crate. Manual or automatic process.
3. Shapes corner piece.
4. Planks and slats currently fed manually, wire fed from spool.
5. Stapling carried out in two stages: plank stapled to corner piece first and optionally to slat.
6. Heads stored 7 to be sold 9 or to be used later or fed into line 10.
11. In fully automated lines heads are manufactured in the same assembly line.
12. Crate industries can manufacture their own heads.

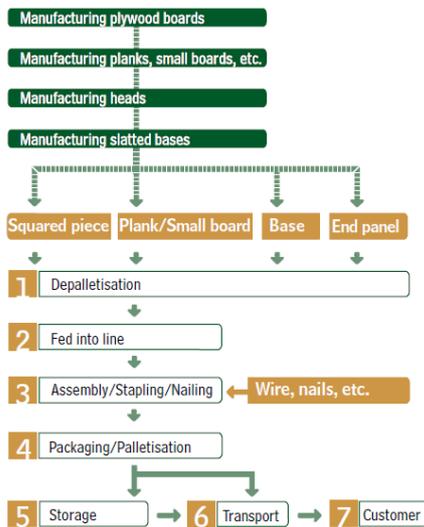
Manufacturing slatted bases



Description

1. Equipment outdoors feeds logs from log-yard to start of processing line.
 2. Logs are cut transversely to required measurements and appropriate size for machine.
 3. and 4. Inside, tangent blades remove bark and "strip" logs as they turn.
 5. Different base pieces are die-cut while logs are being peeled.
 6. Damp pieces grouped and palletised temporarily, and perhaps stored. 7.
 8. Various pieces assembled manually on assembly line to make bases.
 9. One stapling head at end of line joins pieces using wire from spool.
 - 10 to 15 Bases palletised manually to be dried in open air, stored and sold.
- Note - Manufacturing bases is usually a specialised process, although some industries that assemble crates have their own section as part of the assembly line.

Manufacturing crates or packaging (assembly of components)



Description

1. Depalletisation of components (purchased or manufactured) is currently carried out at the warehouse.
2. Components are currently fed manually into the processing lines.
3. Carried out as a sequence in one single line. Several lines involve palletisation and depalletisation operations. Sequence for crates: head (corner piece + plank + slat), rim (heads + sides), crate (rim + heads).
4. Traditional manual palletisation tends to be replaced by automatism and robots.
- 5 to 7 A tendency towards providing a "just in time" service makes storing the product unnecessary. However, products may be stored as stock.

FEDEMCO, guide to good hygiene and manufacturing practices version 1, 2010

Cutlery, kitchenware and table ware

The FEC (Federation of the European Cutlery, Flatware, Hollowware and Cookware Industries) member companies use in their manufacturing processes almost all types of food contact materials, such as e.g. metals and alloys, plastics, ceramics, enamels, rubbers and elastomers, glass, silicones, organic and inorganic coatings, adhesives, wood, cork, pigments, paper, printing inks, etc. which are supplied to them as substances or mixtures by raw material producers or as subcomponents by suppliers in or outside the EU. Whilst other European associations only follow up one specific food contact material and the related EU legislation or Council of Europe (CoE) resolutions, FEC follows up and informs its members about the sector-specific EU legislation and Council of Europe resolutions for all these raw materials, mixtures and food contact articles.

Plastics

The following associations cover the incoming materials used for plastics material:

- CEFIC-FCA European Chemical Industry Council — Food Contact Additives
- PlasticsEurope - Association of Plastics manufacturers in Europe
- The following associations cover the converters of those materials:
- EuPC European Plastics Converters Confederation
- FPE Flexible Packaging Europe

Raw materials used for the production of plastic food contact materials and articles are:

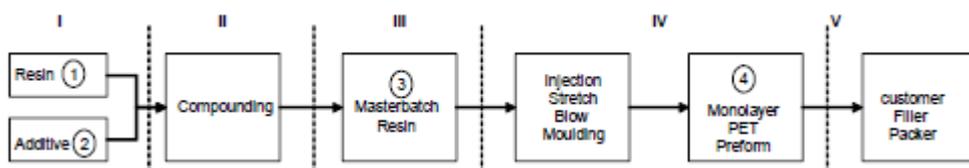
- Resins, almost always purchased as pellets and then submitted to various processing steps such as extrusion, blow-moulding, injection moulding etc.
- Additives, added in-line as such or in solutions during the production of the material or articles, or used off-line to produce a compound master batch that is further processed for the manufacturing of the material or articles.
- Plastic films or sheets, purchased as reels and then coated and/or printed and/or laminated to another substrate.
- Primers, inks, varnishes and coatings, used in the printing process.
- Adhesives and tie-layer resins used to laminate or bond together various layers.
- Where appropriate, non-plastic substrates such as paper, aluminium foil, RCF, etc.

Production plastic vending cups

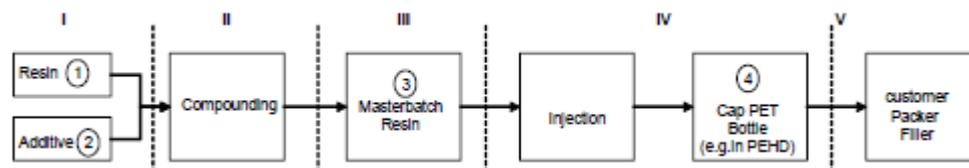
For plastic vending cups, EVA informed that there are 4 manufacturers in Europe who account for approximately 80% of the market: Huhtamaki, Flo, SwissPrimePack, and Coveris.

Production of PET bottle with cap

The raw materials which consist of PET resin, additives and pigments are compounded. A compounder can be located at the converters plant or be an independent company. Preforms are injected and sold either directly to a packer-filler, a subcontracting converter or via a distributor for small businesses (Industrial guidelines on traceability of materials and articles for food contact, 2006).



The cap is manufactured using a similar process as that used to manufacture preforms. However the raw materials and additives used are different (Industrial Guidelines on Traceability of Materials and Articles for Food Contact, 2006).

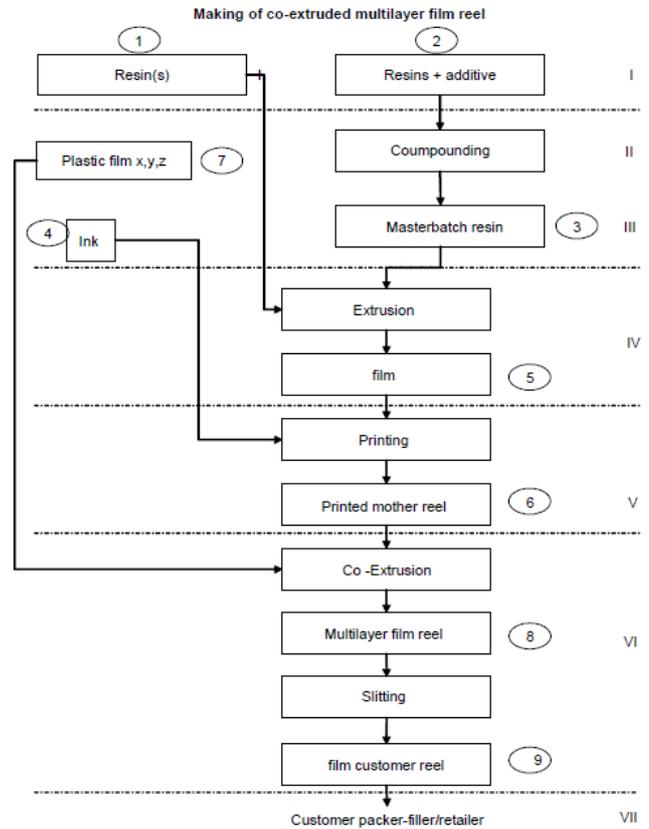


Additional information available at:

- Clear bottle design aspects (European PET Bottle Platform; <http://www.epbp.org/design-guidelines/products>).
- Coloured bottle design guidelines (European PET Bottle Platform; <http://www.epbp.org/design-guidelines/products>)

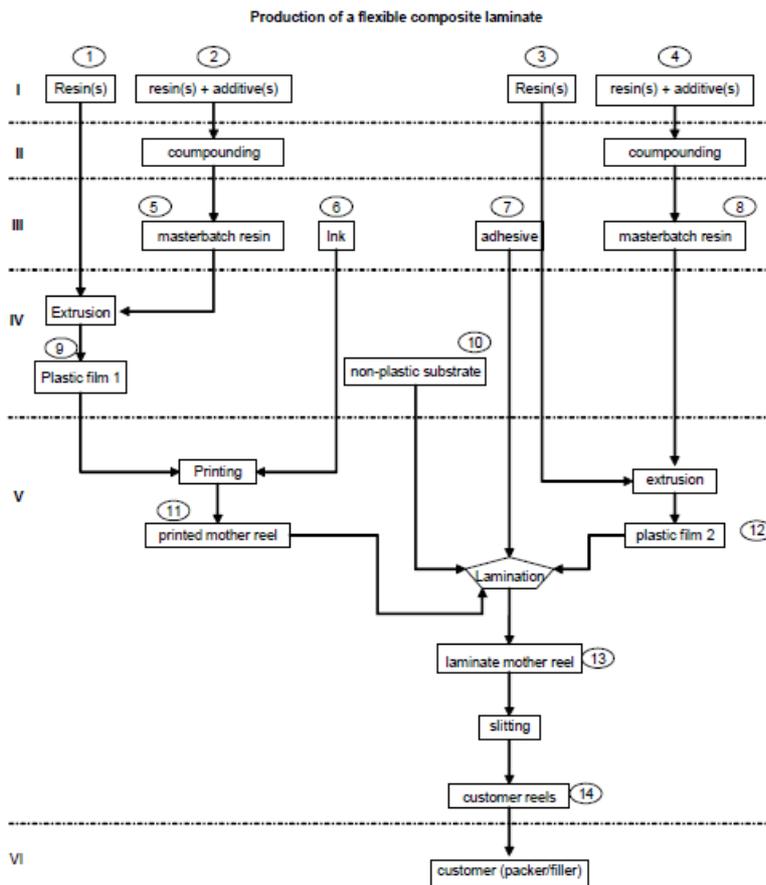
Production of a multi-layer film

In the production of a plastic film the initial step is either extrusion or calendaring. These processes can involve a pure resin and additives or a pure resin and a master batch of resins and additives. The following example has been simplified as typically there are a number of resins, and additives with several different suppliers. The film may be printed and then folded, sealed and cut into bags or it may be printed and then slit into co-extruded multilayer film reel. The raw materials used are numbered 1, 2, 3, 4 and 7 and are obtained from suppliers on levels I, III and IV. Materials no. 5, 6, and 8 are intermediate products made in-house by the converter. Material 9 is the finished product, and is delivered to the customer on level VII, usually a packer/filler (Industrial guidelines on traceability of materials and articles for food contact, 2006).



Production of laminate

The raw materials used are numbered in the scheme from 1 to 10, and are obtained from suppliers on levels I, III and IV. Materials numbered 11, 12 and 13 are intermediate products made in-house by the converter. Material 14 is the finished product, and is delivered to the customer on level VI, usually a packer/filler. For non-plastic substrates such as paper or aluminium foil, the traceability practices and requirements are identical to those of plastic film. Inks and adhesives (as well as coatings) are commonly purchased in a liquid form, and depending on the case are delivered in drums or tanks. For materials delivered in drums, the information provided on the labels or accompanying documents shall be recorded, and full traceability is assured. For liquid materials delivered into large volume tanks, the traceability requirements for bulk storage (see below) shall apply. For liquid materials prepared in-house by the converter (not uncommon for inks, and even rather common for coatings), adequate information from the raw materials and the production history shall be recorded for the traceability. Resins and other starting substances can be stored in silos. Bulk storage implies the mix of several batches of raw material. At that point, it is no longer possible to refer to one batch number but reference is made to a series of batch numbers. Liquid raw materials such as adhesives, inks and coatings, etc. are commonly delivered to the packaging manufacturer in drums which are adequately identified to allow full traceability between the batch of raw material and the finished products in which they were used. However, the following special cases have to be recognized: first, when a container of any such liquid raw material is only partly used for a given manufacturing run, and the rest is used later in another production, a system needs to be in place to maintain the original traceability of the liquid raw material into the next production run. With such system in place, full traceability can still be ensured. Second, when several partly-used units of liquid raw materials are collected into one container for further use, full traceability would require that the collected liquid be assigned a new traceability identifier, and that the traceability information clarifies from which batches or raw materials this new batch was constituted. If this is not feasible for technological or logistical reasons, at least the source of the various incoming batches should be clarified. Liquid raw materials from different suppliers should preferably not be mixed. Third, when large volume containers are used which are refilled before completely empty, the situation is the same as described above for bulk storage of resins in silos, and the information recorded has to be the same.



In-plant production scrap, which is immediately re-introduced into the manufacturing process, does not constitute a separate material and therefore does not need to be considered in separate traceability information. It is therefore excluded from this special case. Other production scrap, which is collected before being re-used in another manufacturing run, shall be stored in a separate container that will be assigned a reference number. If different batches of production scrap are collected and re-processed together, the traceability information shall clarify from which sources the materials originate.

In some cases, production scrap from various origins (finished and semi-finished articles (e.g. different reels), end of production run, production defects, off cuts, edge trimming, transition of formulation) are shredded and stored in a silo of "fluff". This fluff is then regranulated and stored in a silo of regranulate and used as a new raw material in production. The process can be discontinuous: the silo of fluff is first

fully filled and then regranulated. In this case a batch number can be allocated to the waste in the silo of fluff to be regranulated. The process can also be continuous: waste is shredded into fluff and fluff immediately regranulated. In this case the mean time to completely fill a silo of regranulate produced from fluff obtained from production scrap should be estimated. This "average filling time" together with an accurate material accounting of the use of the regranulate will then be used in case of recall if it appears that a defect is originating in the regranulate used.

(Industrial guidelines on traceability of materials and articles for food contact, 2006)

Glass fibres in plastic

The corresponding trade association is APFE – European Glass Fibre Producers Association (www.glassfibreeurope.eu)

In the supply chain continuous filament glass fibre products ("glass fibres") manufacturers can be considered as manufacturers of intermediate materials which are used to reinforce plastic. The manufacturing process consists in melting mineral raw materials to manufacture glass and processing molten glass into continuous filament fibre, applying a surface treatment ("sizing") to the glass filaments serving as processing aid and improving the adhesion of the glass fibre filaments to the plastic matrix. Such materials are regulated by Regulation 10/2011 as additives to plastic. More specifically, glass fibres are included in Annex I of Regulation 10/2011- FCM Substance (No: 38 / Ref No: 55520 / Substance name: glass fibres / Use as additive or polymer production aid: Yes / No restriction). They are a mixture of organic raw materials regulated according to the general requirements applicable to plastic starting substances, monomers, additives, polymer processing aids, etc., according to the function of the sizing components in the final plastic material or article. An industry guidance has been submitted to DG Health and Food Safety / EFSA for review and validation, expected by 31/03/2015. Transitional provision (Reg. 10/2011 Art. 22.4.) foresees that until 31 December 2015 additives used in glass fibre sizing for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19.

Rubbers

Different types of rubber can be produced: elastomers, latex, rubber (natural or synthetic), thermoplastic rubber, thermoplastic elastomer, vulcanised rubber. The rubber products producers manufacture the finished products from a combination of different materials. Documents specifying detailed information on the different production steps were not identified. The Council of Europe's Policy statement concerning rubber intended to come into contact with foodstuffs - Technical Document No. 03 (2003) was adopted by the association ETRMA, but does not provide detailed information on the different production steps, thus it is possible only to attempt a supply chain scheme as follows:

- Suppliers of starting substances comparable to the level a – "substance manufacturer"- described in the Union Guidance on Regulation (EU) No 10/2011.
- Suppliers of raw materials comparable to level b – "manufacturer of intermediate materials".
- Manufacturer, comparable to the level c – "manufacturer of final materials and articles".
- Users, retailers and distributors, comparable to level d – "user of food contact materials and articles", level e – "distributors", level f – "importer" or level g – "retailer".

Regenerated cellulose film

The industry organisation of this category (CIPCEL) does not possess any detailed information on the organisation of the supply chain.

Cellophane is a natural product derived from wood pulp. Trees from managed plantations provide the raw material from which wood pulp is obtained. A pure grade of dissolving pulp is supplied to the cellophane industry in the form of compressed wood pulp sheets or reels.

The cellophane manufacturing process starts with bales or reels of wood pulp being agitated with caustic soda solution and a catalyst to form a slurry. The slurry is fed through a press where it is compressed to produce alkali cellulose crumb. The alkali cellulose is reacted with carbon disulphide under vacuum to make sodium cellulose xanthate. This is then mixed with a weak caustic soda solution to produce viscose.

The cellulose in the viscose is regenerated by extruding the liquid viscose through a jet into a bath of dilute sulphuric acid to form a sheet of film. This is known as the casting operation. The film then passes through a series of wash baths, which treat the film and remove all impurities. Carbon disulphide is recovered during part of this process. Along its path through the casting machine the film is treated with softeners to make the film more flexible, and with anchoring agents to provide a chemical bond between the film and subsequent application of a coating.

At the end of the casting machine the dried base cellulose film is wound up into mill rolls and given a unique number, which then stays with that film through all further operations. These mill roll numbers are the main identity of all cellophane. All production records can be related to the mill roll numbers and samples of daily production are kept for reference. These records include (a) up-stream data of pulp and other chemical use, (b) results of quality control tests, (c) time and date of manufacture and (d) down-stream details of any coating application and conversion to smaller reels and sheets.

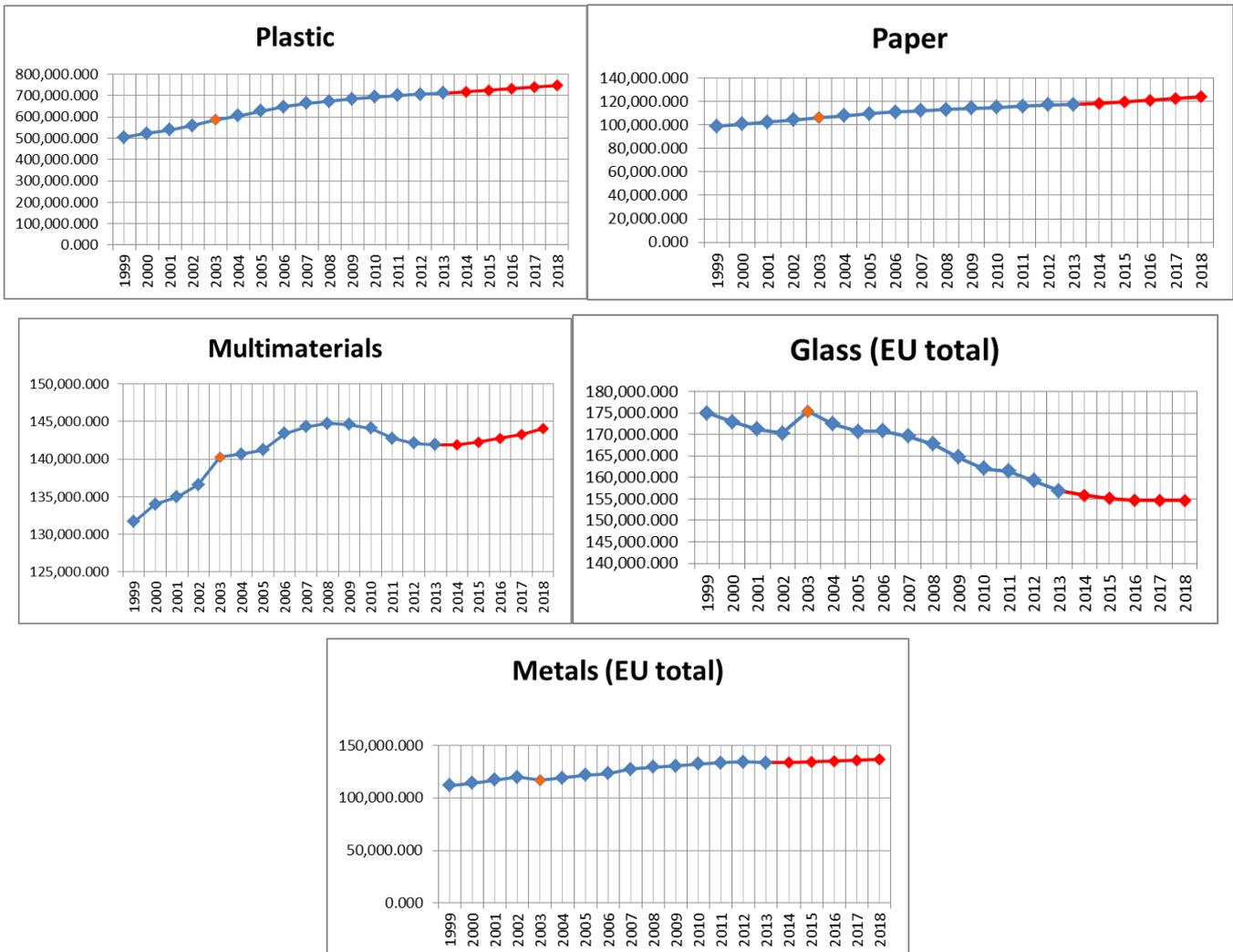
In the context of traceability, it is the down-stream area which is most important as it is only here that the product first becomes recognisable as being for food contact use and thus available for recall in the event of an incident. The mill rolls can be coated with a PVdC, nitrocellulose or other coating to give the final film properties of heat sealability, moisture permeability etc. The coatings are applied from solvent or aqueous dispersions. The coated and uncoated film mill rolls are then transferred to slitting equipment where slit reels of smaller diameter and widths are produced.

Annex 2. Information on volumes / values

This section summarises the main conclusions from statistic data provided by Euromonitor and Pira. While Euromonitor provided data related to volumes (million units sold), Pira provided data on sales (million euro sales). Moreover Pira provided data only for 2013, while Euromonitor provided data between 1999 and 2013 and forecasts for the period 2014-2018. The materials for which data could be provided were also different: Euromonitor provided data for glass, metals, multimaterials, paper and plastics, while Pira provided data for glass, metals, paper, plastics, wood, cork and ceramics. Thus, data from the two sources could not be directly compared for all materials and years. Data were thus first analysed within the same source, and then comparisons were attempted between the two sources, where possible, and some common conclusions could be drawn and are reported.

Trends for different materials

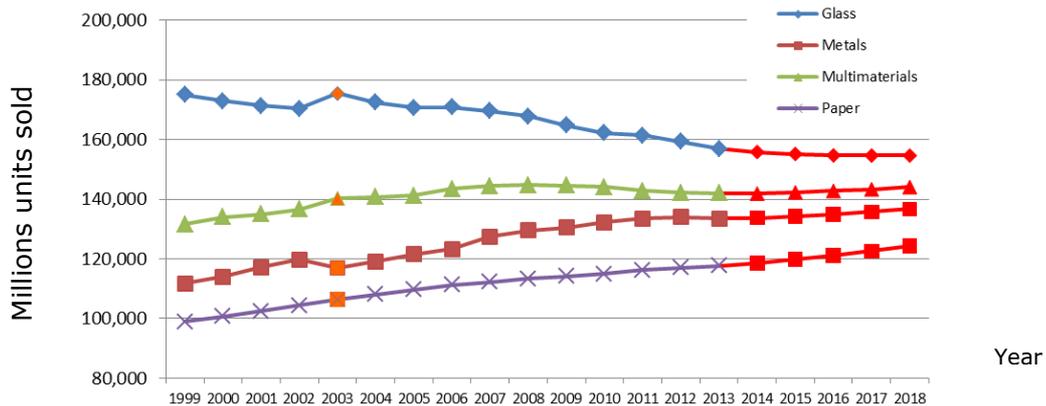
While for paper and plastics markets no differences of any kind can be highlighted, and the multimaterials market data show a very irregular trend over the years, for which no specific link to key years can be identified, some minor changes in trends can be identified for glass and metals between 2002 and 2004. The change in trend was identified in the German market data. Germany is the leading country in the production of glass, and it is one of the leaders for the metals market. The sudden increase of the glass volumes sold in Germany in 2002 seems to be paralleled by a decrease of metal volumes sold in the same years. There was no visible and substantial change in the volumes sold in Europe before and after the entry into force of the Framework Regulation for any of the materials for which data are available. In the following figures the graphic representation of the different materials trend is reported. The year 2004 is marked in orange, while years 2014-2018 are forecasted and shown in red.



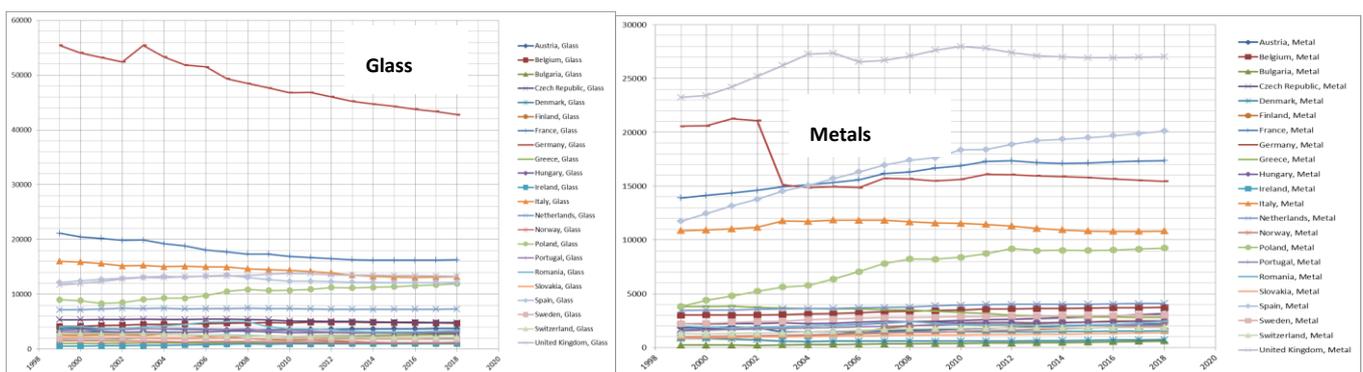
Comparison of the different materials market positions

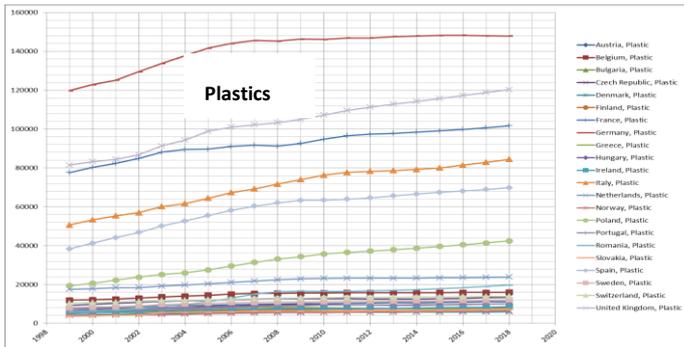
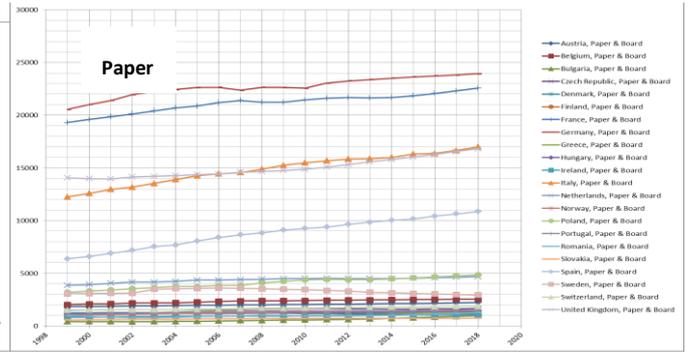
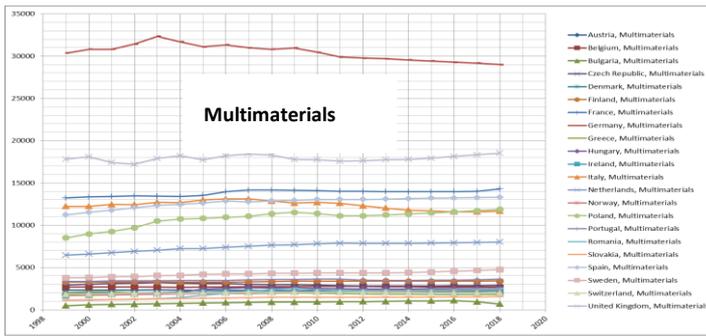
Comparison of the different materials market positions based on volumes

Euromonitor data show that the market of paper, plastics and metals are in constant increase (with plastics showing the most consistent proportional increase), while the glass market is in constant decrease. The forecasts for the period 2014-2018 confirm these trends. These trends can be seen in the graphs reported in the previous paragraph. Plastic FCM are representing the biggest portion of the FCM market, with volumes that are several times bigger than those of the other materials, over all the years for which data have been provided. The other materials seem to have similar amounts of pieces sold over Europe, above all in the most recent years, with the decrease in the glass market. The multimaterials market has an instable trend but is supposed to increase in the forecasts for the period 2014-2018. A graphic comparison of the different materials trend is shown in the following graph.



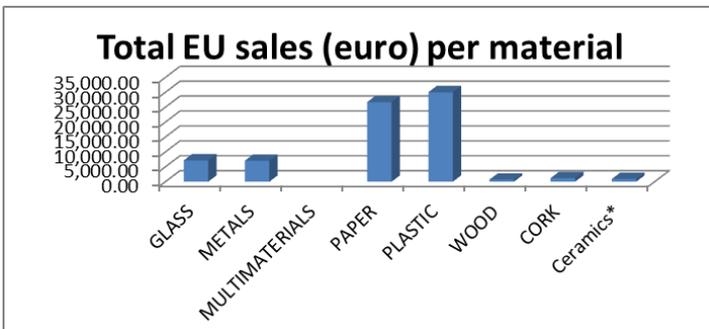
It might be interesting to see how the countries perform in the market of the different materials. Analysing Euromonitor data it is possible to identify the market leaders for all materials for which data are provided. Germany, France, UK, Italy, Spain and Poland seem to have the highest shares of the market for those materials for which Euromonitor data are available. Such conclusions can be seen in the following graphs that show trends over years. These trends represent millions unit sold for the countries considered and for the different materials. All materials show increasing volumes trends except glass. The trend for multi-materials is irregular, likely due to the potential irregular classification and definition of this class of products. Germany, France, United Kingdom, Italy, Spain and Poland appear to have the highest shares of the market for those materials for which Euromonitor data are available.



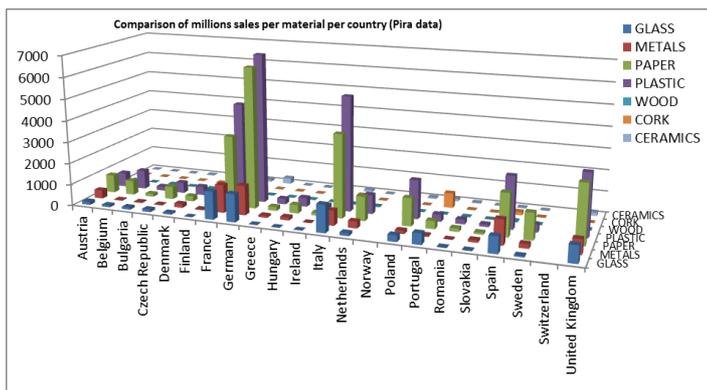


Comparison of the different materials market positions based on sales

The data provided by Pira were analysed. Plastic materials represented the largest market in Europe. The sales data provided by Pira showed that the paper market at EU level in 2013 was larger than other materials with values closer to that of plastics. It should be noted that the Pira data includes liquid/similar cartons (multimaterials) in the category paper. Sales of the different materials are compared in the following graphs.



The sales of the different materials vary greatly from country to country, with Germany, France and Italy seemingly being the leaders for most of the materials. UK, Spain and Poland also present high sales for most of the countries. These conclusions confirm the conclusions reached for the Euromonitor data on the market leaders, and can be graphically seen the following graph.



Cork, wood and ceramics (including ceramic tableware and porcelain/china tableware & kitchenware) sales are very low and almost not comparable with the other materials. The markets for wood and cork are concentrated in fewer countries, with cork market present only in 5 countries (Portugal, France, Spain, Italy and Bulgaria). The market share in the hands of small enterprises varies from material to material. While for paper and plastic the distribution of small, medium and large enterprises in the market per each country (using EU the average) is comparable (with a slight predominance of medium enterprises for plastics), for glass the market seems to be in the hands of large enterprises and for metals the market seems to be in the hands of large and medium enterprises (in equal shares). Alternatively, the market share in the hands of small enterprises is quite high for wood, cork and ceramics. The market shares based on the company size are shown in the following graphs.

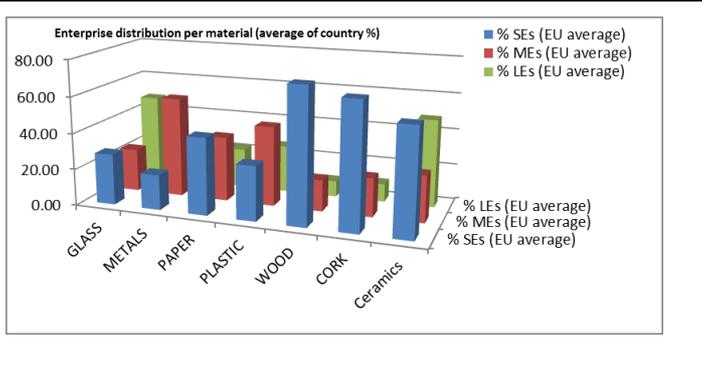


Figure above: EU average values of the percentage of shares of enterprises based by size

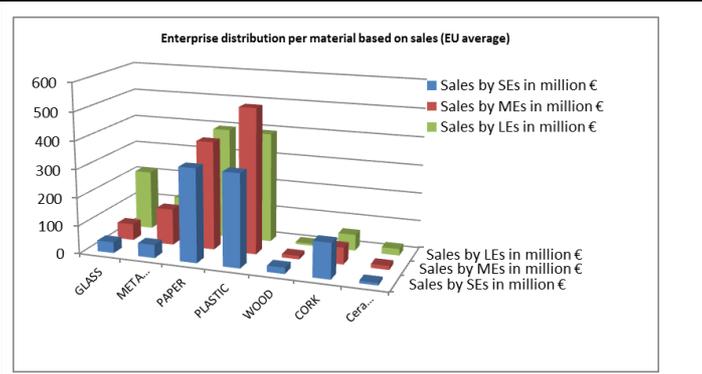
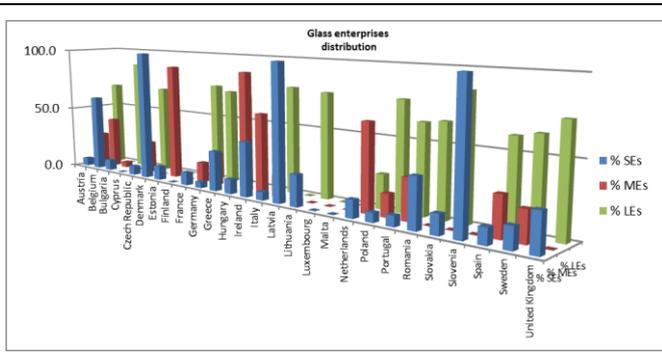
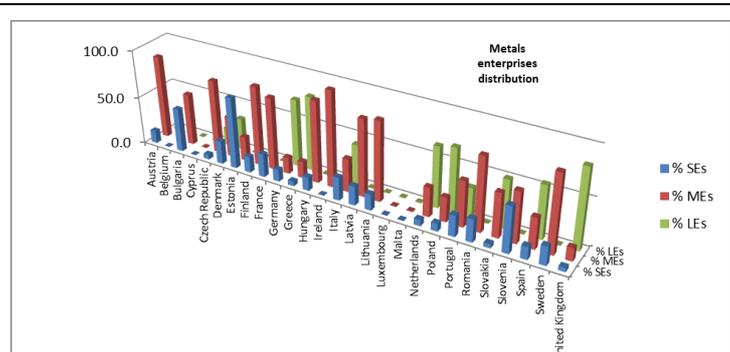


Figure above: distribution by size of enterprises, based on the average of sales

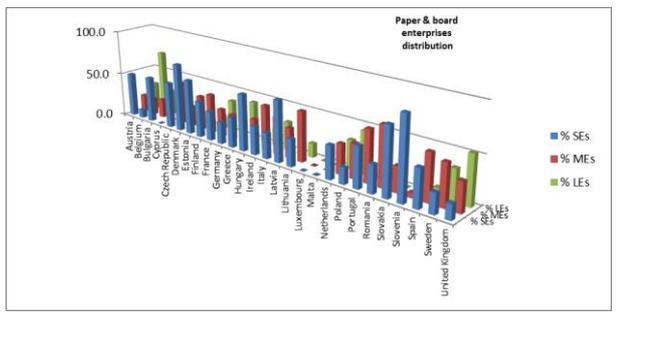
Representation by material:



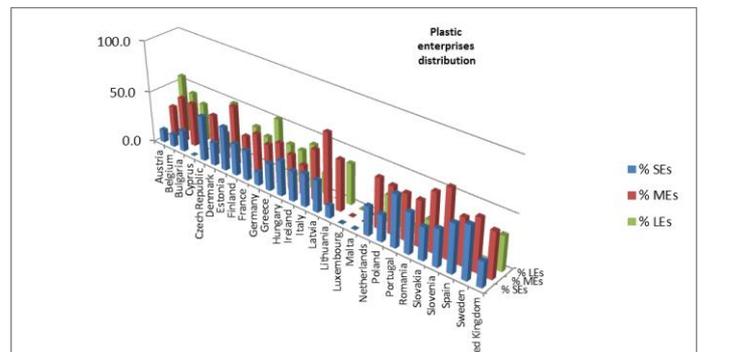
distribution by size of enterprises showing the shares per country for GLASS



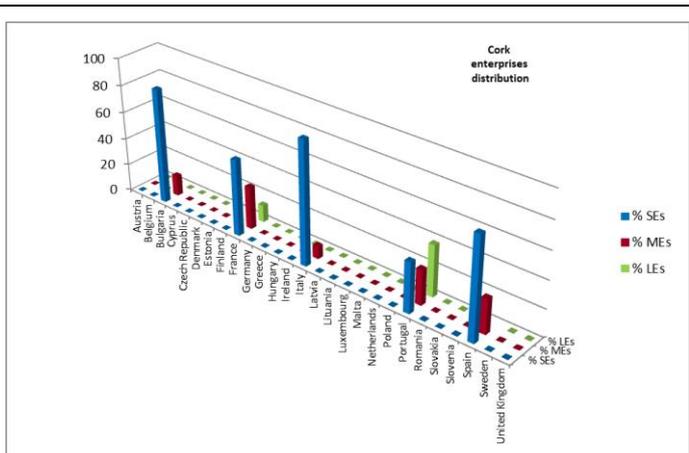
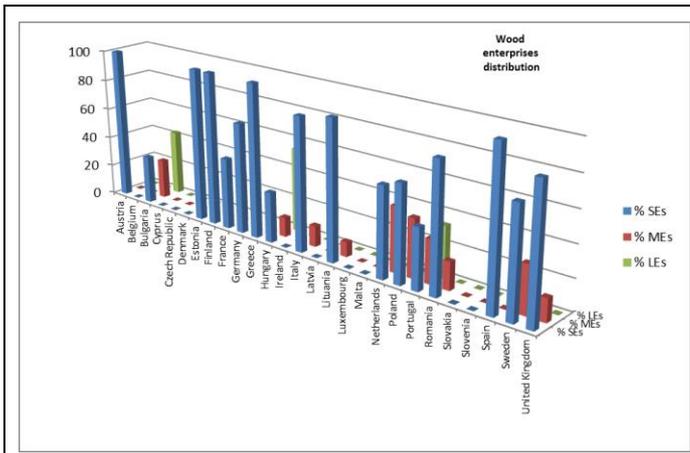
distribution by size of enterprises showing the shares per country for METALS



distribution by size of enterprises showing the shares per country for PAPER AND BOARD

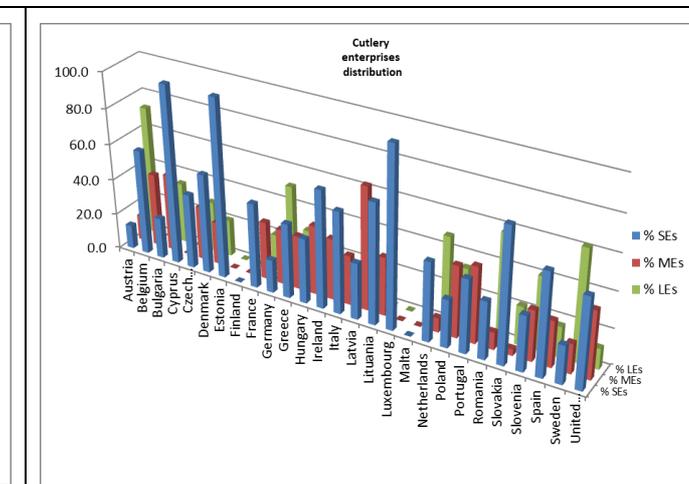
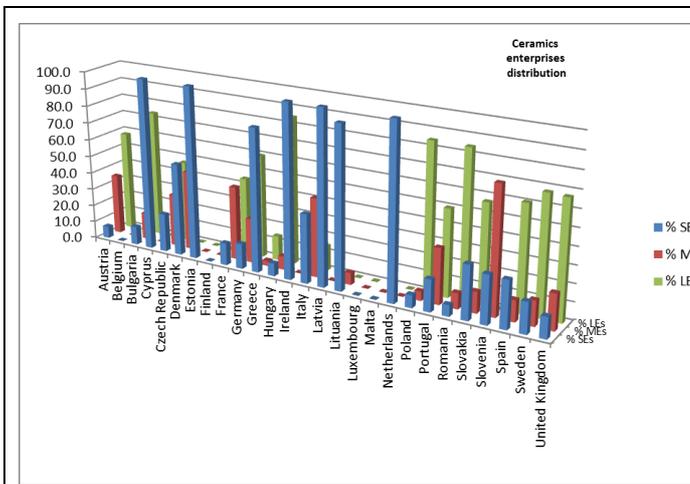


distribution by size of enterprises showing the shares per country for PLASTICS



distribution by size of enterprises showing the shares per country for WOOD

distribution by size of enterprises showing the shares per country for CORK



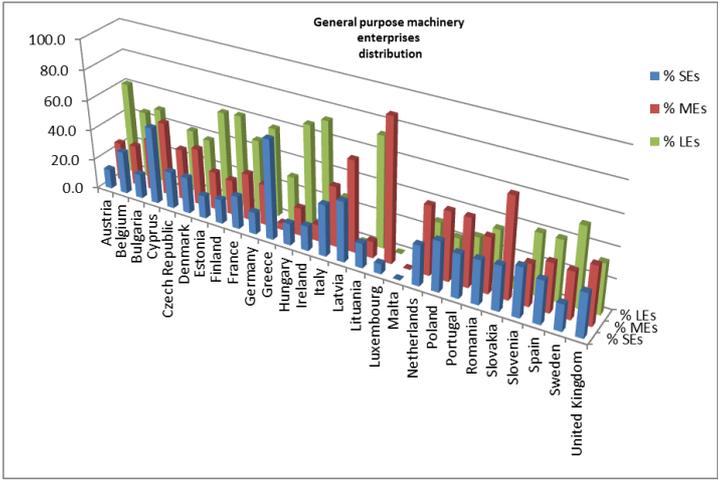
distribution by size of enterprises showing the shares per country for CERAMICS

distribution by size of enterprises showing the shares per country for CUTLERY

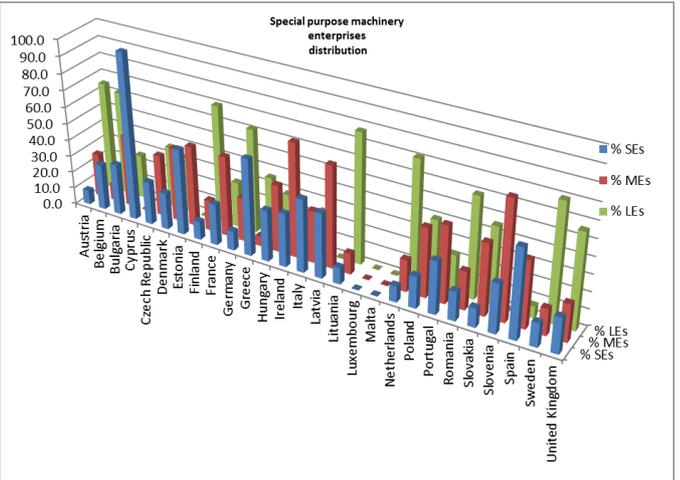
Cutlery and machinery

Distribution of enterprises by size: cutlery seems to be produced for the majority by small enterprises, accounting for half of the production, while machinery (both general purpose and special purpose) show a more or less even distribution in the size of enterprises, with a very minor predominance of medium and large enterprises.

In the next graphs the distribution of the enterprises by size is shown for cutlery and for machinery (both general and special purpose).

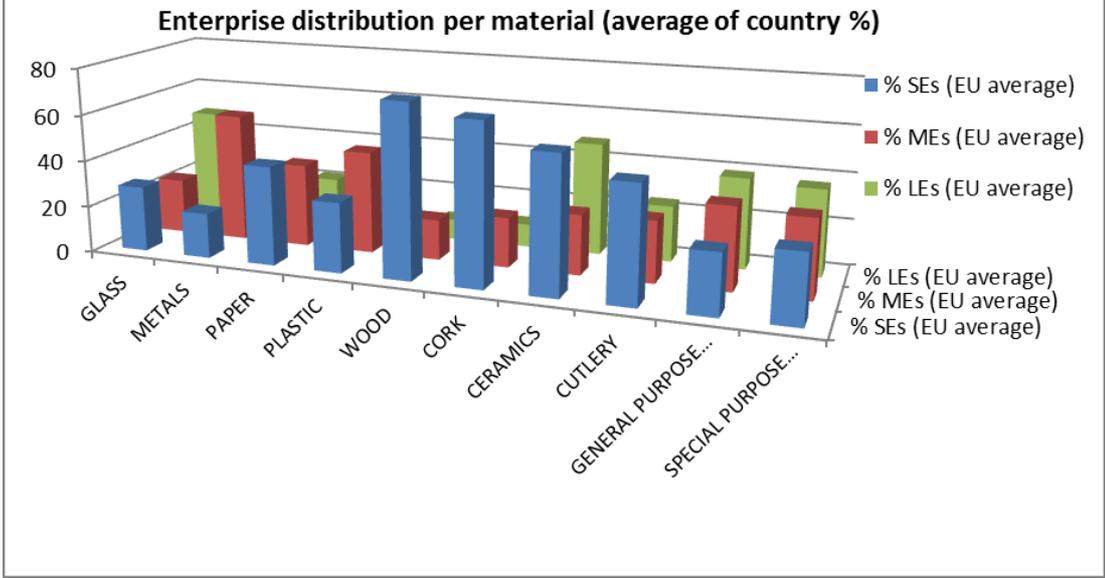


distribution by size of enterprises showing the shares per country for GENERAL PURPOSE MACHINERY



distribution by size of enterprises showing the shares per country for SPECIAL PURPOSE MACHINERY

The graphic representation of the EU average distribution of enterprises by size is shown in the next graph.



EU average distribution of enterprises by size

Annex 3. Summary of information for risk assessment

This section presents available documentation on methodology for risk assessment. It was received via the FIP network from EFSA and from national bodies. It also reviews information from the industrial professional associations.

EFSA

EFSA gives scientific opinions on the use of substances in materials that are regulated at EU level. Available guidance documents are:

- [Plastics](#): Guidance document on the submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA by the Panel on additives, flavourings, processing aids and materials in contact with food (AFC).
- [Active and intelligent substances](#): Guidelines on submission of a dossier for safety evaluation by the EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food.

EFSA also gives a scientific opinion on **recycling processes** that intend to give recycled plastic to be used in contact with food. Available documents are:

- [Guidelines](#) on submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food - Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC).
- Scientific Opinion on the [criteria](#) to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food.

EFSA has published several documents on risk assessment of chemicals. The list is included here.

- EFSA; Report of ESCO WG on non-plastic Food Contact Materials. Supporting Publications 2012:139
- EFSA Scientific Committee; Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC). EFSA Journal 2012;10(7):2750 [103 pp.] doi:10.2903/j.efsa.2012.2750
- EFSA/WHO, 2015. Threshold of Toxicological Concern Approach: Conclusions and Recommendations of the EFSA/WHO Expert Workshop DRAFT for public consultation
- EFSA, 2013. International Framework Dealing with Human Risk Assessment of Combined Exposure to Multiple Chemicals. EFSA Journal 2013;11(7):3313. doi:10.2903/j.efsa.2013.3313.
- EFSA Scientific Committee; Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011;9(5):2140 [36 pp.] doi:10.2903/j.efsa.2011.2140.
- EFSA Scientific Committee; Scientific Opinion on Risk Assessment Terminology. EFSA Journal 2012;10(5):2664. [43 pp.] doi:10.2903/j.efsa.2012.2664

National and professional guidance in the EU

Section III.A of "Overview of the risk assessment and of the national Regulations, as provided by the Member States" of the ESCO report (EFSA, 2012) has analysed the situation of the risk assessment in European countries. JRC desk research using two rounds of feedback from Member States and NRLs, in addition to the information collected from the questionnaires of DG Health and Food Safety in 2012, was integrated. The summary is presented below including a summary of the information collected regarding "who does what" in the field of risk assessment in EU.

List of national bodies that perform risk assessment

| MS | Body | RA and references |
|----|--|--|
| CH | Independent division within the Federal Food Safety and Veterinary Office (FSVO) | - RA of FCM substances - Reference is EFSA for new substances; now only for printing inks (in close cooperation with BfR) - Reference for P&B is CoE |
| AT | Austrian Agency for | - specific positive list of substances does not exist with exception of enamel which is covered by the Austrian |

| MS | Body | RA and references |
|----|--|---|
| | Health and Food Safety (AGES) | ceramic legislation - RA of FCM-substances is focused on "contaminants" (e.g. Bisphenols, Phthalates and other plasticizers, elements) in food or food simulants within the official control of FCM. - In special cases RA of FCM substances regarding the exposure and health effects to the population is carried out. - RA is performed using the usual processes, e.g. laid down by EFSA (in addition e.g. TTC-Concept) or WHO. |
| BE | Conseil Supérieur de la Santé: | - advice required by the ministry of public health; Sci-Com of Agence fédérale pour la sécurité de la chaîne alimentaire (AFSCA): advice required by AFSCA - RA details not available - The assessments differ case by case depending on available data, on type of material. European standards are followed as much as possible. |
| BG | Not available | - Details not available |
| CY | Risk Assessment Unit in the State General Laboratory | - dietary RA, not of FCM substances - RA for some specific cases - For no specific SML, RA based on existing TWI, ADI, etc. + consumption data Additional information Exposure/risk assessment is performed in the cases where there are no specific SML for some FCM either at National level (or other MS or at EU level). Risk assessment is based on the existing TWI, ADI, etc. and the consumption data. |
| CZ | National Institute of Public Health (NIPH) | - RA of FCM substances - Reference is SCF-FCM, EFSA - Some substances present on national positive lists for specific materials (particularly for paper and board) come from BfR recommendations. Additional information National regulation Act No 258/2000 Coll on Public Health Protection, specific measure: DECREE No. 38 of the Ministry of Health of 19 February 2001 Coll., on hygiene requirements on products intended for contact with foodstuffs and foods CZ Zakon 258-2000 introduces very generally the need for risk assessment, without any specific detail. (Hlava V, díl 1, oddíl 1, § 79). The risk assessment for substances in positive lists is performed by the national authority for risk assessment, the National Institute of Public Health (NIPH), based on the technical dossiers submitted by the petitioners according to national rules. Since 2004 the risk assessment is performed by the NIPH and is based on the dossiers submitted by the petitioners, according to the SCF-FCM guidelines and the Note for Guidance of EFSA for plastic FCM. Some substances present on national positive lists for specific materials (particularly for paper and board) come from BfR recommendations. |
| DE | Bundesinstitut für Risikobewertung (BfR) | - RA of FCM substances (BfR Opinions) - Reference is EFSA for substances to be used in P&B: specific guidance for the determination of exposure assuming 100 g/m ² paper and 6 dm ² paper are in contact with 1 kg food - RA for substances used in printing inks are prepared together with FSVO (CH). - Exchange of information with RIVM (NL) on substances which are requested for addition to DE Recommendations and vice versa on petitions for the Warenwet (NL). - Recently a closer cooperation with RIVM in the risk assessment of substances for FCM was discussed. Additional Information Risk assessments are published in form of –Recommendations on FCM (The BfR Recommendations), which are not legal norms. They represent the current state of the scientific and technical knowledge for the conditions under which consumer goods made of high polymer substances meet the requirements of Article 3, paragraph 1 a of the Regulation (EC) No 1935/2004 in respect to their health safety. The Recommendations mainly consist of substance lists; general requirements are also included. Each recommendation focuses on a specific kind of food contact material (e.g. silicones). Restrictions are normally formulated as maximum content in the material. For the inclusion of a substance in the list, a petition has to be filed which has to follow the Note for Guidance of EFSA for plastic FCM . Risk assessment is done by the Federal Institute for Risk Assessment (BfR) which is supported by the respective Subcommittees of the BfR Committee for Consumer Products. If all requirements are met the respective substance is included in the Recommendation. •DE (EFSA Note for Guidance for Petitioners presenting an Application for the Safety Assessment of a Substance to be used in Food Contact Materials prior to its Authorisation) → used as basis for assessment of substances for which an application is submitted (e.g. for substances to be included in BfR-Recommendations) •DE (EFSA Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC)) → taken into account in other cases than applications •DE (EFSA Margin of Exposure approach) → taken into account in other cases than applications NOTE: The BfR publishes "Recommendations" which are treated like recommendations for GMP and contain positive lists etc. Apart from this, the BfR also publishes "Opinions" which contain the results of risk assessment on current topics (e.g. ITX) |
| DK | Danish Technological University (DTU) (framework contract) | - RA of FCM substances - do not follow EFSA's note for guidance of FCM substances - Substances with TDI or exposure reference values (used also for substance of the same group): case by case - Where a margin of exposure reference value, BMDL10, is available, margin of exposure calculations have been used for evaluation of the potential health risks associated with a given migration/exposure. - Potential exposure of chemicals from FCM: most testing using food simulants (data converted into mg/kg food by using the appropriate surface-volume ratio or the factor 6 dm ² /kg food). - Worst case scenario of food consumption to get an estimate of worst case exposure of a given substance is used. - Non evaluated substances: hazard identification by testing case by case and by using different tools (in-vitro test methods, read-across methods and animal testing). For endocrine disrupting substances, mixture effects are also under evaluation. - Potential risk associated with estimated exposure is evaluated if data on substance hazard is available. |
| EE | No national body for RA. Estonian University of Life Sciences provides opinions /expertise - | - Setting up a system for RA of FCM substances - In preparation, but limited resources |

| MS | Body | RA and references |
|----|---|--|
| | Cooperation with German Federal Institute for Risk Assessment | |
| EL | Scientific Council of Food Control (ESET) | <ul style="list-style-type: none"> - No RA of FCM substances - Any available experimental data, and RA of other EU MSs - No risk assessment of FCM chemicals due to the lack of governmental funding. P&B: limits are taken from CoE |
| ES | Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) | <ul style="list-style-type: none"> - RA of FCM substances - Reference for P&B: CoE - So far, no toxicological evaluations of non-plastic FCM substances Additional information (Resolución de 4 de noviembre de 1982 - B.O.E. 24.11.1982) for polymeric materials lists the substances to be used for the manufacture of macromolecular compounds; it includes under its scope silicones, rubbers, coatings, ion exchange resins and adhesives. The risk Assessment is performed by the Spanish Food Safety and Nutrition Agency (AESAN) and petitioners can be official administrations, industry, consumers associations or the AESAN. So far, no toxicological evaluations have been performed of substances used in non-plastic FCM." |
| FI | Finnish Food Safety Authority (Evira) | <ul style="list-style-type: none"> - No RA of FCM substances; CM business operators manufacturing, converting or importing plastic materials and articles, are prioritized for controlling since that is covered by legislation and guidance. - Reference is EFSA - Use of internationally accepted RA principles. Recommendation to operators to use FACET. FI focusses their resources on enforcement activities. |
| FR | Agency for Food, Environment and Occupational Health and Safety (ANSES) | <ul style="list-style-type: none"> - RA of FCM substances - Reference is SCF-FCM, EFSA - A RA for substances with a molecular mass of <1000 Dalton in printing inks has to be performed. Additional information The risk assessment is performed by French Agency for Food, Environment and Occupational Health and Safety (ANSES) It is based on the dossiers submitted by the petitioners, according to the SCF-FCM guidelines and Note for Guidance of EFSA for plastic FCM. Consequently, the evaluation is done according to the usual tiered approach, but in case of very low migration and in absence of genotoxicity structural alerts, a threshold of 0.5µg/kg food is applied. The advices and scientific opinions are usually endorsed into laws, or considered as major recommendations. A compendium of these regulatory decisions is edited by the Journal Officiel de la République Française (JORF) and is known as Brochure 1227 JORF 1994. Matériaux au contact des denrées alimentaires, produits de nettoyage de ces matériaux. Brochure 1227. 5Paris : Journal Officiel de la République Française (éditeur), collection Brochure 1227, 1994/01, 260 p., tabl., ISBN 2-11-073441-8, FRA). For printing inks: FR Avis DGCCRF du 10 juin 2010 specifies that for substances with molecular mass <1000 Dalton risk assessment has to be performed. (Chapter 3.2.1) |
| HR | Croatian Food Agency | <ul style="list-style-type: none"> - RA for some specific cases - Reference is EFSA's note for guidance for FCM substances - Only 4 cases so far (2012-2014) |
| HU | National Food Chain Safety Office (NFCSO) (CA) | <ul style="list-style-type: none"> - general RA procedure (dietary RA) - No experience on FCM RA. Use of EFSA opinions |
| IE | Food Safety Authority of Ireland | <ul style="list-style-type: none"> - no systematic RA of non-harmonised FCMs - A RA assessment may be carried out on an ad-hoc basis (as part of an incident, rapid alert, etc.), - reference SCF/EFSA note for guidance of FCM substances. |
| IT | Istituto Superiore di Sanità (ISS) | <ul style="list-style-type: none"> - RA of FCM substances - Reference is SCF-FCM (now EFSA) - Differences in migration testing for some materials (e.g. P&B: compositional requirements; stainless steel: pre-established limits for metals etc.). - Only legislations from other EU MS that are notified to TRIS system are under mutual recognition. - P&B: Specific provisions indicated for recycled fibres (admitted only in special cases). Additional information Risk assessment is performed according to the SCF-FCM guidelines. To get positive listing, a technical dossier submitted by the petitioners has to be evaluated by the Istituto Superiore di Sanità (ISS), the Technical/Scientific Body of the Ministry of Health, where the risk assessment is performed. The final decision on the positive listing is laid down by the Ministry for Health, the Management Body, after advice from the Consiglio Superiore di Sanità (Higher Health Council). |
| LT | National Food and Veterinary Risk Assessment Institute (NFVRAI) | <ul style="list-style-type: none"> - RA of FCM substances in preparation - No risk assessment works on FCM yet |
| LV | Institute of Food Safety, Animal Health and Environment BIOR | <ul style="list-style-type: none"> - Reference is EFSA-FCM note for guidance for FCM substances - no RA done yet for substances in non-harmonised materials - mutual recognition principle to the FCM is applied when LV gets RASFF notification from other MSs where there is national legislation according material groups which do not fall under Article 5 of Regulation 1935/2004. |
| LU | none | - Use of recommendations from DE, FR, BE or EFSA |
| MT | Not available | - Details not available |
| NL | Commission G4 (Ministry of Health, National Institute for public Health and the Environment (RIVM), Inspectorate, and Industry) | <ul style="list-style-type: none"> - RA of FCM substances, RA for NIAS based on TTC in development - Reference is EFSA (with sometimes adjustments on exposure scenarios) - Most substances on the list from decades ago on basis of only limited information Additional information New substances are evaluated by Commission G4, in which the Ministry of Health, the National Institute for public Health and the Environment (RIVM), the Inspectorate, and the Industry are represented. NL Commodities Act (Packagings and Consumer Articles) has a chapter on risk assessment of non-intentionally added substances (NIAS) based on the TTC principle. (Hoofdstuk III). Risk assessments (Summary Data Sheets) are made according to the same method used by EFSA for plastics, with sometimes some adjustments on the exposure scenarios, e.g. |

| MS | Body | RA and references |
|-------------------|---|---|
| | | for some special products, lower surface to content ratio's (than the 6 dm ² per kg food as used for plastics) are used. Most substances however have been put on the list decades ago on basis of only limited information. |
| NO | Norwegian Scientific Committee for Food Safety (VKM) on requests from the Norwegian Food Safety Authority | <ul style="list-style-type: none"> - RA of FCM substances - Reference not available - Very few RA performed (last in 2008 for printing inks substance) <p>Additional information Risk assessments of non-plastic FCM are conducted by the Norwegian Scientific Committee for Food Safety (VKM) on requests from the Norwegian Food Safety Authority. It is done in the form of summary data sheets</p> |
| PL | National Institute of Public Health – National Institute of Hygiene | <ul style="list-style-type: none"> - RA of FCM substances - Reference is EFSA, BfR , CoE or industry recommendations <p>Additional information BfR , CoE or industry recommendations are used as guidance values for risk assessment related to all materials for which no specific Polish measures exist (namely adhesives, cork, ion-exchange resins, metals and alloys, printing inks, rubbers, silicones, varnishes & coatings, waxes, wood and multimaterials).</p> |
| PT | <i>Not available</i> | <ul style="list-style-type: none"> - <i>Details not available</i> - P&B: CoE is used as guidance for RA |
| RO | <i>Not available</i> | <ul style="list-style-type: none"> - <i>Details not available</i> |
| SE | Swedish National Food Agency | <ul style="list-style-type: none"> - RA of FCM substances - <i>Details not available</i> <p>Additional information SE: Risk assessment provisions: Report on risk profile for food contact materials – Environmental and Food Agency of Iceland (2011); ; Guidance Guide on food packaging safety (January 2012)</p> |
| SI | National Laboratory of Health, Environment and Food | <ul style="list-style-type: none"> - RA of FCM substances; do not use EFSA's note for guidance for substances in non-harmonised materials - Applicable RA guidelines; exposure scenario's: CoE, BfR (case-by case) - Risk characterization: health based values set by one of the competent organizations /committees (EFSA, SCF, SCHER, WHO, US-EPA, ATSDR,...) <p>Additional information When Slovenian authorities perform official control and risk assessment of specific sample of FCM, they use and refer to Resolutions from the Council of Europe or guidance documents from other countries (e.g. the German BfR recommendations).</p> |
| SK | <i>none (part of NRL work)</i> | <ul style="list-style-type: none"> - No RA performed for substances for non-harmonised materials - Reference is EFSA-FCM note for guidance for FCM substances - the necessity of RA of FCM substances is not fixed by law - P&B: list consists of substances which were evaluated by other MSs <p>Additional information Decree of Ministry of Agriculture of Slovak Republic and Ministry of Health of Slovak Republic of 9 June 2003. The risk assessment is not part of this decree.</p> |
| UK | Food Standards Agency (FSA) | <ul style="list-style-type: none"> - FSA supported by the Committee on Toxicity, (independent Scientific Committee on advice to FSA). - general RA procedure - No national legislation on FCM - comply with Article 3 of EC 1935/2004 |
| Nor dic countries | Norden | <p>Document: Norden ("Food contact materials – in-house documentation and traceability, Nordic check lists to industry and trade ", TemaNord 2008:517, Copenhagen, Nordic Council of Ministers</p> <p>Provides guidance on control, traceability and declaration of compliance for FCM operators in general, including all the actors of the supply chain. It is based on EU requirements and proposes lists of information to be retrieved by suppliers to prepare an appropriate in-house supporting documentation. It states that "specific evaluation and risk assessment would have to be conducted on specific materials and articles, and the specific foods in contact and the processing conditions for the uses."). Another Norden guidance specific to Paper and Board Food Contact Materials reports the need to perform risk assessment on NIAS. (Chapter 6.6, Annex 4)</p> |
| Industry | Plastics Europe | <p>Document: "Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under Article 19 of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food".</p> <p>The document considers exposure and toxicological assessment of a substance and its risk characterization. With this guidance document, PlasticsEurope intends to explain how the plastics (plastic intermediate material) producers interpret and respond to their risk assessment obligations for non-listed and non-intentionally added substances under the article 3 of the Framework Regulation (Regulation (EC) No 1935/2004) and article 19 of the Regulation on plastic materials and articles intended to come into contact with food (Regulation (EU) No 10/2011), based on internationally recognized tools and scientific knowledge available to them at the time of writing. This is a living document which will be updated when and if needed.</p> |

Annex 4. Information on generic frameworks on FCMs

4a- Registration of FCM operators

The information presented was found or received from an ad-hoc questionnaire to MS competent authorities. It is only as exhaustive as the replies and feedback obtained for the purpose of this report. The data is presented in the format of a summary.

Overview of national measures in the EU MSs regarding information on registration of business operators:

| MSs | Legislation | FCM registration (for whom) | Responsible entity/ Registry | Applications for FCM business operators |
|-----|---|---|---|--|
| AT | LMSVG (Austrian Food Safety and Consumer Protection Act) | All food contact operators [Art. 6 of Reg. (EC) 852/2004] | Federal Minister for Health, or by the federal institution 'Statistics Austria', | Provincial Governor for the approval of establishments (as per Food Hygiene Approval Regulation, Federal Law Gazette II No 231/2009) |
| DK | BEK nr. 1007 af 19/09/2014 (Afsnit IV, Kapitel 5, §20) | Importers or manufactures of FCM (exemption if market <1,000 pieces and 50,000 kr per year) | Danish veterinary and Food Administration website | Website contains form to be filled by operators, where the company details, the type of business (with reason for application) and the starting date of the business are requested. |
| EE | Toiduseadus (Food Act) RT I 1999, 30, 415, last amended by RT I, 9.10.2014 | All food business operators; in addition to Art. 6 of Reg. (EC) 852/2004 (Ch.1, §8). | Veterinary and Food Board | Data of operator and business, data of representative and type of business (Ch. 1, §7). Application for registration in the register of economic activities for data on the materials and groups of articles intended to be brought into contact with food (Ch. 4, §31). |
| ES* | Real Decreto 191/2011 | FCM operators food businesses and establishments are subject to registration (those located in any other Member State of the European Union may also be entered in the Register | Registro General Sanitario de Empresas Alimentarias y Alimentos | <ul style="list-style-type: none"> - Spanish Agency for Food Safety and Nutrition of the Ministry of Health. - Starting date of business, special authorisations or accreditations required for specific products) - Requires notification for any amendment of inserted data and communication if cessation of activities, and includes procedure for entry, amendment and cancellation of data. - Article 38(4) of Law 30/1992 of 26 November 1992 specifies to which bodies of public authorities the applications should be submitted. |
| FI | Elintarvikelaki (Food act) 2006/23, amended by SDK 68/2015 | operators | No further description found | - more detailed provisions on the registration will be issued in a Ministry of Agriculture and Forestry decree (not available as of yet). |
| LV | Medžiagu ir gaminių, skirtų liestis su maistu, Geros gamybos praktikos taisyklės (Ch. V, 29-44, 6.pielikums). | Companies dealing with manufacture, processing and distribution of materials and articles | Registry of Surveillance Objects | <ul style="list-style-type: none"> - Company data, type of activity, form (annex 6) - Procedure for suspension and renewal of distribution and use (annual surveillance program) |
| NO | Forskrift om materialer og gjenstander i kontakt med næringsmidler (matkontaktforskriften), FOR-1993-12-21-1381 | Production, importation or sale of FCM | Norwegian Food Safety Authority. (Kapittel I, §4c). | - Data of premises and responsible person, type of activity, including imports, type of materials) |
| PL | Law 171 poz. 1225 of 25 August 2006 and its amendments (Dział IV, Art. 61, 63-67) | Food contact operators, 14 days before they are allowed to start their business | <ul style="list-style-type: none"> - district sanitary inspector or - state border sanitary inspector | <ul style="list-style-type: none"> - Registration and approval, conditional approval, extending conditional approval, suspension and withdrawal of approval for food businesses - Article 67 lists all information to be provided for application (location data of company and identification data of responsible person, type of business, start date of activity, information on official controls carried out in the food business). |
| SI | Decree of the Official Gazette of the Republic of Slovenia No 57/2008 of 10.6.2008, p. 6225 | Companies that produce, process and first market materials and articles intended to come into contact with foodstuffs. | Registration applications can be submitted online, using the official website indicated by the decree. | <ul style="list-style-type: none"> - official form for business / plant details, type of activity, type of materials/products submitted to the authorities for registration - foresee monitoring of implementation by Health Inspectorate of the Republic of Slovenia (ZIRS) - includes fines for failing to comply and conditions for withdrawal of registrations. |

* Regarding Industry guidance documents, Spain has a GMP document (Guía para la Implantación de las buenas prácticas de fabricación para empresas que elaboran materiales y objetos destinados a estar en contacto con alimentos) done by CONSEBRO- Asociación de Industrias Agroalimentarias de Navarra, La Rioja y Aragón, that mentions that companies dealing with FCM must be registered in the Registro General Sanitario de Alimentos (RGSA). It also contains some information about the details required for the registration and who has to register.

4b - Declaration of compliance and supporting documents

The harmonised EU framework regulation requires that a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 must be available for all materials and articles, intermediated products or semi-finished products at any stage of the commercial cycle, except for the retail stage. Information was found or received from MS competent authorities. It thus can only be as exhaustive as the input or feedback obtained for the purpose of this report.

Overview of national measures or information in the EU MSs regarding DOC and supporting documents (SDs):

| MSs | Legislation | DoC | Supporting documents |
|-----|---|--|--|
| BE | Arrêté royal du 11 mai 1992 (Art 8,9) | Certification that FCM comply with rules | - Technical information to ascertain the composition of FCMs |
| BG | Ordinance n. 3 of 04/06/2007, Art 2 Annex1 | <ul style="list-style-type: none"> - Name and address of the company producing the materials or articles or of the person importing them - Date of issue of the declaration - Name, type and intended use of FCM - Statement that material / articles comply with rules - updated in the event of any substantial change in the production of the material or article that may cause changes in the migration of substances | <ul style="list-style-type: none"> - DoC and its relative supporting information documented (to be available at the request of the competent authorities). - Results of the laboratory tests performed, the test conditions and the name and address of the test laboratory |
| CZ | Zakon 258/2000 states in para. 1,2 of section 26 | <ul style="list-style-type: none"> - Producer/importer must ensure their products are safe and test/assess compliance with requirements - Importers do not need to test and assess the composition and properties of products if this is done by the producer abroad and the relative documentation is provided (to be available to public authorities if needed) | "an implementing regulation will specify the scope of furnishing objects of common use with a written statement and instructions and their requisites". |
| DK | Order 822 of 26/06/2013 annex 5 point 5 | <ul style="list-style-type: none"> - FCM must have DoC when put on the market in earlier stages than retail stage - identification of the materials or substances - DoC must document compliance with applicable rules - To be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available | <ul style="list-style-type: none"> - SDs showing that FCMs and substances used to produce them respect the provisions of the order - Reporting test results / calculations - Evidence on safety or reasoning demonstrating compliance - SDs prepared and shown to the control authorities. |
| FR | "Note d'information n°2014-108 du 5 juin 2014. Objet : Matériaux et objets destinés au contact des denrées alimentaires" Section 2.5, 2.6, 3.3 | <ul style="list-style-type: none"> - DoC with the applicable regulatory texts - Information on the substances - Use of FCMs (in particular, contact time and temperature, type of foodstuff, type of contact) - Operations under a traceability system - Art. 6 of Decree No 2007-766 amended by No 2008-1469 requires written declaration on compliance with provisions of Art. 3 and 4 of the Reg. 1935/2004 for FCM not already covered by EU measures (all stages except sale or free distribution) - Provided to the inspection authorities on demand - Does not necessarily have to be physically attached to the goods (i.e. paper or electronic format) - Must be updated in the event of regulatory amendments or changes likely to alter the inertness | <ul style="list-style-type: none"> - Composition of the FCMs - Treatments carried out - Specific migration tests, overall migration tests, organoleptic tests, calculations - Other evidence of compliance - Responsibilities of operators with respect to compliance work along the supply chain |
| DE | guidance "Good Manufacturing Practice (GMP) and Compliance Declaration for Food Contact Materials: Interpretation of the Official Control (2009/52)" Section 2.1, 3.3 | <ul style="list-style-type: none"> - DoC is required for the materials that are specifically regulated (plastic, cellophane, ceramics, recycled plastic and certain epoxy compounds). - Information of DoC in Reg. (EU) No 10/2011 is useful also for other materials - For packed foodstuffs, the food manufacturer is responsible for the entire product, including the packaging materials and the related DoC. - Issues on migration of components (substances used, impurities and reaction products, migration thresholds, purity requirements and limits in the FCMs and foodstuffs) might be part of the DoC | SDs supporting the DoC: <ul style="list-style-type: none"> - Formulas, analysis data and mathematical models on the migration process. - Data and laboratory reports - Documentations on the evaluation of substances, - Declarations / in-house considerations |
| IT | D.M. 1973, Note n. 2964 -2006, Note 32249-2011, Linee guida (CAST) on Reg. EC 2023/2006 | <ul style="list-style-type: none"> - DoC must be issued by the producer - Data of the manufacturer or the importer - General reference legal requirements and specific legal requirements, - Information about the identity of the producer/ importer, type of material used, usage restrictions - Date and signature of the individual responsible | <ul style="list-style-type: none"> - Specification of composition - Certification/DoC from the supplier - Test reports on starting material, raw materials, semi-processed and/or finished articles - Any information demonstrating compliance to Competent Authorities |
| NL | Commodities Act Regulation on packagings and consumer articles states in Ch. 0, point 0.9 | <ul style="list-style-type: none"> - Identity and address of the business operator - Identity of the materials or articles, intermediate products or semi-finished products thereof, or substances intended for the manufacture of FCMs - Date of the declaration - Declaration that the material is compliant with the requirements of the reference legislation - Information on the presence of any restricted substance with its levels of specific migration | |

| MSs | Legislation | DoC | Supporting documents |
|--------|--|---|---|
| | | <ul style="list-style-type: none"> - Specific use(s) intended for the material - Written declaration on compliance with provisions of Art. 16 of Reg. 1935/2004 for all FCMs (all stages except retail), intermediate products and semi-finished products thereof, as well as substances - DoC has to be reissued if any change takes place | |
| NO | Reg. 1381/1993 (Art. 4a, 25a); Food Act Ch. II, §14, 15 | <ul style="list-style-type: none"> - DoC has to be issued by the company. | <ul style="list-style-type: none"> - SDs to substantiate compliance - Submitted to Authority on request - Food Act requires provision of SDs to the enforcing bodies. |
| Norden | Guidance "FCMs: In-house documentation and traceability, Nordic check lists to industry and trade" (Ch. 2, 3 and 4) | <p>Information to be inserted in the DoC for each actor of the chain:</p> <ul style="list-style-type: none"> • Name and address of supplier • Information on substances/materials • Risk assessment of chemicals • Information on restrictions • traceability • information on use • DoC shall be updated when changes happen | <ul style="list-style-type: none"> - lists of information to be retrieved by suppliers to prepare an appropriate in-house SD. - SDs have to support all information required in the DoC |
| SE | Norden Guidance, in chapters 2, 3 and 4 (see above) General guide on food packaging safety from Normpack | <ul style="list-style-type: none"> - DoC must be produced for materials that are governed by regulations and directives for specific products and substances, i.e. plastics, ceramics, epoxy derivatives, elastomers, rubber, cellophane (regenerated cellulose) and for active and intelligent materials - Applies to all materials - Reports as example Reg. EU 10/2011 requirements among which: <ul style="list-style-type: none"> • Identity and address of the business operator • Type of material • Date of the declaration • Declaration that the material is compliant with the requirements of the reference legislation • Information on the presence of any restricted substance with its levels of specific migration • Specific use(s) intended for the material - Annex 5 gives examples of questions to be answered in self-monitoring, - Annex 6 reports the Normpack certificate as example of a document in which a neutral party certifies the FCMs is fit for purpose and that consultation has taken place between food producer and packaging supplier. | <p>Mentions the need of SDs. (The packaging manufacturer is responsible for having documentation available that shows what the packaging can be used for)</p> |
| SI | Act on health suitability of foodstuffs (repealed at end of 2015) Art. 20, 24 | <ul style="list-style-type: none"> - States that FCMs that are being imported may bear a certificate from an authorised body of the exporting country stating that they are health-compliant. | <ul style="list-style-type: none"> - provisions of SDs to inspectors on: <ul style="list-style-type: none"> • Type, composition and purity of raw material • Chemicals used in the manufacture of FCMs |
| ES | Guía para la Implantación de las buenas prácticas de fabricación para empresas que elaboran materiales y objetos destinados a estar en contacto con alimentos) | <p>done by CONSEBRO- Asociación de Industrias Agroalimentarias de Navarra, La Rioja y Aragón, section 5.6, Annex 4, point 1, 3</p> <ul style="list-style-type: none"> • Manufacturers must have a DoC (for regulated materials) or a document that certifies the suitability of the material in contact with food (for materials where it is not obligatory to draw up a DoC) • The final article can only be compliant if all the requirements have been met throughout the production chain • DoC has to be required from raw materials suppliers • Compliance must be documented at each stage of manufacturing | <ul style="list-style-type: none"> - It reiterates the need of complete documentation regarding the life of the materials/products and production process but without specific link to DoC, such as: <ul style="list-style-type: none"> - Specifications - Formulae - Processes relevant to compliance and safety of the finished material or article - Records covering the various manufacturing operations performed which are relevant to compliance and safety of the finished material or article and with respect to the results of the quality control system - Documentation must be checked and maintained |
| CH | Joint Industry Group (JIG) on packaging for food contact prepared | <p>Provides a checklist to assess the completeness and quality of a DoC, that includes also the following required information:</p> <ul style="list-style-type: none"> • Identification and address of all involved operators • Type of material • Date of declaration • Compliance with legislation • Information about substances used • Intended use of material | <ul style="list-style-type: none"> • The explanatory part of the checklist implies that SD is necessary, including it in some explanations, even without explicitly requiring it. |
| EU | "Industrial guidelines on traceability of materials and articles for food contact" | <p>Note: By industry professional associations APEAL, BLIC, CEFIC FCA, CEI-Bois, CEPE, CEPI, CITPA, CIPCEL, CPIV, EAA, ETS, EuPC, FPE, FEFCO/ProBox, FEVE, PlasticsEurope, SEFEL</p> | <ul style="list-style-type: none"> • information that has to be documented in order to ensure traceability at all stages of the manufacture of FCM and for every company involved in the production |

4c - Basis for enforcement

Note: in the analysis of enforcement information, a broader meaning of the term has been taken. Thus, material researched encompassed not only provisions on the setting/management of enforcement bodies or enforcement campaigns but also considered available information on the mean to perform the enforcement (e.g. availability of testing methods).

Overview of national measures or information in the EU MSs on information/requirements related to basis for enforcement:

| MS | Legislation | Descriptions of enforcement requirements |
|----|--|--|
| AT | BGBl. I Nr. 13/2006 BGBl. I Nr. 63/2002 Accreditation Act 2012 BGBl. II Nr. 161/1997 BGBl. II Nr. 275/2008 | BGBl. I Nr. 13/2006: - institutions and bodies entrusted or that may carry out compliance assessment of food and FCM samples taken during official controls and inspections (§ 65 (1), § 72, § 73) - accreditation for such institutions and bodies (all tasks of the Austrian Agency for Health and Food Safety are specified in the BGBl. I Nr. 63/2002 and all the information on the accreditation requirements are set in the Accreditation Act 2012) (§ 68 (2), § 72 (4), § 73 (4)) - methods to be used for compliance testing must be suitable (§ 68 (1)) - general requirements for the professional qualification of personnel carrying out compliance assessment (§ 70, § 72 (4), § 73 (2)) BGBl. II Nr. 161/1997 - requirements for the professional qualification (e.g. training, education, etc.) of personnel involved in compliance assessment (§ 1-4) BGBl. II Nr. 275/2008 - specific details on initial training, practical and theoretical training and demonstration of proficiency, final examination and eventual further training (with specific training plans for the different types of officials and inspectors) |
| BE | Loi du 24 janvier 1977 | - role of controls and relative actors (staff of the Federal Public Service for Public Health, Food Chain Safety and Environment appointed for this purpose by the King) (Art. 11, 12) - swearing of an oath before the Minister or his representative for staff |
| CZ | Zákon 258/2000 Sb. Vyhlaška 38/2001 Sb | - very general basis for actors and duties for generic enforcement, without any specific detail on FCMs in particular (Hlava V, díl 1, oddíl 1, § 80, § 84, oddíl 4, § 88 – 90) - information on the use and on the characteristics of different products and materials. It also states that in case no official validated analytical methods exists, a method with adequate characteristics, may be used. (část první, § 2-7) |
| EE | Toiduseadus (Food Act) of 25 February 1999 Veterinaar- ja Toiduameti põhimäärus RTL 2007, 49, 898 Veterinaar- ja Toiduameti Peadirektor Käskkiri No. 86 of 01 April 2011 Veterinaar- ja Toiduameti Peadirektor Käskkiri No. 65 of 26 March 2013 Veterinaar- ja Toiduameti Peadirektor Käskkiri No. 205 of 18 December 2014 | Toiduseadus - appoints the Veterinary and Food Board (VFB) as a competent authority for FCM - establishes enforcement conditions and tasks, specifying all what has to be assessed (e.g. state and use of food business and its premises, processing materials, produced articles, equipment, handling, labelling, documentation, hygiene requirements, etc.) (Ch. 8) - modalities of controls (e.g. sampling, visiting premises, collecting documentation) (Ch. 8) - introduces and regulates a Food supervision fee to be paid by the businesses for the controls that have to be performed in their premises (Ch. 8) - allows the supervising official to take measure in cases on non-compliances and specifies measures (Ch. 8) - Veterinary and Food Board is the authority coordinating the preparation of the contingency and of the multi-annual control plan (Ch. 8) - tasks and duties of the laboratories that analyse the samples (that are authorised by the Veterinary and Food Board upon written application and payment of a fee by the laboratory) and the reference laboratory (that are appointed by a directive of the Minister of Agriculture upon written application). (Ch. 9, § 52-53) Veterinaar- ja Toiduameti põhimäärus - organisational structure of the Veterinary and Food Board - defines its tasks which include the supervision of the manufacturing, processing and marketing of FCM (§ 6 No. 3, § 11 and § 14 No. 1)), the authorisation of a laboratory for analysing samples taken during official controls (§ 14 No. 4) and the organisation of trainings for official control personnel (see § 16 No. 6) Veterinaar- ja Toiduameti Peadirektor Käskkiri No. 86 of 01 April 2011 - guidance document addressed to officials of county veterinary centres who exercise supervision in the field of FCMs and describes how to determine the "risk level" of a FCM plant, based on which the frequency of official inspections is set - states that the beginning of each calendar year the county supervisory officials shall prepare a plan of official controls Veterinaar- ja Toiduameti Peadirektor Käskkiri No. 65 of 26 March 2013 - the risk level of a storage company can be lowered and consequently the frequency for inspections decreased, if during two consecutive inspections no non-compliances are found Veterinaar- ja Toiduameti Peadirektor Käskkiri No. 205 of 18 December 2014 - description of annual plan for official controls in food and FCM plants (recalling Käskkiri No. 86). Provides instructions for the documentation and reporting of inspection outcomes |
| FI | Elintarvikelaki Sections that apply to FCM: §2; §29-41, 44-53, 54b-54e | - all actors and responsibilities in enforcement, including custom and border authorities and bodies - competences of control authorities/bodies, national reference laboratories (NRLs) and approved laboratories for testing of official samples (and specific requirements on competence, reliability of results, trained personnel) - written quality system for control authorities/bodies and NRLs and approved laboratories - requirement for national control programme, control plans and municipal food control plan to include description of control measures and information (specifies information and measures) - describes modalities of controls - introduces administrative coercive measures - states the right to carry out inspections, obtaining information, performing sampling, obligations of control authorities (notification, information, and guidance), and official registers |
| F | Code de la | Code de la consommation |

| MS | Legislation | Descriptions of enforcement requirements |
|----|---|--|
| R | consommation (as amended up to 01/01/2015) Note d'information n°2014-108 | <ul style="list-style-type: none"> - fixes sanctions in conjunction with Art. 131-38, 131-39 and 131-21 of the Code Pénal (L212-1, L 213-1, L 213-2 I, L 213-2-1, L213-3, L213-4, L213-5, L213-6, L214-1, L214-2, L214-3) - reports a Chapter with provisions on prevention (L.221-5) Note d'information n°2014-108 <ul style="list-style-type: none"> - general guidance on compliance work - general principles for compliance testing and the DoC work (see section 2.1) - responsibilities of operators with respect to compliance work along the supply chain (3.3) |
| DE | AVV RÜb of 3rd June 2008 LFGB of 3rd June 2013 (BGBl. I S. 1426) | AVV RÜb of 3rd June 2008 <ul style="list-style-type: none"> - states that EC 882/2004 Art. 6, 10, 11 apply to the official controls of FCMs (§2, 3, 4, 7, 8) - criteria for control personnel (qualification, characteristics of inspections teams, conduct and duties during inspections) (§2, 3, 4, 7, 8) - criteria for controls bodies (capacity and performance assessed by proficiency testing schemes issued by the Federal Office and monitored by the competent authorities) (§2, 3, 4, 7, 8) - criteria for sampling (decided in close collaboration between the competent authorities and the official testing laboratories and analysis of samples, for the cooperation and exchange of information between interested party in the controls chain (§2, 3, 4, 7, 8)) - states that competent authorities shall establish quality management systems (§ 5) LFGB of 3rd June 2013 (BGBl. I S. 1426) <ul style="list-style-type: none"> - states necessity to classify establishments in risk categories, based on which the control frequency will be determined (from once every three years to a maximum of once a day) (§ 6) - stipulates the number of samples per year (e.g. 0.5 samples of tobacco products/cosmetics/ consumer product (incl. FCM) per 1000 inhabitants) (§ 9) - defines the multi-annual national control plan (MANCP) as individual integrated control plans of federal states and a national section, specifying timeframe and actors, and the national monitoring plan meant for the performance of official controls of compliance, with detailed information on all data that have to be collected (§ 10, 11) LFGB of 3rd June 2013 (BGBl. I S. 1426) <ul style="list-style-type: none"> - delegates responsibility for official controls to the level of the federal states and defines the duties for periodic official controls and sampling of the competent authorities (including measure for encountered non-compliances) (§ 38, 39) - detailed requirement for controls/compliance tests to be performed by specially trained personnel and defines rights of authorised personnel (§ 42) - permits sampling by authorised personnel, requiring a portion of the sample to remain with the producer for cross-check, and it obliges the business operators to cooperate and provide all the necessary information (§ 43) |
| IT | Circolare XIII del 27/03/2001 del Ministero della Sanità Decreto legislativo 25 gennaio 1992, n. 108 | Circolare XIII del 27/03/2001 del Ministero della Sanità <ul style="list-style-type: none"> - legal background and general guidance to official controls on how to perform controls, especially for recycled/reused FCM, - importance of supervision of producer businesses (collection of samples, compliance of batches produced, corresponding documentation for checks) Decreto legislativo 25 gennaio 1992, n. 108 <ul style="list-style-type: none"> - necessity of controls and applicable sanctions |
| NL | Regeling van de Minister van Volksgezondheid, Welzijn of 14th March 2014 | <ul style="list-style-type: none"> - rules for assessing compliance with migration limits (including details on migration conditions, simulants /substitute simulants, methods, alternative methods, needed equipment, detection, calculation of results, application of correction factors) (Ch.s 0.7, 0.8, 4.1, 4.2, 5, 6, annex I-IV; Ch. II, 1, annex I) - mention that assessment of substances not included in the EU list has to take place on the basis of internationally recognised scientific risk assessment principles or based on the TTC principle (Ch.s 0.7, 0.8, 4.1, 4.2, 5, 6, annex I-IV; Ch. II, 1, annex I) |
| NO | LOV-2003-12-19-124 (Ch. II, § 5-11, 13, 14, Ch. VI, § 33) FOR-1993-12-21-1381 | LOV-2003-12-19-124 <ul style="list-style-type: none"> - sets actions the enforcing authorities can do and obligation for producers to provide the requested material - sets the obligation for companies to take any necessary measure and to inform the authorities if problems are encountered, to ensure that the location, design and operation of activities meet appropriate hygienic standards, to ensure that the personnel is properly trained, to ensure the traceability of materials and its availability to authorities, to provide access to premises, assistance, and allow sampling FOR-1993-12-21-1381 <ul style="list-style-type: none"> - supervision and implementation of the legislation on FCMs is responsibility of the Norwegian Food Safety Authority (Mattilsynet) (Kapittel VII, § 27, § 28) |
| PL | Ustawa z dnia 25 sierpnia 2006 (Dz. U. 2010 nr 136 poz. 914) | <ul style="list-style-type: none"> - description on how official controls are performed and competences of each body (Art. 88-94) - appointment of the bodies of the State Sanitary Inspection as competent for official controls of FCMs, their rights when performing controls (e.g. to enter the food business at any time, to analyse technological processes and recipes to the extent necessary for controls, to have access to all documentation pertinent to the purposes of the control, to collect samples of FCM for laboratory testing) (DZIAŁ V, Art. 73, 76, 78) - accreditation for bodies of the State Sanitary Inspection (DZIAŁ V, Art. 73, 76, 78) - duties regarding the controls to be performed at the border by border sanitary inspectors (based on compulsory notification of the importer 48 hours before the arrival of the shipment), that will issue a compliance certificate, and according to regulations by the health minister (Art. 79-84) |
| SK | VÝNOS z 9. júna 2003 č. 1799/2003 – 100 Regionálne úrady verejného zdravotníctva v sr - Metodický návod EXTERNÉ AUDITY | VÝNOS z 9. júna 2003 č. 1799/2003 – 100 <ul style="list-style-type: none"> - requirements of validated analytical methods verification of compliance (§ 8) Regionálne úrady verejného zdravotníctva v sr - Metodický návod EXTERNÉ AUDITY <ul style="list-style-type: none"> - internal requirements for the implementation of GMP external audit systems for manufacturers - basic processes and responsibilities of persons involved in the process of auditing and evaluation systems for GMP manufacturers (with check list for GMP audits) |
| SI | Uradni list RS, št. 47/04 z dne 30. 4. 2004 (16-20. člen, 22. člen, 27. člen, 32,33. člen, 37,38. člen) | <ul style="list-style-type: none"> - actions and actors of official controls - instructions on inspections, sampling, testing, etc. |

| MS | Legislation | Descriptions of enforcement requirements |
|----|---|---|
| | repealed at the end of 2015 | |
| CH | Legge federale sulle derrate alimentari e gli oggetti d'uso of 9th October 1992 Ordinanza sulle derrate alimentari e gli oggetti d'uso of 23rd November 2005 | Legge federale - sets the obligation of self-monitoring for the manufacturers (Art. 23) - general rights and duties for official control authorities (incl. regular controls, sampling) (Art. 24) - delegates responsibility for official controls to cantons and their specially trained personnel and specialised laboratories (Art. 40) - delegates responsibility for training of authorised personnel to the cantons (authorised personal has to fulfil the requirements set by the Swiss Federal Council) (Art. 41) - third-party institutions can be authorised to take over tasks related to official controls (Art. 43a) Ordinanza - states the duty of self-monitoring for manufacturers (Art. 49) - states the duty to perform regular official controls for FCM (incl. sampling) and defines basic requirements for sampling and requirements for personnel authorised to perform official controls (Art. 56-58, 63) - official control laboratories and national bodies performing inspections need to be accredited (according to ISO 17025 and ISO 17020, respectively) (see Art. 62) |
| CH | Bewertung von „Konformitätserklärungen“ für FCM im Vollzug auf Basis der SVI-JIG Checkliste vom 19.02.2012 | Issued by the Association of Chemists 'Verband der Kantons-chemiker der Schweiz' - GMP guidance document - checklist to assess the completeness and quality of a Declaration of Compliance and it provides further explanations on the required information. The document is addressed to inspectors for use during official controls |
| UK | 2010 No. 2225 FOOD, ENGLAND The Materials and Articles in Contact with Food (England) Regulations 2010 | PART 5: defined offences Defines execution and enforcement power to each food authority port health authority and food agency. (for Reg. 1935/2004 and 2023/2006) - defines offences by third party - gives a three year time limit for enforcement. Illustrate rights for general defences - defines when samples needs to be analyses (section 19), secondary, -defines application of samplings |

4d - Sanctions

It is forbidden to hold for sale, to sell or to give away any materials or articles intended to come into contact with foodstuffs that do not meet the requirements specified in Regulation (EC) No 1935/2004. Consequently national measures should have sanctions described for both infringement of Articles 1 to 5 and 15, 16 and 17 of the Framework Regulation (EC) No 1935/2004 as well as for regulations for its application, such as Articles 1 to 7 of Regulation (EC) No 2023/2006. Sanctions may range from fines/penalties, imprisonment, confiscation of non-compliant goods (or rejection at borders, and/or bearing costs of destruction of goods), closing down premises, liabilities. These are summarised below.

Overview of national measures in the EU MSs mentioning or establishing sanctions:

| MSs | Document | Sanction fines/ Confiscation, Disqualification from practice/ imprisonments |
|-----|--|--|
| AT | BGBI. I Nr. 13/2006 (and amendments) | - fixes sanctions (detailing the different amounts based on the gravity level of the law infringement and detailing each specific type of foreseen infringement) incl. FCM - up to imprisonment, including the cases of negligence. - confiscation of the non-compliant items. - disqualification from the practice of commercial activities if multiple law breaches - judgement published on one or more periodicals at the convicted person's expenses. - establishes the terms of liability of the business operators, jurisdiction, and obligation notify the appropriate Provincial Governor and the Federal Minister for Health of the outcome of the criminal proceedings (§81-94). |
| BE | Arrêté royal du 11 mai 1992 | - reference to the Loi du 24/01/1977 (Art. 11, 11bis, 13, 8, 3, 3/1, 15, 16, 17, 18, 19, 20), - fixes sanctions for failing to comply with the legislation. - penalties from written warning to imprisonment (doubling if offense repeated within 3yrs) - seizing /confiscation of spoiled or harmful products (or import refused). |
| CZ | Zákon 258/2000 | - penalties depend on gravity of law infringement and conduct of subject - fines up to 10 x when repeated failure to comply with same obligation(s) (sections 92-93). - rules of administrative procedure and participants in proceedings (section 94). |
| DK | BEK n. 822 of 26/06/2013 (sect. 28) and BEK nr 1007 of 19/09/2014 (sect. 35) | - fines to any business that infringes the provisions of those orders and of EU legislation - penalty may increase up to two years of imprisonment if the infringement was committed intentionally or "caused harm to health or a risk of such harm, or resulted in, or was intended to result in, financial gain for the person concerned or other persons". |
| EE | Toiduseadus (Food Act) 1999 and its amendments | - fine for Violation of the requirements for handling food and FCMS, specifying the case where the violation is committed by a legal person (Chapter 10, §533). |
| FIN | Elintarvikelaki (Food act) 13.1.2006/23 | - provisions for foods are also applicable to FCMS where appropriate. (§2). - series of actions (removal of violations, prohibition, withdrawing from the market and informing the public, seizure, use or disposal of a foodstuff, cancelling the approval of food premises, cancelling the approval of a laboratory, marketing prohibition, penalty payments and penal provisions as established by the Penal Code) against frauds and non-application of Finnish law for food operators (§55-69). |
| FR | Code de la consommation | - fixes sanctions for frauds and those who sell fraudulent goods. It is valid for all FCMS. (L.212-1, L.213-1, L.213-2 I, L.213-2-1, L.213-3, L.213-4, L.213-5, L.213-6, L.214-1, L.214-2, L.214-3); |

| MSs | Document | Sanction fines/ Confiscation, Disqualification from practice/ imprisonments |
|-----|--|---|
| | (amended up to 01/01/2015) | <ul style="list-style-type: none"> - establishes that "the responsible of the first placing on the market of a product is required to verify that it complies with regulations. At the request of officers authorized to implement legislation, he has to justify the verifications and checks". - Penalties for legal persons foreseen by the Criminal Code (Article 131-38, Article 131-39, and Article 131-21) and their amount "shall be five times the amount laid down for natural persons by the law criminalising the offence". - Penalties foreseen are fines up to 1 million euros and imprisonment up to seven year, - also possible to ban professional or social activities or the "permanent closure or closure for a maximum period of five years of the undertaking's establishments, or one or more of the establishments, used to commit the acts forming the offence". |
| DE | (BGBl. 1998 I S. 5) (BedGgstV), amended by Art. 1 V v. 2013 (BGBl. I S. 1682) | - fixes sanctions for non-compliance with legislative requirements, incl. EU 1935/2004 Art. 15 (1, 3) and Art. 17 (2) (see §12 BedGgstV in conjunction with §31, §32, §58, §59 and §60 of Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Lebensmittel- und Futtermittelgesetzbuch - LFGB)). |
| NO | LOV-2003-12-19-124 last amended by LOV-2014-12-12-68 from 01.01.2015 (Food Act) | <ul style="list-style-type: none"> - fixes sanctions for failure to comply with legal provisions. (Chapter 5, §25-28). - penalties depending on the type and on the gravity of the law infringement. - range includes closure of premises, coercive fines, information to the general public and penal measures (imprisonment up to two years or a writ). - Forskrift om materialer og gjenstander i kontakt med næringsmidler (matkontaktforskriften), FOR-1993-12-21-1381 refers to §28 of the Food Act for the sanctions foreseen after the infringement of the provisions established by this law (§29). |
| PL | Dz. U. 2010 nr 136 poz. 914) | - sanctions (fines) are foreseen for contravening requirements set down in EU 1935/2004 Art. 3, EC 2023/2006 Art.4 and EC 282/2008 Art. 4-8. (Dział VIII, Art. 100-102). |
| SI | 57/2008 z dne 10. 6. 2008 | <ul style="list-style-type: none"> - fines up to 30.000 euro for not respecting the law provisions (compliance with Article 3 of (EC) Regulation 1935/2004). (7. člen). - fixes sanction measures and fines for not respecting the provisions of law and/or not allowing controls or not collaborating with authorities (Act on health suitability of foodstuffs and products and materials that come into contact with foodstuffs) - fixes sanctions in case of non-compliance with Regulation EC 1935/2004 Art 3, 15, 17 |
| CH | Legge federale sulle derrate alimentari e gli oggetti d'uso 1992 (updated 2013) | declares general criteria when to consider a sample as non-compliant (Art. 27). It defines possible general actions in case of non-compliance (Art. 28-31). It fixes sanctions in case of non-compliance with legislative requirements (Art. 47-51). |
| UK | 2010 No. 2225 FOOD, ENGLAND The Materials and Articles in Contact with Food (England) Regulations 2010 | <p>PART 2: General Requirements for Materials and Articles</p> <ul style="list-style-type: none"> - considers as offences contravening specified provisions of Reg. 1935/2004 Art. 3, 4, 11(4)/(5), 15(1)/(3)/(4)/(7)/(8), 16(1) (declaration of compliance); 17(2) (traceability), and for contravening Art. 4 of Reg. 2023/2006 - designate competent authorities <p>PART 5: defines <u>offences and penalties</u> r liability for the offences (para. 13)</p> |

4e- Certification systems

A much greater emphasis can be found in the certification systems in the context of GMP than in the context for controls. The information collected on certification systems with mentions pertinent to accreditation and official controls is summarised in **Error! Reference source not found..** It refers to the certification systems responding to the need for authorisation of laboratories to perform compliance testing and details on requirements for compliance testing laboratories. The most complete (and relatively recent – 2014) at national level were those of Switzerland and Austria.

Overview of national measures in the EU MSs with mentions on certification systems for official control:

| MSs | Document | Description |
|-----|---|--|
| AT | Food Safety and Consumer Protection Act BGBl I Nr 13-2006 (last amended by BGBl. I Nr. 67/2014) | <ul style="list-style-type: none"> - appoints the Austrian Agency for Health and Food Safety for the official control duties (§65 (1)). - states which institutions for compliance assessment of food and FCM samples taken during official controls and inspections (§65 (1), §72, §73). - sets general requirements for the methods to be used for compliance testing (§68 (1)) and for the professional qualification of personnel carrying out the compliance assessment (§70, §72 (4), §73 (2)). - requires the accreditation of all laboratories which carry out the compliance assessment for samples taken during official controls and inspections (§68 (2), §72 (4), §73 (4)). - Agency's laboratories must possess an accreditation in accordance with the Federal Act on the accreditation of conformity assessment bodies (Accreditation Act 2012) that supplements Regulation (EC) No 765/2008²¹⁰ - It provides directions on the accreditation procedure, on the obligations of accredited conformity assessment bodies, on the terms for the termination, withdrawal, suspension and reduction of accreditation, on measures for non-compliance and on enforcement. |
| CH | Ordinanza sul sistema svizzero di | - sets rules for accreditation of bodies that perform product testing, assess product compliance |

²¹⁰ Regulation (EC) No 765/2008 on the requirements for accreditation and market surveillance relating to the marketing of products, and regulates the accreditation of conformity assessment bodies laying down the necessary procedural provisions

| | | |
|------------|--|---|
| | <p>accreditamento e la designazione di laboratori di prova e di organismi di valutazione della conformità, di registrazione e d'omologazione (Ordinanza sull'accREDITamento e sulla designazione, OAccD) del 17 giugno 1996 (RS 946.512), as of 1 July 2014</p> <p>Ordinanza sulle derrate alimentari e gli oggetti d'uso (ODerr) del 23 novembre 2005 (RS 817.02), as of 15 July 2014</p> | <ul style="list-style-type: none"> - sets conditions for designation registration and approval bodies with liability and fees. - provides a list of international criteria applicable to the Swiss Accreditation Service and to the conformity assessment bodies (ISO standards) - Specifies details of the accreditation process for laboratories and other institutions which are entrusted with compliance assessment - States that official control laboratories and national bodies performing inspections need to be accredited (according to ISO 17025 and ISO 17020, respectively) (see Art. 62). |
| CZ | Zákon 258/2000 Sb. (with its amendments) | - mentions the need for certification system, without any specific detail (Hlava V, díl 1, oddíl , §84 (2), §108 (1)). |
| DE | (AVV Rahmen-Überwachung - AVV RÜb) vom 3. Juni 2008, last amended by Verwaltungsvorschrift vom 14. August 2013 (BANz AT 20.08.2013 B2) | - states that official control laboratories are nominated by the federal states and that they need to have a QM system (§ 4(3), 5(1) AVV RÜb). |
| SE | SE Normpack General guide on food packaging safety | - mentions the need of a quality system and reports the certificate Normpack can release to attest compliance of the producer. (p6, bilaga 6) |
| SI | Uradni list RS, št. 52/00 z dne 13. 6. 2000, last amended by Zakon o spremembah in dopolnitvah določenih zakonov na področju zdravja – ZdZPZ (Uradni list RS, št. 47/04 z dne 30. 4. 2004) | <p>Act on health suitability of foodstuffs</p> <ul style="list-style-type: none"> - states that official testing laboratories have to be certified. (22. člen, 38. Člen) - document was repealed by the end of 2015. |
| Ind | Industrial guidelines on traceability of materials and articles for food contact* | - states that converters can carry out audits to ensure that the supplier's process is in control, basis on ISO 9000 procedures (Section VI, VI.2). |

In the context of GMP the information was very detailed and therefore is fully summarised and analysed in Annex 5, including on certification systems. The analysis refers to the coverage of the checklist for GMP (from EU Regulation (EC) 2023/2006).

Annex 5. Information on Good Manufacturing Practice (GMP): availability of and contents of documentation on GMP from MS and industry

(next page)

Annex 5a: availability of documentation on GMP at MS level (national / supranational measures)

| Class | Document |
|-------------------------|---|
| Mentions generic to FCM | <p>CH VKCS AGFCM Checklist Konformitätsbewertung E140725. The Swiss Packaging Institute (SVI) has developed and revised a checklist for Industry to assess declaration of compliance. It is used by inspectors for controls. No guidance document is available, but they provide courses.</p> <p>CZ Zakon 258-2000 expresses the need to follow GMP, without any specific detail. (Hlava V, díl 1, oddíl, § 84 (2), § 108 (1))</p> <p>DE Good Manufacturing Practice (GMP) and Compliance Declaration for Food Contact Materials: Interpretation of the Official Control (2009/52)</p> <p>DK DVFA Chemicals Contaminants in Food Checklist only specifies the necessity of following GMP. (p.13)</p> <p>EE suggests business operators to use GMP guidelines elaborated by industry organizations in addition to UK GMP guidelines</p> <p>ES Guía de trazabilidad en empresas fabricantes de artículos monouso de plástico para alimentación y bebidas, ANAIP/FAMA</p> <p>HU Regulation 49/2014 states that GMP can minimise the presence of pollutants in foods, without any more detail. (3. § (1-2))</p> <p>IT Nota del Ministero della Salute n° 2964 del 24/01/2006 mentions the need to produce FCM according to GMP.</p> <p>IT Rapporti Istituzionali 11/37- CAST project: Guidelines for the application of the Regulation 2023/2006 to the supply chain of materials and articles intended to come into contact with foodstuffs ISSN 1123-3117. Edited by M.R: Milana, M. Denaro, R. Feliciani, A. Maggio, A. Maini and G. Padula</p> <p>LT Medžiagų ir gaminių, skirtų liestis su maistu, Geros gamybos praktikos taisyklės - medžiagų ir gaminių, skirtų liestis su maistu, geros gamybos praktikos taisyklės © Lietuvos Pakuotojų Asociacija, 2007</p> <p>NL "Infoblad documentatie FCM mei 2014" May 2014: short guidance document on how to apply Reg. 2023/2006 and dir. 1935/2004</p> <p>Norden: there are three Norden guidance documents (on paper and board, on printing inks and on food contact materials in general)</p> <p>Nordic check lists to industry and trade, ANP 2008:709 © NCM, 2008 ISBN 978-92-893-1645-3</p> <p>SE Normpack General guide on food packaging safety specifies the importance of following GMP EU requirements. (p7)</p> <p>SK Foodstuffs Code 1799/2003 states that FCM have to be manufactured according to GMP. (§ 4 (1)) regionálne úrady verejného zdravotníctva v sr metodický návod - externé audity, Správne výrobné postupy u výrobcov materiálov a predmetov určených na styk s potravinami; Doc. MUDr. Ivan Rovný, PhD., MPH, 2010, KONTROLNÝ LIST - auditu systému SVP (správne výrobné postupy): "GMP requirements", "Check list for control GMP" and "Guidance for performing audits in producers of FCM" are still in use</p> <p>UK Guide to United Kingdom Legal Compliance and Good Practice for Business Documentation, materials and articles in contact with food, June 2009; UK is revising the GMP guidance. The new version is not available yet (the 2009 guide is no longer in use)</p> |
| Cork | <p>CoE Policy statement concerning cork stoppers and other cork materials and articles intended to come into contact with foodstuffs states that cork FCM should be manufactured according to the CE Liege guidance "Code of cork stoppers manufacturing practice".</p> |
| Glass | <p>SK Foodstuffs Code 1799/2003 states that glass FCM have to be manufactured according to GMP. (§ 36 (1))</p> |
| Metals and alloys | <p>IT Legge n. 243 dell'1 giugno 1988 states that varnished tin free steel FCM have to be produced according to GMP, no further details (Art. 1, Allegato I); Nota n. 12174 del 23/04/2010 states that tin free steel and tinfoil FCM have to be produced according to GMP.</p> <p>HU Regulation 9/2014 states that GMP can minimise the presence of pollutants in foods, without any more detail. (3. § (1-2))</p> <p>CoE Metals and alloys used in food contact materials and articles states that metallic FCM shall be manufactured in accordance with Regulation (EC) No. 2023/2006. (Chapter 1, 3.1)</p> |
| Paper and board | <p>Norden guidelines on paper and board "Paper and Board Food Contact Materials", (TemaNord 2008:515, Copenhagen, Nordic Council of Ministers). It is a GMP document intended for producers of P&B, to ensure compliance, and it is based on the CoE Resolution on paper and board materials and articles intended to come into contact with foodstuffs and its related 5 Technical documents. DK FI NO SE Norden Paper and Board Food Contact Materials provides information on GMP. (Chapter 3, Annex 3).</p> <p>HR NN125-2009 only states that P&B products must be manufactured according to GMP requirements, no detail. (Članak 100)</p> <p>ES BUENAS PRÁCTICAS DE FABRICACIÓN para la fabricación de papel y cartón para contacto con alimentos, Primera publicación - Septiembre 2010 (based on CEPI document)</p> <p>CoE Policy statement concerning paper and board materials and articles intended to come into contact with foodstuffs state that paper and board FCM should be manufactured in accordance with the "CEPI guide for good manufacturing practice for paper and board for food contact". The document reports also the text of the CEPI guidance document. (Resolution RESAP (2002)1, 3.1, 3.1)</p> <p>CoE Policy statement concerning tissue paper kitchen towels and napkins presents GMP based on the "CEPI guide for good manufacturing practice for paper and board for food contact" and adapted to the production processes used in tissue mills and to reflect the specific characteristics of kitchen towels and napkins. (Chapters 1.2.4, 8)</p> |
| Printing ink | <p>CoE Policy statement concerning packaging inks applied to the non-food contact surface of food packaging states that packaging inks should be manufactured according to the "Good Manufacturing Practices for the production of packaging inks formulated for use on the non-food contact surfaces of food packaging materials and articles intended to come into contact with foodstuffs" (prepared by CEPE), and they should be applied according to the "Code for Good Manufacturing Practices for flexible and fibre based packaging for food" (prepared by FPE in co-operation with CITPA). (Chapter 3.2.2, 3.2.3, Technical document n.2 part 1, part 2)</p> <p>Norden Guidance on Printing inks. Note: The 'Nordic check lists to industry and trade' is solely used as a guidance for establishing declarations of compliance and supporting documentation for FCM, and this report will be updated later this year</p> <p>LU no national tools available regarding details on GMP; but the Switzerland legislation on printing inks (RS 817.023.21 Ordonnance du DFI sur les objets et matériaux) is used as well as the EUPIA guidelines on printing inks and the norden guidelines on printing inks</p> |
| Rubber | <p>CoE Policy statement concerning rubber products intended to come into contact with foodstuff only states that rubber FCM should be manufactured according to GMP. (Chapter 3.2.1)</p> |
| Varnishes coatings | <p>CoE Policy statement concerning coatings intended to come into contact with foodstuffs states that coatings should be manufactured in accordance with guidelines on GMP for coatings intended to come into contact with foodstuffs. (Appendix to resolution, 3.2)</p> |

Note: no mentions were found for silicones, waxes, wood, adhesives, ion exchange resins, multimaterials, and ceramics. No GMP beyond 2023/2006 for CY, IE, LV, LU, MT, PL, PT, RO, SI. No answer from AT, BE, BG, HR, CZ, FR, EL, HU.

Annex 5b - analysis of contents of GMP documentation at national level from MSs

The table represents an analysis of GMP documentation retrieved for MSs (Information at Member State level and referring further specifications on coverage of the checklist for GMP (from EU Regulation (EC) 2023/2006)).

The contents of the materials received in 2012 by DG Health and Food Safety were already analysed by DG Health and Food Safety in different files with overlapping information in some cases. The present overview is therefore a synthesis of the information that the JRC examined and compiled to the present report. The analysis concerned the checklist for GMP (from EU Regulation (EC) 2023/2006):

- Raw Materials: starting materials need to be selected and comply with pre-established specifications to ensure compliance of the material or article with the rules applicable to it
- QA: Adequacy of personnel, organisation of the premises and equipment, Machinery and tools, Manufacturing processes, Pre-established instructions and procedures
- QC: Monitoring of the implementation and achievement of GMP, Identifying any measures required to control any failure to achieve GMP

| MS | Contents | Evaluation |
|---|--|---|
| DE <u>Germany GMP documentatio</u> n: | <p><u>Raw materials</u> No information</p> <p><u>QA</u> <u>Adequacy of the personnel:</u> no notes <u>Organisation of the premises and equipment:</u> 1. Machinery and tools 2. Manufacturing processes ~Compliance is required at each stage of the manufacture, not just in relation to the production of the final product as the composition of a migrate can only be fully understood with help of information on all of the substances used, their impurities and chemical reactions involved. ~Manufacturers of starting or intermediate products need to consider compliance-related aspects that arise or may arise either at their stage of the manufacture or at a subsequent stage and must consider substances used, impurities and reaction products that result from use of substances chosen and those that result from downstream production processes, any restrictions (purity requirements and migration thresholds and limits in foodstuffs and FCMs) and, lastly, any compliance work that needs to be carried out at downstream stages (with this being delegated by manufacturers who must provide written specifications of the work needing to be done and any necessary information). <u>Presence of pre-established instructions for the procedures:</u> no notes</p> <p><u>QC</u> <u>Monitoring the implementation and achievement of GMP:</u> ~Require official control to conduct random tests to determine whether GMP is being implemented and whether manufactured products are compliant. <u>Corrective measures to remove any inefficiencies and non-compliance:</u> no notes <u>Documentation:</u> ~Need compliance related documentation at each stage of the manufacture, which can be controlled and need to be made available to competent authorities when these last conduct random tests. This documentation needs to be solely available to authorities and the downstream stages of the production chain have no right to inspect the document and for competitive and confidentiality reasons, they will not usually receive it. ~Compliance declaration (for specifically regulated FCMs, like plastics, ceramics or recycled plastic for example) must contain at least information on identity and address of the manufacturer of the articles or materials, the identity of the materials or articles (or substances intended to manufacture these last), the date of the declaration, confirmation that materials meet relevant requirements, sufficient information on the substances used and any restrictions or specifications applicable to them, any information on substances which are subject to a restriction in food (e.g. information on their SMLs) and if appropriate purity information. Compliance document also needs information on type or types of food with which it can be in contact, time and temperature of storage and treatment and ratio of food contact surface area to volume used to establish compliance. Lastly, additional information is required when a plastic functional barrier is used in a plastic multi-layer material or article to confirm that this material is compliant with Article 7a. ~There are two types of documentation required: one is the internal documentation which remains on site and is only available to the competent authorities, while the other is the product-accompanying declaration (which delegates outstanding compliance work, specifies conditions of use of product for example).</p> | <p><u>Raw materials</u> -No information on raw materials</p> <p><u>QA</u> -Some information on the manufacturing processes and duties of manufacturers (such as ensuring good communication between the various steps involved in the FCM production chain) but none on the adequacy of the personnel, the organisation of the premises and equipment and none on the machinery and tools.</p> <p><u>QC</u> -Some information on monitoring the implementation and achievement of GMP, none on corrective measures used to remove any inefficiencies and non-compliance and detailed information on the requirements vis-à-vis documentation.</p> <p>Overall German document is not detailed enough and does not specify important parameters required to achieve a product manufactured under GMP and fully compliant with legislation. Information on documentation is particularly detailed and complete, however.</p> |
| DK <u>Denmark and Finland GMP checklist</u> (Which also | <p><u>Raw materials</u> ~Suppliers of raw materials and chemical must contain, at least, information on the name and address of supplier, chemical name and CAS-number (or generic name for raw materials), DoC and documentation on risk assessment of the chemical (e.g. whether chemicals are on positive lists in the legislation, EFSA assessment and the intended use), information on components subject to specific restrictions (e.g. SMLs), information for dual-use chemicals (like additives) and specifications on purity. ~Raw materials and chemicals also need to be traceable.</p> | <p><u>Raw materials</u> -Some good information on raw materials but not detailed enough. Checklist guidance focuses mainly on the identification of the materials and their suitability for use and less on the importance of GMP being employed by</p> |

| MS | Contents | Evaluation |
|---|---|--|
| <p>covers Sweden, Iceland, Norway, the Faroe Islands, Greenland and Aland):</p> | <p><u>QA</u> <u>Adequacy of the personnel:</u> no notes <u>Organisation of the premises and equipment:</u> 1. Machinery and tools 2. Manufacturing processes ~Producers (wherever they may be working) of intermediates (like printing inks) have the responsibility of selecting chemicals for which a risk assessment is available and to produce products which comply with legislation when used according to the instructions of use provided with them ~Manufacturer needs to have relevant knowledge about test conditions to be able to assess the reliability of the documentation <u>Presence of pre-established instructions for the procedures:</u> no notes</p> <p><u>QC</u> <u>Monitoring the implementation and achievement of GMP:</u> no notes <u>Corrective measures to remove any inefficiencies and non-compliance:</u> no notes <u>Documentation:</u> ~DoC of chemicals needs to contain EFSA opinion of the chemical substances (if available), producer's DoC and documentation on toxicological testing, risk assessment of compliance from other countries that follow guidelines (like FDA) and any restrictions in other legislation (for example if the chemicals are regulated as food additives). ~DoC for raw materials needs to have EFSA or other international risk assessment ~Compliance shall be documented</p> <p>Updated information on printing inks checklist for Nordic countries <u>Raw materials</u> ~Any chemicals or raw materials produced for the production of FCM need documentation for compliance with the requirements set out in EU Regulation 1935/2004. ~The suppliers of printing ink chemicals and raw materials should provide, at the very least, chemical name and CAS-number for all substances used (including pigments and colorants), EFSA opinion on the substance if available, producer's risk assessment and documentation on toxicological testing or a risk assessment of chemical substances from other countries (following that country's regulatory body's guidelines), any restrictions found in other legislations (for example if the chemical is covered by food additive legislation, need to know what purity requirements are laid out under that regulation) and lastly, any non-regulated FCM chemicals/raw materials should not be mutagenic, carcinogenic or repro-toxic and must be used behind an appropriate functional barrier. They also need to provide their name and address and information on critical points in the printing process (which includes drying, curing of ink formulation on the substrate and instructions of use of the ink, for example if it must be used in combination with a functional barrier).</p> <p><u>QA</u> <u>Adequacy of the personnel:</u> no notes <u>Organisation of the premises and equipment:</u> 1. Machinery and tools 2. Manufacturing processes ~Sampling of the printed FCM for subsequent analysis shall take place at critical points during the production ~Analysis should in general follow a standardised or validated method from accredited laboratories. ~Producer needs to produce products which will comply with legislation if used according to guidance or specifications provided with it. ~Producers of the final ink formulations (either from raw materials or intermediates) and suppliers of printed FCMs need to provide similar information to raw material suppliers, but in addition need information on traceability, DoC and documentation on the risk assessment of the chemicals in the FCM (which includes answering whether the chemicals are on positive lists in the legislation for example), information on migration analyses of the FCM (specifying test conditions, simulants used, duration of the tests etc...), purity and identity information for dual-use additives, the confirmation that migration of non-evaluated substances that are not MCR is below the general 'detection limit' of 10ppb, advice on conditions and any restrictions of use of final FCM and lastly, provide adequate information to the manufacturer of FCMs including instructions of use and covering critical points in the production. <u>Presence of pre-established instructions for the procedures:</u> no notes</p> <p><u>QC</u> <u>Monitoring the implementation and achievement of GMP:</u> no notes <u>Corrective measures to remove any inefficiencies and non-compliance:</u> no notes <u>Documentation:</u> ~Supporting documentation for declarations of compliance includes details on recipes, analytical methods, migration testing and the evaluation of migration results. These supporting documents need to be available to authorities upon their request and within a short time frame ~DoC and supporting documentation also needs to illustrate that the product meets EU regulation requirements. ~DoC needs to be updated if legislation changes or if there are changes in the composition or production of the FCM but should be revised periodically whether or not changes have occurred. ~Documentation needs to be in a language understood by the industry as well as the national public food inspection ~Dialogue between stakeholders is essential and each member of the production chain needs to know about the legal frame under which their</p> | <p>the supplier of these materials or the handling/storage of raw materials, to prevent their contamination or deterioration.</p> <p><u>QA</u> -There is insufficient information and guidelines on the QA system. No information on the requirements of personnel, details on machinery, tools or the premises and, lastly, no information on requirement of having instructions for the procedures. Some information on manufacturing process is available, but these are mainly concerned with production of intermediates in the first document. The new Nordic report with checklists for the control of printing inks and printed FCM has more information and highlights the importance of subsequent analyses being required at critical points of the production and the need to check whether the product being made is conforming to a large number of specifications (whether chemicals used to make the product are on positive lists, migration specifications, any restrictions on use of final article etc...). New report still does not have any information on the requirements of the personnel, machinery and tools and presence of pre-established instructions for the procedures.</p> <p><u>QC</u> -There is no information on QC in old document. New report with checklists for the control of printing inks and printed FCMs does have some information but only concerning the documentation requirements, especially concerning the DoC.</p> <p>The Nordic checklist provided outlines a long check-list of information to be requested by producers, inspectors, customers etc..., which are in place to ensure that the materials are suitable for intended use and meet certain purity criteria and guidelines. It lacks any information on manufacturing processes to be used with these materials or procedures in place to monitor compliance or correct any non-compliance and could not be used to ensure products manufactured are all compliant with EU legislation. The new report also has some additional suggestions for work needing to be carried out in the future (EU Commission organising a workshop with MSs on in-house documentation for FCMs and the research and development of test methods being prioritised to avoid costly industry or in-house testing, for example), along with some extra points.</p> |

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| | <p>suppliers and customers work. ~DoC and documentation provided to customers' needs to fulfil the customer's demands and enable them to take adequate measures to ensure correct use of printing inks. ~Knowledge is still lacking with respect to test methods and test conditions for different materials, as well as what can be regarded as sufficient in-house DoC and supporting documentation.</p> <p>Extra points Some of the most common photoinitiators (4-methylbenzophenone and benzophenone) must be controlled by using in-house documentation that demonstrates that migration of them both is below 0.6mg/kg.</p> <p>Negative lists (drafted by EuPIA) include chemical which should not be used in printing inks and should be taken into account by printing inks producers and maybe in printing inks production. These lists are not relevant to the DoC as they do not give any information on the compliance of the chemicals used. The responsibility for evaluation of migration (determining whether migration of substances is within official SMLs if) and risk assessment of transfer of chemicals in the printed FCMs is on the producer, user and importer of FCMs Producers must supply instructions for the correct use of printing inks and highlighting some critical control points in the process, while the user of the printing inks must follow these instructions and indicate this using a DoC. The type of additives and solvent that can be used should be discussed with the ink maker prior to its use on press. Some ideas for future work to be undertaken are highlighted, most notably indicating the importance of the EU Commission arranging a workshop with MS on in-house documentation on FCMs, including printed FCMs, improving compliance by gathering participants from the whole food chain to attend training courses or workshops aimed to develop DoC together and the research and development of test methods should be prioritised to avoid costly industry or in-house testing, for example.</p> | |
| <p>IT <u>Italian GMP documentation</u> n:</p> | <p>Was subject to a detail review by materials, as follows: Aluminium - manufacturers of thin foil and foil intended for the production of alufoil trays Paper and board production -Applicable to companies producing paper and board from virgin fibre or recovered paper Paper and board conversion -Applicable to all businesses producing packaging in paper and cardboard. The conversion cycle involves converting paper and cardboard used on their own or in combination with primary or secondary packaging intended for contact with foodstuffs Flexible packaging -Flexible packaging chain includes paper, plastic film, regenerated cellulose, aluminium foil used in their own or in combination for primary and/or secondary packaging intended to be used in contact with food Wood -Includes round timber, sawn timber and semi-processed articles that have undergone a reaction in volume but that have not been chemically treated (e.g. with glue) as starting materials -Guideline is applicable to companies of wood producing fruit and vegetable packaging, and/or wood fibre and/or plywood, cutting boards, chopping blocks and boards intended to come into contact with food" "Plastic Packaging -Production and conversion processes are included Metals and metal alloys, coated and not-coated -All materials and articles made of coated and uncoated metals to be used in contact with food products Cork and cork stoppers -Covers cork stoppers or parts of cork stoppers or any other material or article for cork stoppers in which the main component is cork and which is intended to come into contact with food. Cork stoppers or the cork part of stoppers in which the cork manufactured article is at least 51% are covered by this GMP legislation Glass -Applicable to the sector of glass for food contact containers (bottles, jars, tableware etc.). Glass is produced industrially in a 2-stage process by pressing and blowing the molten glass in moulds" The detailed analysis done in 2012 can be provided upon request</p> | <p><u>Raw materials</u> -Very detailed information with specifications of raw materials' characteristics for a number of materials outlined. There is limited information on the GMP requirements of starting materials used by glass manufacturers. Could additionally have requirements laid out for other materials that were not covered (for example regenerated cellulose for cellulose casings and carton), but for which industry associations provided GMP documentation. <u>QA</u> -Very detailed information, with specifications for required QA system by materials. For glass manufacturers, there were sufficient details on important components of the QA system, except regarding the presence of pre-established instructions for the procedures. <u>QC</u> -Very detailed information on QC requirements.</p> <p>The Italian document is also very detailed and covers requirements of raw materials, QA and QC effectively for a number of different materials and therefore manufacturing sectors. It could usefully have information on GMP for other materials that were not covered but for which industry associations exist and provide their own GMP document. The document could also be made more simple and concise by summarising the general guidelines for manufacturing under GMP and then specifying any additional points for materials that require such additional</p> |

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| | | <p>information (for example any additional information on the requirements of raw materials to be used in printing inks, which are specific to only printing inks). This could make the document a lot shorter and easier to navigate.</p> |
| <p>LU Luxembourg GMP documentation n:</p> | <p><u>Raw materials</u> <u>QA</u> <u>QC</u> ~Any material containing higher migration than the legal limits permit will be removed from the market and a rapid alert will be sent out to all those participating in the European alert system. ~Document makes reference to Regulation (CE) 1935/2004 which states that products coming into contact with food must be made using GMP and any materials or objects not in contact with food when sold must be accompanied by the mention that they are suitable for contact with food, give an explanation of their use or have a symbol indicating their correct use. If relevant, the material also needs to contain instructions of use to ensure appropriate and safe use of the materials and articles. ~This document does not really deal with GMP for FCM and instead outlines the testing conditions and limits for melamine and formaldehyde in kitchenware. It emphasizes that a number of kitchenware utensils exceed melamine and/or formaldehyde limits (especially when exposed to high temperatures) and therefore discourages use of melamine utensils when deep-frying or cooking or heating foods in the microwave and suggests that utensils made of this material should be used at temperatures below 70C. ~Document specifies that melamine objects are not for use at temperatures above 70C or for use in microwaves. This information needs to be specified to the consumer to ensure the safe use of the utensils, using an adequate label.</p> | <p><u>Raw materials</u> - No information on the requirements of raw materials in the document sent by Luxembourg. <u>QA</u> - No information on the requirements of the QA system <u>QC</u> - Information provided is not detailed enough. The only information provided on the QC system is that any materials found to have higher migration than the legal limits permit will be removed from the market as quickly as possible and a rapid alert will be sent out to all members participating in the European RASFF and that any materials sold for food contact use, that are not in contact with food already, must be accompanied by the mention that they are suitable</p> <p>The document does not really cover GMPs for FCMs and instead mostly focuses on highlighting the testing conditions and limits for melamine and formaldehyde in kitchenware. It highlights the uses of melamine and formaldehyde utensils (e.g. not suitable for use at temperatures above 70C or for use in microwaves).</p> |
| <p>LT Lithuanian GMP documentation (translated from Lithuanian using Google translate):</p> | <p><u>Raw materials</u> ~Company producing FCM must check that raw materials and other substances used in production of FCMs comply with legislative requirements. They also require written information about the correct use and/or processing of these materials and must identify and evaluate these suppliers. ~Raw material suppliers must be known to be reliable so that their products meet safety and quality requirements as illustrated by product specifications or documents provided by the suppliers. ~Any change in raw materials used, technologies used or suppliers requires an analysis to be carried out on them. <u>QA</u> <u>Adequacy of the personnel:</u> ~Any personnel involved in FCM production must be familiar with both Lithuanian and EU legislation. ~Any personnel handling raw material or finished product FCMs must have knowledge of FCM legislation and must abide by it. ~Any personnel with contagious symptoms that could be passed through raw materials or finished products is not allowed to work with raw materials or final products or in management positions. ~All employees undergo some training before starting work (FCMs and GMP and hygiene conditions in the workplace). ~There needs to be a person responsible for supervising and ensuring GMP compliance in the company. <u>Organisation of the premises and equipment:</u> ~The premises must be protected against potential contamination and regularly maintained in accordance with internal procedures. ~Production facilities must be adapted to carry out processes so that they meet safety requirements ~Premises need to be organised/arranged so as to avoid contamination of raw materials and final products by manufacturing processes. ~Any production and storage facilities, if needed, must be equipped with indoor climate monitoring, maintenance and recording devices to prevent/detect potential contamination. ~Ventilation needs to be adequate and provide a barrier to contamination of production and storage facilities (especially with regards to dust). Ventilation also inhibits vapour condensation, eliminates doors dust and reduces the risk of product contamination through air. ~Persons who are not employed in the production and storage facilities may only enter these areas according to established company procedures. ~Company needs to have developed a description of the hygiene requirements of any visitors.</p> | <p><u>Raw materials</u> -Good information provided on the requirements of raw materials but could have had additional information on the GMP and QA requirements of the suppliers and the importance of communicating the end-use of the product to the supplier. <u>QA</u> -Very detailed information provided (including detailed information on hygiene practices to be used and methods used to avoid contamination). <u>QC</u> -Very detailed information provided. Could have had a little more information on the importance of documentation and the importance of recording and documenting any corrective action taken to avoid re-contamination.</p> <p>The Lithuanian document appears to combine GMP and hygiene guidelines into the one document and seems to provide a very good overview of all the key components of GMP</p> |

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| | <p>~All sewage disposal systems should be able to withstand the maximum load possible and be arranged so as to reduce the risk of contamination of raw materials, products or drinking water.</p> <p>1. Machinery and tools</p> <p>~Buildings and equipment must be suitable to perform the processes required of them</p> <p>~Any production and storage facilities, if needed, must be equipped with indoor climate monitoring, maintenance and recording devices to prevent/detect potential contamination.</p> <p>~Parts of equipment that need to be cleaned should be easily accessible or removable</p> <p>~Any lamps in production or storage areas should be protected so as to ensure that they are not broken and that if they are, these broken pieces do not contaminate the product.</p> <p>~Equipment should be arranged in the facility so as to avoid cross-contamination of products from raw materials and other sources of pollution.</p> <p>~Equipment needs to be operated, maintained and repaired according to the manufacturer's orders and instructions</p> <p>~Any equipment or surfaces covered in paint need to be maintained so that no loose paint (which could be a source of contamination) is released.</p> <p>~Any equipment used to produce the product must meet technical requirements to do so and can only be used for its intended purpose.</p> <p>~An effective pest control needs to be in place in the facilities.</p> <p>2. Manufacturing processes</p> <p>~Potential risk factors (2, 4-compounds) need to be identified at all stages of production</p> <p>~Raw materials and damaged packaging materials need to be separated, with damaged goods being returned to the manufacturer if possible. If return is not possible, any rejected materials must be separated and marked as pending assessment (where the decision will be made to return them to the supplier, destroy them or use them in production).</p> <p>~All raw materials, products, product packaging must be clearly identified so that raw materials and final products can be clearly distinguished.</p> <p>~In order to avoid cross contamination between raw materials and products, equipment shall be used carefully (with containers separated and secured).</p> <p>~Equipment used must be designed so that it can be cleaned (with cleaning being scheduled and recorded).</p> <p>~Production parameters must be correctly set on production equipment.</p> <p>~The production of any by-products or waste must be either disposed of or stored in such a way that prevents its use as a raw material, product or water or environmental pollutant.</p> <p>~Products must be transported in clean vehicles so as to avoid contamination</p> <p>~To ensure products are suitably safe, laboratories must carry out chemical and, if necessary, microbiological studies.</p> <p>~Finished products all obtain a batch number and are accompanied by a form which contains the product name, production date, from where the raw materials were obtained and the person responsible for them and their signature</p> <p>Presence of pre-established instructions for the procedures:</p> <p>~All manufacturing processes must be clearly defined, described and regularly reviewed to ensure that products produced are in accordance with quality and safety specifications laid down.</p> <p>~Document contains a list of the most important chemical, physical and biological contaminants and prevention methods (ex for chemicals they include heavy metals, industrial chemicals, cleaning chemicals, physical contaminants include dust, pebbles, hair etc... and biological contaminants include pathogens and other bacteria). All prevention strategies include GMP implementation and other factors such as pest control and ventilation for example.</p> <p><u>Monitoring the implementation and achievement of GMP:</u></p> <p>~Producers of FCMs need to ensure traceability of key raw materials, other ingredients and the product. The final packaging manufacture must provide additional internal labelling to ensure/demonstrate traceability.</p> <p>~Any companies that have additional aspects or have made changes to the GMP documents (compared to the requirements set out in EU legislation) must inform control authorities at the beginning of the inspection and these changes/differences must be described and approved.</p> <p>~The control requirements must be defined for each company</p> <p>~Periodically (at least once a year), internal audits must be carried out to monitor GMP and to determine whether results have been correctly recorded. Any irregularities need to be corrected (with the steps taken to correct these recorded)</p> <p>~Any documents highlighting steps taken to ensure control is maintained in the company need to be kept for at least 2 years.</p> <p><u>Corrective measures to remove any inefficiencies and non-compliance:</u></p> <p>~Any non-conforming materials must be removed from the market and detained.</p> <p>~Any product found to be non-compliant needs to be handed over to a group of people responsible for handling non-compliance and its causes. This group needs to determine whether there were violations of GMP, whether contamination occurred in storage or production areas and determine how many non-conforming products could have entered the market.</p> <p>~Any non-compliant products that enter the market will be notified to enforcement and inspection agencies (by the head of the production company) who will then withdraw all the possible non-conforming products (those made using the same raw materials, processes, etc...) from the market. Once the cause for non-compliance is identified, corrective action must be taken to avoid re-contamination.</p> <p><u>Documentation:</u></p> <p>Company should have internal documents and procedures, which define each of the materials or articles intended to come into contact with food, the person responsible for handling raw materials or monitoring final product quality and safety.</p> <p>Extra comments</p> <p>"Document appears to combine GMP and hygiene guidelines into one document.</p> | <p>and how to implement and monitor these. The document was sent in Lithuanian and all translations were done using Google Translator and therefore any uncertainties were either ignored or interpreted as best possible.</p> |

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| <p>UK UK GMP documentatio n:</p> | <p>The document is also in Lithuanian and therefore all knowledge drawn from the document has been with the aid of Google Translator."</p> <p>Raw materials ~GMP requires the cooperation with supplier of raw materials and knowledge of the needs of the customer. ~Raw materials need to be carefully selected to ensure that their components comply with requirements of the appropriate EU legislation and are of necessary quality standard. ~Need to respect any quality or purity criteria information that renders materials unsuitable for use based on safety grounds ~Each raw material should have a specification agreed between the supplier and manufacturer, which includes chemical and physical properties, purity criteria to ensure final product meets agreed manufacturing quality and end use requirements ~Raw materials should be tested when they arrive (or samples arriving prior to delivery should be tested) or should come with a declaration of compliance from the supplier which highlights any legal requirements of specifications adhered to ~Raw materials should have a name, reference number and batch or delivery number to enable their identification and traceability. Traceability needs to be maintained throughout the production chain and needs to exist at least to level of one stage back and one stage forward. ~Raw materials also need to be stored in conditions that prevent their contamination or deterioration, with rejected materials being clearly marked and stored separately from those that will be used. ~Raw materials should be used on a first-in first-out basis and only raw materials that have passed quality control procedures are used</p> <p>QA <u>Adequacy of the personnel:</u> ~The entire workforce needs to be committed to the objectives of GMP and understand the obvious benefits to the business. ~Training programmes should be established to ensure that all personnel are fully aware of their functions and responsibilities and are able to carry them out. <u>Organisation of the premises and equipment:</u> 1. Machinery and tools ~Equipment used should be suitable to manufacture the products required and be maintained in good repair (clean and, if necessary, calibrated) with maintenance documentation established and monitored. 2. Manufacturing processes ~FCMs should ideally have no measureable transfer or migration (or migration only within limits in law) of substances into the foodstuffs, when appropriately used. ~When manufacturing the material or article, need to consider the following: type of material and food to be packaged, processes and equipment involved, end-user specifications and compliance with health, safety and consumer protection regulations, as well as environmental policies and manufacturing processes. ~Manufacturing instruction document is required giving details on the raw materials, quantities and the equipment to be used, with critical parts of the process to be recorded and checked by the operator. ~Need to know the requirements of the customer to ensure a product is suitable for their needs and where the requirements cannot be ascertained, the product needs to highlight restrictions of its use (related to storage conditions, process temperatures, food types that can be used with the product etc...) <u>Presence of pre-established instructions for the procedures:</u> ~Requires production instruction documents which are issued for each batch of products manufactured and detail materials, quantities and equipment to be used and highlights any critical processes in the manufacture and any specific precautions to be followed. ~Product test specifications are required for each product which detail the tests (and the appropriate tolerances for the test) required during and following manufacture to ensure the batch is fit for intended use according to agreed tests.</p> <p>QC <u>Monitoring the implementation and achievement of GMP:</u> ~Testing of product samples at selected stages of the process should be carried out in order to monitor that they meet required quality standards and specifications at each critical stage. Sampling at critical points in the manufacturing process is essential in order to ensure finished product is successfully made, while analysis needs to follow a standardised or at least documented method. ~All measuring equipment needs to be maintained and tested/calibrated to ensure test results are accurate ~Product packaging should be selected to protect it during shipment and storage, ensuring it meets requirements for the product packaged and its means of transport. ~All products (including raw materials) should be stored in conditions that prevent their deterioration and where appropriate, a method exists to test materials that may have been held for some time. <u>Corrective measures to remove any inefficiencies and non-compliance:</u> ~A quality review procedure is required which, in the event of non-compliance at any stage of the process or of a complaint, a procedure should exist to take action to find the cause, rectify the problem and, if needed, make changes to the manuals or other controls to prevent reoccurrence. One person also needs to be appointed to accept responsibility for ensuring this rectification process takes place. <u>Documentation:</u> ~Require manuals that cover orders receipt, formulation, manufacture and product delivery to agreed standards. Recording systems are in place to ensure that the correct action for each stage can be verified. ~All product delivered must be accompanied by a DoC confirming that it meets agreed specifications or EU laws and must be updated whenever a change in production or materials supply changes the behaviour of the product</p> | <p><u>Raw materials</u> -Very detailed information on raw materials, with information required on them and details for their subsequent use being highlighted.</p> <p><u>QA</u> -Very detailed information covering all three aspects of QA (adequacy of the personnel, organisation of the premises and equipment and presence of pre-established instructions for procedures).</p> <p><u>QC</u> -Very detailed information on all three aspects of QC, which ensures compliance of products manufactured and corrects any non-compliance that arises. Could vaguely indicate the frequency of the controls required in order to implement the QA system.</p> <p>Very detailed information for all 3 areas of interest (raw materials, QA and QC) but does not break down GMP requirements by material and has only a single GMP document from all industry sectors, unlike the Italian document. I would say this document could be used as a reference for compilation of a European reference GMP document as it highlights all the requirements industries need to meet and does so concisely and clearly.</p> |

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| | <p>~Each product also has data sheets detailing relevant chemical, physical and safety data and suitable end uses and application of the product. All testing done on the product during its manufacture should be recorded and retained, as should data on the legal compliance of the product</p> <p>~Business operators should remember that they are obliged to make available their DoC and supporting documentation to enforcement officers in the case of request.</p> | |

Annex 5c – availability of GMP documentation for different materials at industry level under European umbrella organisations

GMP documentation containing different levels of GMP information for different materials at the level of European umbrella organisations

| Material category | Associations | Document |
|------------------------|--|--|
| general | | Industrial guidelines on traceability of materials and articles for food contact, prepared by a joint work of many FCM industry associations |
| Adhesives | FEICA (The Association of the European Adhesives and Sealants Industry) | Guideline on Good Manufacturing Practices in the Production of Adhesives and Sealants Intended for Food Contact Materials (2008) Guideline for Good Manufacturing Practice of food packaging adhesives in Reference to Regulation (EU) No 2023/2006 (2014) |
| Printing inks | EUPIA (European Printing Ink Association) - sector of CEPE | Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials (3rd revised version, March 2009- supersedes October 2005 version) |
| Varnishes and coatings | CEPE (European Council of Paint, Printing Ink and Artists' colours Industry) EMPAC (European metal packaging association) | CEPE - Good Manufacturing Practices (GMP) Food Contact Coatings, 2010 update CEPE - Guide to good hygiene and manufacturing practices for metal cans, packaging and closures for foodstuffs (May 2006) CEPE - Code of good industrial practices on traceability of materials and articles for food contact, 2004 EMPAC - Guide to good manufacturing and hygiene practices for metal packaging in contact with food (May 2009) |
| Ion exchange resins | SOIA (a member of CEFIC) | Guidelines for good manufacturing practice for synthetic organic ion exchangers and adsorbents intended for food contact applications. Contains guidelines to meet EC1935/2004 (Framework Regulation) and EC 2013/2006 (Good manufacturing practice), specific for ion exchange and adsorbent resins. Asked for a copied, but not yet received |
| Resins | ERMA (European Resin Manufacturers Association) | No information |
| Waxes | EWf (European Wax Federation) | Note found stated "EWf confirmed that there is no information on GMP on website and no plans to make information available" |
| Ceramics | CERAME-UNIE (European Ceramic Industry Association) UEAPME (Union Européenne de l'Artisanat et des Petites et Moyennes Entreprises) | CERAME-UNIE'S position on product safety and market surveillance package (version August 2013) No GMP exists specific to the sector |
| Glass | APFE now GlassFibreEurope | |
| | Glass Alliance Europe (used to be CPIV) | Guidelines for the glass industry – Registration, Evaluation, Authorisation and Restriction of Chemicals, REACH (2010) Glass, Glass articles and the EU REACH Regulation (May 2012) |
| | FEVE (The European Container Glass Association) | Glass and food contact regulation (version Dec 2011) Gap analysis for the Life Cycle Assessment of Container Packaging (version Oct. 2012), M. Finkbeiner, ISBN 978-3-00-041338-4 |
| Metals and Alloys | APEAL (Association of European Producers of Steel for Packaging) | Guide of Good Manufacturing Practices for the EU Steel for Packaging Industry (version: 09-01-07) -Guide applies to Good Hygiene and Manufacturing for steel packaging intended to come into contact with foodstuffs.) |
| | EAA (European Aluminium Association) | Code for good manufacturing practices for The European aluminium industry: Good Manufacturing Practice for aluminium alloy semi and end products intended to come into contact with foodstuffs (version updated review of April 2012)- Note: supersedes previous version of 2008. |
| | EMPAC (Metal Packaging Manufacturers Association) | Guide to good manufacturing and hygiene practices for metal packaging in contact with food, Edition 1: May 2009 |
| | EURO INOX EUROMETAUX (European Association of Metals) NICKEL INSTITUTE (European Nickel Industry Association) | No GMP exists specific to the sector |
| | FEC (Federation of the European Cutlery, Flatware, Holloware and Cookware Industries) | No GMP exists specific to the sector |
| Paper and Board | ACE (The Alliance for Beverage Cartons and the Environment) | No information received or available |
| | CEPI (Confederation of European Paper Industries) | Good manufacturing Practice for the Manufacture of Paper and Board for Food Contact (version: Issue 1 – September 2010) Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact (version: issue 2, September 2012) Developed by the European paper and board food packaging chain: CEFIC (suppliers of chemicals), CEPI (paper and board manufacturers), CITPA (paper and board converters), FPE (paper and board multi-layer manufacturers) Review of the Industry Guideline for the Compliance of Paper & Board Materials and Articles for Food Contact by Dr Alistair Irvine, PIRA International PART 1: Peer review of the Industry Guideline pre-publication version (2009); PART 2: Updated review of the Industry Guideline as amended (2010) |
| | CITPA (International Confederation of Paper and Board Converters) | Uses the FPE guidelines |
| | ETS (European Tissue Symposium) | Use CoE policy statement 'Policy Statement on kitchen towels and napkins' Some information: http://www.europeantissue.com/sustainability/production/good-manufacturing-practices/ |

| Material category | Associations | Document |
|----------------------|---|---|
| | FEFCO (European Federation of Corrugated Board Manufacturers) | International Good Manufacturing Practice Standard For Corrugated & Solid Board – Acceptance Conditions and Procedure for Certifying Bodies, second edition, January 2006 - More recent: Uses the CEPI guidelines, |
| | ECMA (European Carton Makers Association) | ECMA – Good Manufacturing Practice Guide (Version 1 – September 2011) |
| Rubber Rubber | ETRMA (European Tyre and Rubber Manufacturers Association) | Industrial guidelines on traceability of materials and articles for food contact, (no year) - industrial guidance for all materials with specifications related to rubber in Annex 6. highlights aspects of QA, QC, QM (quality management) and the minimum requirements etc. A draft document from work initiated with the European Council for rubber products exists (under discussion for list of positive substances). |
| | IISRP (International Institute of Synthetic Rubber Producers European Section) | No information |
| Silicones | CES (Centre European des Silicones) -sector of CEFIC | CES – Good Manufacturing Practices for Organosilicon Materials Intended to Come into Contact with Food, 2009 Note: only highlights the fact that most of the products member associations produce are not 'articles or materials' but raw materials and are thus excluded from the scope of Regulation (EC) 2023/2006". |
| Cork | CELiege (Confederation Europeenne de Liege) APCOR (Associacao Portuguesa de Cortica) | Code International des Pratiques Bouchonnières (Version 6.03) International Code of Cork Stopper Manufacturing Practices (ICCSMP) 6.04 Edition: highlights the steps involved in the production of cork. Detailed information on the requirements of the QA and QC systems and some, less detailed, information on raw materials. A new technology for volatiles reduction on natural cork stoppers: INNOCORK process Cork culture, nature, future; Cork information Bureau 2010. Quality, www.realcork.org |
| Wood | FEDEMCO (Spanish Federation of Wooden Crates and their Components) | Guide to Good Hygiene and Manufacturing Practices for the Sector of Wooden Packaging and their Components Intended to come into Contact with Food (2010) |
| Plastics | CPME (Committee of PET Manufactures in Europe) | No info |
| | EFBW (European Federation of Bottled Waters) member of FoodDrinkEurope | some information on the website itself http://www.efbw.eu/safety.php?classement=02 No additional info |
| | EPFMA (European Polyvinyl Film Manufacturer Association) | No info |
| | EuCIA (European Composites Industry Association) | No info |
| | PlasticsEurope EuPC (European Plastics Converters) CEFIC | Plastics Europe + EUPC + FCA CEFIC (found under CEFIC) Guidelines for Good Manufacturing Practice for Plastic Materials and Articles Intended for Food Contact Applications Versions: December 2005, First update April 2007, Second update April 2008, New update: <u>June 2011</u> SQAS GMP/Food Contact (Final Draft): Safety and quality assessment questionnaire to complement GMP guidelines. Developed for plastics. |
| | FPE (Flexible Packaging Europe) | Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food. (A FLEXIBLE PACKAGING EUROPE initiative realised in close co-operation with CITPA). Version 6.0, July 2011, FPE Europe. |
| Recycled Plastics | EuPR (European Plastics Recyclers) | No information on GMP on website |
| | PET Container Recycling Europe | No information on GMP on website |
| | PRO Europe (Packaging Recovery Organisation Europe) | No information on GMP on website |
| Reg.cellulose | CIPCEL (Comite International de la Pellicule Cellulosique) | Guide to Good Manufacturing Practice for non-edible Cellulose Casings (booklet) |
| Textiles | EURATEX (European Apparel and Textile Organisation) | Use CoE on tissue paper and napkins (see ETS) |
| Other | CECED (European Committee of Domestic Equipment Manufacturers) | No information received. |
| Other | CE.T.I.E (Centre Technique International de l'Embouteillage et du Conditionnement) | No information received. |
| Other | FoodDrinkEurope (Association of the food and drink industries of the EU) | No information received. |
| Other | EVA (European Vending Association) | No GMP: not have special GMP guidelines but have produced some documents about BPA, lead in brass or polystyrene used in vending cups. |
| Other | EUROPEN (European Organization for Packaging and the Environment) | No information received. |
| Other | FPME (Food Processing Machinery Europe) | No information received. |
| Other | PACK2GO Europe | Document not very detailed and does not outline requirements of raw materials, QA or QC systems. |
| Other | EDANA (International Association serving the nonwovens and related industries) | No GMP - do not have any GMP documentation for food contact materials (published or unpublished) as food contact is a 'niche' area for their members and the wider non-woven community. |

Annex 5d Analysis of GMP contents of documentation retrieved from industry associations

The analysis reflects an overview of information on GMP from industry associations and refers to the coverage of the checklist for GMP (from EU Regulation (EC) 2023/2006):

| Association | Contents | Evaluation |
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| <p>General</p> <p>"Industrial guidelines on traceability of materials and articles for food contact" prepared by a joint work of FCM industry associations from glass, metal, plastic, paper & board, regenerated cellulose, rubber, wooden crates, tissue</p> | <p>Raw Materials Starting materials need to be selected and comply with pre-established specifications to ensure compliance of the material or article with the rules applicable to it "The business operator ensures that the incoming starting materials are supplied with information given by the relevant supplier. This information is either printed on the starting materials' containers, or reported on labels, bar codes, or in accompanying documentation. Information must be provided which enables the identification of: 1. Name of supplier and type (grade) of starting material; 2. Location of production, date, batch number and/or shift of manufacture and/or order number; 3. When appropriate (for example in the case of plastics) documents certifying the legislation with which they are complying; 4. Documents of analysis that, depending on their nature, report the key attributes against the agreed specifications. The downstream user often carries out further analyses in order to confirm the suitability of the starting materials for their intended use. Also, according to ISO 9000 procedures, downstream users can carry out audits to ensure that the upstream supplier's process is under control, and therefore the relevant technical attributes of the starting materials are constantly maintained. It gives requirements for shipped materials and articles</p> | <p>Raw materials -Some information QA -No information QC - Some information available for the individual materials related to recall (see for those materials)</p> |
| <p>ADHESIVES</p> <p>FEICA</p> | <p>Raw materials ~Raw materials shall be in compliance with different food regulation ~The company shall establish and regularly review specifications for incoming raw materials ~Raw materials should comply with restrictions that are relevant to their use ~Raw materials that are authorised food additives may be used as components in the food packaging too ~ FEICA has recently developed a "Rejection list" of substances in order to check the status of the raw materials against further critical substances (Annex II), which should also help for the evaluation of the raw material. In case the information received from the supplier is not sufficient (e.g. no chemical identity, no compliance information, etc.) the raw material can either be rejected or checked by analytical screening ~ flowchart of evaluation of raw materials and adhesives by producer QA Adequacy of the personnel: ~The top management of the company shall define its GMP and QA system and make their commitment to implement it known to employees. They shall also conduct reviews at planned intervals and shall ensure the availability of resources ~The top management shall appoint qualified persons responsible for implementing and maintaining the GMP and quality assurance system ~Company shall provide training in GMP and quality assurance requirements for its personnel, temporary and external staff (to an appropriate level) with the effectiveness of the training monitored and recorded ~Refresher training should be organised and documented Organisation of the premises and equipment: ~When stored outside, all raw materials and products shall be protected from contamination ~External pathways should be suitably maintained so as to avoid contamination to raw materials or finished or unfinished products during transportation ~Construction and layout should permit adequate maintenance and cleaning ~Pest prevention should be in place both in the building and in surrounding area ~Where necessary, separate storage areas shall be available to prevent contamination of incoming materials, products, cleaning agents etc.. 1. Machinery and tools ~All parts of equipment coming into contact with the products should be maintained and cleaned ~All products shall be made of a material suitable for the intended use ~Fixtures, piping and ducts shall not cause condensation or leakage to fall on to the product and temporary engineering and modifications should be avoided and shall not become permanent. 2. Manufacturing processes ~The company shall prevent cross-contamination with non-GMP products ~Raw materials, packaging materials and finished and unfinished products shall be protected from contamination during transport,</p> | <p>Raw materials -Not detailed enough as there is no specification that the supplier must be GMP compliant, no mention of any specifications/criteria materials and supplier must meet, no mention of purity requirements of starting materials, or of the need for materials to be suitable for contact with food and, lastly, no mention of any forms of control of these incoming materials. QA -Some information on QA system, but there is a distinct lack of information on the presence of pre-established instructions for the procedures, the necessary communication between suppliers and manufacturers and, lastly, insufficient information on the importance of keeping production processes under control, especially stages/processes considered critical. In addition to the points referring to EU legislation, this GMP document highlights measures that can be implemented to prevent chemical contamination and specifies, in detail, hygiene practices that need to be adhered to as well as storage of materials and layout of the premises (to ensure contamination does not occur), which seems to be out of the scope of EU legislation and I therefore believe that it does not need to be considered for addition to the legislation. QC -Detailed information provided. No further information required.</p> |

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| | <p>storage and delivery ~Pallets shall be inspected before use and need to be suitable for use with the intended products and clean. ~Transport vehicles shall be checked before loading and should be kept clean and free from pests and foreign bodies</p> <p>3. Measures to prevent chemical contamination include ~Chemical and cleaning materials being controlled so as to prevent contamination (for example cleaning products shall be suitably identified and stored in designated areas while chemicals that could cause food contamination shall not be used) ~Compressed air coming into contact with the food contact products shall be suitably filtered</p> <p>Presence of pre-established instructions for the procedures: no notes</p> <p>QC Monitoring the implementation and achievement of GMP: ~The company shall establish and regularly review specifications for incoming raw materials, packaging and finished products ~The company shall have written procedures for identification and tracking of all products (from receipt of incoming raw materials to delivery of product) ~The effectiveness of the traceability system shall be demonstrated either by an audit of existing recall records or by simulation ~The company shall have regular internal audits to confirm the compliance to GMP ~The company shall extend its GMP management system to relevant outsourced processes with a written contract drawn up. ~Outsourcing and suppliers shall also be audited, evaluated and approved and monitored by the company, with records being kept.</p> <p>Corrective measures to remove any inefficiencies and non-compliance: ~The company shall have written procedures in place for identifying, segregating and processing non-conforming products. It should also have procedures for dealing with non-compliance and incidents and shall take action to eliminate the causes of the non-compliance and incidents to prevent recurrence. ~Such corrective measures need to be implemented as quickly as possible and be made available to the competent authorities for inspections. ~The company should have a written procedure for identifying and analysing the root causes of complaints, with subsequent actions taking place to eliminate these causes</p> <p>Documentation: ~Company shall have procedures for preparing and controlling documents and records ~Documents should be properly approved, reviewed and updated with changes and current version status indicated and shall be available at the point of use. ~Records shall be maintained to provide evidence of the effective operation of the GMP management system and retained for the period covering the normal shelf-life of the product</p> <p>Additional point: Management of change: ~A procedure must be in place to identify, monitor and document and changes in raw material composition, product composition, process aids, personnel etc... ~flowchart for evaluation of adhesive in application of downstream user ~template for DoC</p> | |
| <p>CORK C.E.LIEGE</p> | <p>Raw materials ~Any raw materials accepted must have their region, the forest or property from which they were procured, the quantities and the year harvested recorded ~Any cork that is unsuitable for use in the manufacture of stoppers needs to be segregated and clearly identified so as to ensure it is not used in later stages of manufacture ~Need to separate cork that comes from different areas ~Cork needs to be purchased from durable sources, which are certified ~Cork destined to be used for the manufacture of stoppers needs to have had at least 9 months of growth ~Burnt cork, green cork and yellow stained cork all cannot be used ~Any yellow-tinted cork needs to be rejected at any stage of the production or transformation. As soon as it is detected, it needs to be stored in a clearly identified zone reserved for unsuitable cork.</p> <p>QA Adequacy of the personnel: ~Need to have qualified and trained personnel who are in charge of controlling quality or need to subcontract this task to a competent body ~Need to evaluate and qualify all the suppliers of chemical products entering into production processes, as well as any cork suppliers</p> | <p>Raw materials -Some information on raw materials but not enough on the requirements of the suppliers or the purity requirements of the starting materials. QA -Very detailed information on the requirements of the QA system. Additional details on hygiene practices and specifications on the QC -Some information on the various elements of the QC system mentioned, but lacking in clear specifications. Could have additional information on how to control GMP compliance and outlining corrective methods that are to be used if any non-compliance is identified in products.</p> |

Organisation of the premises and equipment:

1. Machinery and tools

- ~Need a cleaning schedule of the premises, which also needs to be enforced
- ~Need a pest control program with controls being recorded. The products used to prevent pests are not to come into contact with the stoppers.
- ~Need to be able to record humidity and temperature in the storage areas
- ~Need to put in place appropriate methods to avoid the presence of domestic animals and to reduce the number of wild animals in the facilities
- ~No food or drink is to be consumed in work areas and smoking is also forbidden. These rules need to be clearly visible
- ~Machinery used to fill and coat the stoppers (with the coating being done using solvents) must have air and solvent extraction systems and must be protected with anti-inflammatory systems.
- ~Do not use wooden drying ovens
- ~Need to have a maintenance plan for the equipment which is used
- ~Machines and transfer systems selected should avoid breaking the stoppers.
- ~Check every 6 months to see whether measuring equipment is functioning correctly and record the outcomes and take any necessary action.
- ~Need a system in place to protect the material in case of broken glass
- ~Need a plan to control the emptying of the circuits and machines to avoid mix up of products of different batches.

2. Manufacturing processes

- ~Anyone operating machinery needs adequate protection, which is adapted to the task they perform.
 - ~The company must identify wastewaters and gases produced and must come up with methods to dispose and deal with these last.
 - ~The manufacturer must ensure that different types of additives used in the production of cork stoppers are compatible.
 - ~Chemical products and their packaging must be correctly labelled, must contain expiration information and cannot be used once this date has passed, they need to be in good condition and they must be stored as indicated by their supplier.
 - ~Any chemical products used to formulate cork stoppers or any other type of stopper must be suitable for this use and must be used under conditions outlined by supplier.
 - ~The manufacturer must not use products that contain active halogens in the transformation of cork, with this rule also applying to the products used to clean production installations.
 - ~Company must prove that inks used to mark the stoppers conforms to legislation regarding heavy metals
 - ~The use of a new chemical product, not currently in use in the cork industry, can only be accepted if the supplier or manufacturer provides a DVT
 - ~Never dry non-washed stoppers with washed stoppers, no matter what previous treatments were used
 - ~Need to ensure that uncomfortable stoppers and collars are absent during all manufacturing, semi-finished and finished steps of production.
 - ~Containers for stoppers, collars and any other cork materials must be clean, dry and odourless. Any stored materials need to be correctly identified and bags made of natural fibres are not to be used
 - ~Any pummelled cork that results from preparation of cork or manufacture of the collars or stoppers needs to be correctly identified and stored in a dry, covered and clean area (in bags or containers) or in appropriate conditions, in either case, in a segregated area from the stoppers and collars that are to be used.
 - ~Need to test all products that have been stored more than 6 months in specific conditions before their use
 - ~Storage areas for carton packages need to be physically separated from the storage areas of the stoppers and collars using a rigid and inert element
 - ~Cork or cork products must not be transported with odorous products
 - ~Any transportation of cork will be subject to a specific registration which details both origin and destination of the product, the control of the cleanliness of the truck/container (which has to have taken place before shipping) and reference details of the shipping.
 - ~Carton packages need to be stored in an area separated from stoppers and collars that are still being worked on and will be controlled under specified conditions.
 - ~Chemical products need to be stored in a specific zone and identified
 - ~Need to monitor that drying ovens and the facilities are not contaminated with halogen compounds once a year
 - ~Need to use new bags to deliver product to final clients
 - ~The company needs a plan to reduce energy use and reduce its impact on the environment
- Presence of pre-established instructions for the procedures:**
- ~The company must have and apply written instructions for each procedure
 - ~The document provided has clear guidelines on how to carry out each stage of the manufacturing process

QC

Monitoring the implementation and achievement of GMP:

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| | <p>~Any innovative technique will be accepted if the procedure is validated by an accepted validation dossier. ~Traceability of the cork products must be guaranteed from their arrival in a plant all the way through to the client ~Need to compile data on controls and their results Corrective measures to remove any inefficiencies and non-compliance: ~A control plan must be in place which corresponds to the industry's activities and which complies with the present CODE document ~Any non-conforming products must be controlled and complaints from clients must be dealt with Documentation: ~Both producers and subcontractors need to have a valid declaration of conformity for each activity and operation concerned. ~Both producers' and subcontractors' details need to be registered for each activity or operation that they carry out, with this being done by type of product. Details required include delivery date of raw or starting materials, the delivery number, the name of the supplier or subcontractor and the quantities received. ~The industry must have up-to-date registrations, which conform to the requirements laid out in this document, with these registrations being maintained for at least one year. ~Lubricants and cleaning products, used for machinery or equipment, which come into contact with cork must have technical documents that confirm that they can come into occasional or accidental contact with food, without any negative safety consequences. ~Documents on chemical products used in the production of cork stoppers are needed to confirm that they conform to the regulations of food contact materials</p> <p>Additional point ~Only the international organisation is responsible for carrying out the audit and eventually attributing a company with a certificate of conformity, with this certificate being the only proof that societies that are audited are working in compliance with this code. ~The International Code of Cork Stopper Manufacturing Practices (ICCSMP) describes and establishes procedures to be observed by the cork industry. It was created with the aim of implementing QC standards throughout the entire production process by guaranteeing a contamination-free product. This code defines the correct practices to be adopted when stabilising cork after harvest, during cork stopper production and during the transportation of stoppers. Any companies applying for accreditation from ICCSMP undergo audits on a yearly basis to ensure practices defined by the ICCSMP are abided.</p> | |
| <p>GLASS FEVE</p> | <p>Raw materials "The traceability of materials used in the production of glass packaging containers cannot be precisely defined by this guideline, for two reasons. Firstly, raw materials must be stored in large quantities before they are used, so that a definite identification of the individual deliveries or suppliers (if there is more than one supplier for the same raw material) is not possible from information relating to the glass containers produced. This is especially true for the recycled cullet that is, depending on the glass colour and the production site, often the main raw material in the glass melt. Secondly, glass melting furnaces are continuously operated facilities in which raw materials are introduced on one side, while molten glass is removed on the other side and formed into a product after a thermo-chemical melting process has taken place. This process, in which partial mixing occurs, is another factor inhibiting a definite traceability of the starting materials used to make particular glass containers." (industrial guidelines) QA: no detailed information Glass only has to comply with the Framework legislation and GMP (as well as some ISO standards describing specific migration tests of lead and cadmium which can be used on a voluntary basis) QC no detailed information "The Good Manufacturing Practice (2023/2006/EC) is another piece of legislation, developed under the Framework Regulation, which concerns all materials as well. The requirements of this regulation applying to glass packaging concern mainly the implementation of quality assurance and quality control systems and the establishment and maintenance of appropriate documentation (paper or electronic) relevant to compliance and safety of the finished article which should be made available to the "competent authorities" on request." (Glass and food contact regulation (version Dec 2011))</p> | <p>Raw materials - some information but lacking clear specifications. QA - No information QC - Some information but lacking clear specifications.</p> |
| <p>GLASS Glass Alliance Europe</p> | <p>Guidelines for the glass industry – Registration, Evaluation, Authorisation and Restriction of Chemicals, REACH (2010) + Glass, Glass articles and the EU REACH Regulation (May 2012)</p> <p>Raw materials The articles made by the glass industry consist of the substance glass, which is not on the "candidate list" and can be assumed never to be on it. Thus, there is no duty under Article 33 to communicate information on substances in articles for articles made entirely of glass. Furthermore, since the glass industry is normally supplying articles made of glass and not a substance, there is no need to supply safety a data safety sheet to the customer (based on REACH TITLE IV: Information in the supply chain Article 31)</p> | |
| | <p>An "Industry Joint Working Group" has developed a Guidance Document, aiming to: o Clarify how to apply the requirements of Regulation 10/2011 to the sizing ingredients according to their function in the plastic; o Provide a procedure for verifying the</p> | |

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| | <p>compliance and safety of the sizing ingredients. • This Industry Guidance has been submitted to DG Health and Food Safety (and by DG for Health and Food Safety to EFSA) for review and validation. • When the Industry Approach will be validated by DG for Health and Food Safety, it will be disseminated across the supply chain.</p> | |
| <p>METALS AND ALLOYS</p> <p>STEEL</p> <p>APEAL</p> | <p>Raw materials Raw materials must be stored and handled in a manner that prevents their mix up, contamination or deterioration Raw materials need to be of a purity standard suitable for their intended use, which can be verified either through incoming Quality Control or a supplier's certificate stating they meet the specifications. Suppliers are approved if they are able to supply materials and services which meet specific requirements (with inspections or other activities, if needed, being performed on the supplier's premises). Suppliers are monitored and results of evaluations are recorded Suppliers of raw materials need to certify and be aware that their products are suitable to be used in the production of materials or articles intended to come into contact with food. Materials not meeting acceptance criteria are properly identified and controlled</p> <p>QA <u>Adequacy of the personnel:</u> ~Need defined responsibilities and authority of management with respect to GMP implementation. Personnel, whose job is related to the manufacture or control of FCMs, have their duties provided in job descriptions or other suitable documents ~Personnel need to have adequate education or experience to perform the tasks required of them ~The organization provides training on GMP related to the production of FCM to its personnel and temporary or external staff, where necessary. Records of training are kept for all current and recent employees.</p> <p><u>Organisation of the premises and equipment:</u> 1. Machinery and tools ~Buildings, premises and equipment used in the manufacture or storage are assessed in line with the specific production step and maintained in good condition so as to produce materials of a consistent quality suitable for food contact use. 2. Manufacturing processes ~Procedures are in place to avoid cross-contamination during production, storage, handling and transport ~Appropriate hygiene standards are maintained for personnel, factories, warehouses and transportation. ~A pest control program is in place, or if it not, documentation needs to be provided to justify this lack ~Storage and transport conditions are such that contamination of the food contact materials is avoided ~All materials are clearly identifiable ~There is an adequate contamination prevention procedure based on risk assessment and procedures in place to avoid contamination through packaging, storage and transport operations ~There is a physical separation or a validated control system to segregate raw materials and products from non-conforming materials ~Water supplied must be of a certain quality and the supply must be tested regularly to ensure conformance</p> <p><u>Presence of pre-established instructions for the procedures:</u> ~Operation procedures and process operating windows have been established and documented ~Changes in raw materials used or raw material suppliers are subject to change control ~There is a procedure to control changes in operating practices or windows so that any changes affecting the composition or risk for contamination might be detected or flagged.</p> <p>QC <u>Monitoring the implementation and achievement of GMP</u> ~There is traceability from incoming starting material to outgoing FCM ~Raw materials and products are examined to determine their compliance with specifications and purity criteria (raw materials may be examined by supplier and then delivered with a certificate of analysis) ~Every food contact material code has one unique specification ~If the product formula and specifications change, then there is a change control procedure in place which changes food contact material code ~Internal audits or self-assessments are conducted at planned intervals to assess that GMP are being implemented and maintained. ~The responsibility of planning, conducting and reporting results of audits/self-assessments and maintaining their records are specified in a procedure ~There is a procedure in place to evaluate the quality standards of a new raw material supplier before approval</p> <p><u>Corrective measures to remove any inefficiencies and non-compliance:</u> ~A procedure is established for handling product recalls and complaints with subsequent actions determined by the seriousness and frequency of complaints.</p> | <p>Raw materials -Detailed information provided QA -Detailed information provided. Specifies the requirements of machinery and tools succinctly (which Italian GMP document lacks any guidance on) but could use some additional information on the importance of both controlling processes, especially at any critical points. Additional guidance on the communication required between manufacturers and suppliers should also be made available. QC -Detailed information provided. No further information required.</p> |

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| | <p>~Risk management procedure in place to handle contamination issues ~Procedures to deal with incidents are established, along with actions taken to prevent a recurrence (with these actions being assessed for their effectiveness) Documentation: ~Documented specifications exist for raw materials as well as finished products ~Documentation system exists which records product formula, operating procedures. Product release specifications and other critical information. ~Any equipment that is used to produce FCM is identified to enable collection of relevant information on it (contents, control status etc...) ~Control records are maintained on items such as raw materials, rejected materials, manufacturing conditions, Quality Control data test results, testing procedures and storage and distribution data</p> | |
| <p>METALS AND ALLOYS ALUMINIUM EAA</p> | <p>Raw materials ~Only approved suppliers are entitled to supply raw materials and these are approved and accepted once the quality standards of their materials has been verified (can be done using an audit on the supplier's premises) ~Suppliers must be aware and certify that their products are suitable to be used in the production of materials intended to come into contact with food ~Raw materials need to be of a certain purity, suitable for their use ~Raw materials must be stored and handled in a way which prevents their mix-up, contamination or deterioration ~Materials not meeting acceptance criteria are properly identified and controlled to prevent misuse</p> <p>Adequacy of the personnel: ~Management responsibilities for GMP implementation are assigned, defined and documented. ~Personnel supervising or performing the manufacture or control of FCM should have the appropriate training, education and/or experience to perform assigned tasks. ~Relevant personnel shall receive ongoing training on GMP for the production of FCM, which should be documented</p> <p>Organisation of premises and equipment: ~Buildings, premises and equipment used in the manufacture or storage should be assessed in line with specific production step and maintained to produce materials of a consistent quality suitable for food contact use ~Procedures are in place to ensure cross-contamination during production, packing, storage, handling and transport does not occur ~Procedures to prevent cross-contamination when transitioning from non-FCMs to FCMs ~Appropriate hygiene standards are maintained for personnel, factories, warehouses and transportation methods. ~A pest prevention program is in place (justification in case of absence of such a program) ~Water that comes into contact with the food contact materials should be of suitable quality and tested regularly to ensure compliance with requirements ~Materials are clearly identified ~Storage and transportation will avoid contamination of the food contact materials</p> <p>1.Machinery and tools ~Major equipment, transfer lines, containers and tanks that are used to produce food contact materials are identified to indicate contents, batch designation and control status.</p> <p>2.Manufacturing processes Presence of pre-established instructions for the procedures</p> <p>QC Monitoring the implementation and achievement of GMP: ~There is traceability from incoming starting material to outgoing food contact material ~Samples from end products (the final production stage before prior to the packaging getting in direct contact with food) are retained for a specified time period depending on final usage ~Work contracted out is subject to audits and must comply with GMP of contracting body ~There is a procedure in place to enforce regular internal audits or self-assessments to demonstrate compliance with GMP ~There is a procedure in place to evaluate the quality standards of a new raw material supplier before they are approved. This may be based on technical discussions but could include an audit on the supplier's premises.</p> <p>Corrective measures to remove any inefficiencies and non-compliance: ~There is a system implemented for recording and investigating complaints including product recall if necessary. ~Complaint investigation shall result in recommendations for corrective actions if needed ~There is a risk management procedure in place to handle contamination issues</p> <p>Documentation: ~There is a documentation system in which product formula, operating procedures, operating windows and product release specifications and other critical information are documented</p> | <p>Raw materials -Detailed information provided QA -Insufficient detail on QA procedure as there is no detail on manufacturing processes or pre-established instructions for the procedures. There could also usefully be guidance on communication requirements between manufacturer and supplier, as well as information on critical points and the importance of ensuring products manufactured will be suitable for food contact and the use specified by the manufacturer. Document also highlights the importance of preventing contamination when transitioning from non-FCMs to FCMs, but this does not need to be added to EU legislation. QC -Detailed information provided. No further information required.</p> <p>Guideline does not apply to any further processing of these products, such as packing or filling, which will need to be covered by a separate GMP document.</p> |

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| | <p>~Control records are maintained on raw materials, rejected materials, manufacturing conditions, production records, QC data, testing procedures and standards, test results and storage and distribution information. This document shall be made available to competent authorities upon request</p> <p>~Documented specifications do exist for raw materials and finished products</p> <p>~Raw materials and products should be examined to determine their compliance with specifications and purity criteria (for raw materials this can be done by the supplier and documented in a certificate of analysis)</p> <p>~Every food contact material code has one unique specification</p> <p>~The change control procedure ensures that the food contact material code changes when product formula and specifications are changed</p> <p>Additional information</p> <p>~Procedures to control changes that can alter the composition or organoleptic of the food contact material, directly or indirectly, as well as contamination prevention procedures, should be in place (management of change)</p> <p>~Changes in raw materials or raw materials suppliers are subject to change control</p> <p>~Potential composition changes outside specifications need to be flagged and a judgment needs to be made (possibly supported by new safety assessments) to confirm continued compliance with food contact regulations</p> | |
| <p>METALS AND ALLOYS</p> <p>EMPAC</p> | <p>Raw materials</p> <p>Guidelines and control of the manufacturing process of raw materials are beyond the scope of the document but it does note the importance of these materials meeting specifications and being suitable for their purpose and highlights steps which the supplier could do take to ensure suitability, such as:</p> <p>~Ensuring that raw materials are manufactured under supplier's own GMP</p> <p>~The supplier could provide a batch test certificate</p> <p>~Supplier could provide a certificate of conformity against relevant regulatory requirements or standards</p> <p>~The supplier commits to comply with auditable manufacturing and hygiene procedures which are periodically checked by customer audit</p> <p>~Selection of starting materials: Materials need to be accompanied by recommended conditions of use and should be selected based on their suitability for the particular application for which they will be used</p> <p>~Suppliers must be reliable and subject to an approval and monitoring procedure and must also provide a Declaration of Compliance for their product</p> <p>QA</p> <p><u>Adequacy of the personnel:</u></p> <p><u>Organisation of the premises and equipment:</u></p> <p>Premises requirements:</p> <p>~Raw materials, packaging materials and products must be protected against contamination during storage, transportation and delivery</p> <p>~Ventilation needs to be adequate in production and storage areas</p> <p>~Packaging materials need to be contaminant free before use</p> <p>~Procedures in place to avoid cross-contamination in warehouses</p> <p>~Raw materials and products not stored too close to potential sources of contamination (for example chemicals or mechanical parts)</p> <p>1. Machinery and tools</p> <p>~No residue of oil/grease left in areas which could contaminate the product</p> <p>~Excess grease is wiped off</p> <p>~During corrective maintenance, product on the line (if cannot be removed) is protected from contamination</p> <p>~All parts of equipment coming into contact with the products, as well as handling equipment, are well maintained and cleaned</p> <p>~All equipment is made of a materials of suitable use</p> <p>2. Manufacturing processes</p> <p>~Procedures should be in place to ensure that only specified materials are used for the appropriate application and that only specific authorised materials are used for manufacturing processes</p> <p>~Process conditions must be maintained within prescribed limits in accordance with the supplier's recommended conditions of use</p> <p>~General care should be taken during the production process to avoid a contaminated or unauthorised food contact surface (by avoiding environmental contamination or use of cleaning materials or lubricants in the vicinity of the product)</p> <p>~Avoid contamination of food contact material during post-manufacturing handling by correctly selecting packaging for the materials and by ensuring that procedures are in place to ensure that storage and transport does not lead to contamination of the food contact surface (because of storage or transport beside inappropriate products/materials, for example)</p> <p>Preventing chemical contamination:</p> <p>~All cleaning agents shall be suitably labelled and stored in a designated area</p> <p>~Cleaning products used to clean equipment shall be odourless as shall products used to wash hands</p> | <p>-Guidance on the GMP and good hygiene practices for the manufacturers of light metal packaging, metal cans, ends, closures and metal drums where the end-use is for contact with foodstuffs for humans or animals.</p> <p>-Document covers all the manufacturing process stages from coil cutting to the shipping of ready-for-use empty cans, drums, ends and various other components</p> <p>_Within the scope of the document: cans and ends for foodstuffs, pails and drums used for foodstuffs, metal caps, lids and crowns for bottles and jars for foodstuffs.</p> <p>-NOT within the scope: Aluminium monobloc aerosols, collapsible aluminium tubes, aluminium or steel beer kegs and semi-rigid aluminium trays.</p> <p>Raw materials</p> <p>-Detailed information provided</p> <p>QA</p> <p>- Good information provided but lacking information on requirements of the personnel and the presence of pre-established instructions for the procedures. Gives detailed guidance on how to prevent chemical contamination and highlights some measures to help prevent contamination. Guidelines mention the importance of maintaining process conditions within prescribed limits (based on supplier's recommended conditions of use). Good information contained on the importance of having a clear and efficient route of information flow between the various manufacturing stages and the producer and consumer, which will clarify how product is to be used and it's end performance.</p> <p>QC</p> <p>-No information at all.</p> <p>Notes</p> <p>~Guideline deals with both hygiene and good manufacturing practices in one single document</p> <p>~Need a clear and efficient route of information flow between the various manufacturing stages, the producer and consumer, to clarify how products should be used, what it should be used for and expected performance of the product. With this information, a Declaration of Compliance from supplier to customer is provided at each stage</p> |

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| | <p>~Machinery lubricants should be risk managed by maintenance and should not leak, so as to avoid contaminating the product. ~Compressed air blown on product should be suitably filtered Presence of pre-established instructions for the procedures: no info</p> <p>QC: no information</p> | |
| <p>FEC</p> | <p>FEC member companies follow the EU GMP Regulation as well as the existing GMP guidelines for the type of materials they use. E.g. the EU GMP guideline for plastics for food contact when making plastics components or articles or the CoE/EDQM Resolution on metals and alloys and articles made thereof for food contact. Depending on the types of materials and size of the company they check and control raw materials and have QA, QC and traceability systems in place. "REACH web tool", which was made so that members of FEC can have their own " portal" and have access to it at any time. They can fill in how far they are with the implementation of REACH in their own companies. The web tool allows them to have a continuous benchmark comparison with what should be needed for their companies to be fully compliant with REACH. The web tool is also continuously adapted with the latest developments and changes of REACH. Because of the great number and the wide difference in raw materials and manufacturing methods used by FEC members. The industry/sectorial self-regulation and guidance documents provided by FEC are mostly only very general: we have a very strict FEC Code of Conduct, to which each member or new member has to subscribe. the risk assessment is done at individual company level, whereas FEC regularly provides its members information on specific risks of certain substances such as e.g. Bisphenol A, uncoated aluminium, certain nanomaterials, certain biocidal products, DEHP, etc.</p> | |
| <p>PAPER AND BOARD CEPI</p> | <p>Raw materials ~Raw materials and additives used in the production of FCM need to be assessed to ensure they comply with current regulatory requirements (this could be through use of EU or MS approved food contact lists) ~Records need to be maintained of raw material deliveries in order to determine whether these meet regulatory requirements. ~Recipes of the end product, including raw materials and additives used along the way, must be compiled and retained ~Suppliers of recovered paper must supply documented evidence of conformity</p> <p>QA Adequacy of the personnel: ~It is the management that has the ultimate responsibility for ensuring that GMP is integrated, applied and reviewed and documented. It is also their duty to ensure that appropriate personnel are trained and given responsibilities under the system ~New and existing personnel should be trained on GMP requirements and hygiene aspects specific to the food contact product (with training records being kept)</p> <p>Organisation of the premises and equipment: ~Appropriate rules for housekeeping and cleaning of production areas, equipment and areas used by personnel working on FCM (lockers, working spaced etc...) need to be established, with rules being mainly applied to areas directly involved in production of the food contact material (and not offices or engineering facilities which are remote from the production facility). ~Buildings, machinery, conveyors, transport devices etc... must be cleaned regularly ~Regular inspection of facilities should occur ~A documented pest control must be in place ~In the event of a breakage (of glass or plastic for example) in the area of food contact product, a procedure must be in place to ensure that the food contact product being produced at the time is free from any debris. ~All external warehouses should be suitable for the purpose, well maintained, have appropriate atmospheric conditions and be in a state of good hygiene.</p> <p>1. Machinery and tools ~Engineering, maintenance and technical equipment, together with any temporary construction arrangements used should be removed as soon as the task is complete.</p> <p>2. Manufacturing processes ~A documented risk assessment should be performed if significant changes have taken place in the equipment or process used to manufacture the material or if the raw materials are different or coming from a different supplier. ~Inks, varnishes and adhesives used for printing and converting should be selected to ensure the lowest possible levels of migration in food (apart from UV cured inks, which should not be used any packaging application) ~Certain grades of recovered paper are not suitable for use in food contact materials as the normal high quality standard cannot be guaranteed. ~If both food and non-food contact grades of paper are produced in the same mill, there needs to be appropriate measures in place to ensure that only the appropriate grades of paper are used to produce the food contact material. ~ All vehicles used for transporting finished paper should be suitable for the purpose and in a good state of hygiene ~Converting operators are responsible for applying a range of substances to paper and board (ex. inks and adhesives) ~UV cured inks should not be used in any packaging, unless manufacturers are producing the newer and safer versions (once their suitability for food contact was ascertained by manufacturers)</p> <p>Presence of pre-established instructions for the procedures:</p> | <p>Covers CEPI, FEFCO -document provides guidance on how to fulfil GMP requirements of paper and board manufacturing -document does not cover the operations of the converter -document applies to the entire production process</p> <p>CEPI document gives guidance on implementation of EU GMP regulation in the paper and board manufacturing sector, with certain elements being considered as fundamental elements of GMP and others needed only sometimes, based upon a risk assessment. ~Use of final paper or board products is very varied (from being used in direct contact with moist foods to indirect packaging) so emphasis on use of GMP check-list to determine which steps are required or avoidable, based on final use of product ~But use of paper and board coming into direct contact with food is estimated to be less than 3.5% of all direct contact food packaging, it can be considered to have a low consumer exposure ~If a manufacturer does not implement one of the optional GMP steps, documentation must be provided to state the reasons for this action ~Paper and board is predominantly composed of cellulose fibres (where cellulose's main constituent, B-glucose, has no adverse health effects), contrary to plastics. Importance of the quality of recycled paper and board used is highlighted and suppliers need to demonstrate that they are not using certain sources of recovered paper (such as paper that has come into contact with waste and then been sorted or household wastes such as used paper towels for example) as normal standards of high purity cannot be guarantee. Specific regulations apply depending on whether the paper is in direct contact with the food, or whether there is either a plastic or aluminium layer between the paper and the food. ~Review and implement changes in regulations, customer demands and other rules and procedures related to food contact materials, with changes being communicated within the organisation.</p> |

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| <p>~Documented procedures must be in place to ensure that raw materials are used in a way which is consistent with the requirements of the end use of the paper and board</p> <p>QC</p> <p>Monitoring the implementation and achievement of GMP:</p> <p>~Evidence of compliance comes from: 1. a formal declaration of compliance is prepared for each type of FCM, which shall be available to both customers and enforcement authorities 2. business operators will maintain appropriate documentation and records (which demonstrate compliance and could include test conditions and results, evidence of safety or other analyses)</p> <p>~Business operators are free to use whichever tools they feel are appropriate to facilitate and implement the operation of traceability of the food contact material or article itself but not the raw materials. However, it is recommended that they have a system in place to establish the origin of the raw materials, in case of defective incoming materials</p> <p>~Both backward and forward traceability will be ensured due to the extensive documentation</p> <p>~Need to determine a shelf life period for traceability documents (usually these are in line with the shelf-life of the product)</p> <p>~Risk analysis should cover the entire production process and comprise both an identification of all the possible hazards that may occur along the production chain and the quantification of the risk of an adverse occurrence.</p> <p>~A documented risk assessment shall be performed when significant changes have taken place in the equipment or process used to manufacture the material or article or its supply of raw materials</p> <p>~Inks, varnishes and adhesives used for printing and converting should be selected to ensure the lowest possible levels of migration into food by following the requirements of the Regulation 2023/3006. This process should be facilitated by consultation with the suppliers of those materials and their guidance on the substances' use</p> <p>~Traceability shall be ensured at all stages in order to facilitate control, recall of defective products, consumer information and attribution of responsibility by meeting the requirements of Regulation 1935/2004. There is no single set of rules related to traceability and therefore traceability will vary from operation to operation and will consist of the elements within traceability guidelines that are necessary to achieve the requirements in the Regulation</p> <p>~Documentation does not cover incoming starting materials but producer should have procedures in place to establish the origin of these materials to determine liability for incoming defective materials</p> <p>~The traceability chain for paper and board packaging for food is taken to start from the paper reel at the dry end of the paper machine and key element transferred to the next stage is the batch number of the converted packaging</p> <p>~Retention of batch samples at the papermaking stage is recommended in case of suspected chemical or physical contamination. In such a case testing of the samples can identify the exact time of contamination and the source and thus reduce the number of products to be recalled.</p> <p>~Retention of samples in the case of conversion operations will depend on the nature of the operation</p> <p>~Documents stating traceability should be kept in line with the product's shelf life</p> <p>~Testing shall be performed at a frequency which relates to the likelihood of a particular restriction being exceeded (with testing not being required if a substance can show that it could never exceed its restrictions)</p> <p>Corrective measures to remove any inefficiencies and non-compliance:</p> <p>~The functioning of a traceability system should be demonstrated by periodic testing (with a product supplied to a client being classed as defective. The operator then needs to test the ability to successfully and rapidly recall the product and identify others that are likely to share the same characteristics enabling recall of all defective products)</p> <p>Corrective measures to remove any inefficiencies and non-compliance:</p> <p>~The retention of batch samples at the papermaking stage is recommended wherever possible in case of biological or chemical contamination. In such a case, the various samples from the different batches could be tested and the point of contamination identified, potentially reducing the amount of batches to be recalled.</p> <p>~The functioning of a traceability system should be demonstrated by periodic testing (with a product supplied to a client being classed as defective. The operator then needs to test the ability to successfully and rapidly recall the product and identify others that are likely to share the same characteristics enabling recall of all defective products)</p> <p>Documentation:</p> <p>~There is a need to maintain efficient documentation (of the end use of products for example) available in case of external inspection. Such documentation could include results of risk analysis, changes in supply and suppliers, raw material usage, traceability documentation etc...)</p> <p>~Need guidelines to determine the testing frequency and in cases where no test has been taken, documentation to justify this must be prepared</p> <p>~A formal declaration of compliance shall be prepared for each grade or type of FCM, which must be available for immediate inspection by both authorities and customers (which includes: manufacturer details, product description, confirmation of compliance with Regulation 1935/2004 and the Guideline prepared)</p> <p>~Business operators should maintain appropriate documentation and records which serve as evidence of the statements made in the declaration of compliance and should include conditions and results of testing, calculations, other analyses and evidence of the safety or reasoning demonstrating compliance.</p> <p>~Declaration of compliance should highlight the presence of any dual-use additives which have been used in the manufacture of and are present in the paper and board.</p> | <p>Raw materials</p> <p>- Information provided is good but could use additional information on requirements that supplier must meet (for example having their own QA and GMP systems) but does contain good information based on which suppliers to be used, based on the verification of their materials previously. Good information on the requirements of raw materials regarding purity and the storage and separation of products to prevent their mix-up and contamination.</p> <p>QA</p> <p>- Detailed information provided. Document could also include information on the importance of having communication between manufacturer and supplier and of knowing the end-use of the product being manufactured. QA system should also draw attention to the more critical points of the production that need to be adhered to. Document also highlights some of the important points that are relevant to paper and printing inks exclusively.</p> <p>QC</p> <p>- Detailed information provided. Could highlight the importance of carrying out audits to determine GMP compliance and outline the necessary steps required to reduce the risk of contamination or product mix-up.</p> <p>Additional points</p> <p>Future developments:</p> <p>~Biological tests may become more frequently used to assess the safety of additives that do not currently have EFSA approval and to validate paper and board recycling processes. Biological tests would be implemented in the hope of replacing some chemical tests.</p> <p>~Correction factors need to be determined to take into account the fact that paper and board often don't have as high migration of substances as other FCMs (such as plastic) because paper and board often have brief contact with the food, the food packaged is dry or the food is removed and washed prior to consumption, reducing migration potential. Use of correction factors may be able to reduce the need for testing particular substances as a calculation could show that migration would not exceed permitted levels and this would better reflect contact conditions and could increase the use and diversity of use of safe FCMs.</p> <p>~Use of a correction factor may also remove the need for a paper or board manufacturer to know the end use of the product as the correction factor could allow the calculation of a grade of paper which would then be sold for a range of appropriate applications.</p> |
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| <p>ETS</p> | <p>Raw materials ~Raw materials used should be produced by processes that reduce dioxins to levels as low as reasonably achievable. ~Kitchen towels and napkins can be made from virgin fibres, recycled fibres or from a mixture of both. They can also be made from synthetic fibres. ~Raw materials (includes fibrous and non-fibrous ingredients) are only purchased if they meet the requirements related to the end products and only from 'qualified suppliers' (which are identified either by their ISO 9000 certification or through experiences dealing with this supplier who has consistently supplied compliant materials) ~Any materials from a new supplier or of a different grade need to be assessed for suitability ~Any recycled fibres supplied need to be accompanied by details on the grades supplied and materials should be subject to documentary, visual and olfactory controls. ~All incoming raw materials should be clearly identified and stored so as to avoid any accidental use of materials not suitable for contact with food. ~Raw materials being delivered need to be accompanied by the date of delivery and the name of the supplier (with the delivery being inspected when received to ensure that it complies with relevant requirements).</p> <p>QA Adequacy of the personnel: ~Management has to make a strong commitment to the quality policy and ensure that appropriate responsibility and authority is given, understood and applied at each level of the organisation. ~Personnel should be made aware of their responsibilities and duties and should undergo training, which needs to be performed and assessed in a suitable manner (with records of training being maintained). New employees should be made aware of FCM manufacturing requirements during their introductory period. Organisation of the premises and equipment: ~Premises need to be organised so as to avoid contamination or confusion when production of several grades of tissues occurs in the same plant. ~Raw materials and other storage areas need to be kept clean and hygienic to minimise the risk of their contamination.</p> <p>1. Machinery and tools ~Inspection, measuring and test equipment should be regularly maintained and calibrated, with results from calibration procedures kept for at least one year.</p> <p>2. Manufacturing processes ~Each producer has to keep under control any critical points in the process. ~Handling, storing, packing and delivery of the products needs to be maintained under control. ~Items in stock need to be well identified and can only be dispatched if they are suitable for intended end use. ~A procedure needs to be in place that ensures that only products that meet the agreed quality standards are dispatched. ~Guidance document provides the hazards that may be encountered at any of the manufacturing stages and a means of prevention</p> <p>Presence of pre-established instructions for the procedures: ~The process has to be clearly defined and planned and it needs to be demonstrated that the process is continuously occurring under controlled conditions.</p> <p>QC Monitoring the implementation and achievement of GMP: ~Guidelines contain specific rules on traceability and a requirement for validation of the final product purity with every new (or substantial change in a current) tissue product. ~If it can be shown by calculation, taking into account the conditions of manufacture, that the restrictions laid down cannot be exceeded, no testing for compliance with restrictions is needed. ~Standard test conditions for paper and board cannot be used for tissue paper and therefore these guidelines describe test methods that take into account the unique properties of tissue paper (and taking into account whether or not the tissue paper is printed or not, and in the case of printing on the paper, any migration tests performed should have the printed surface in contact with the food). ~A quality system needs to be in place and implemented in order to ensure products are conforming to specific requirements. ~All products are labelled so that relevant data of the production history can be traced and efficient recall can be conducted in the case of non-compliance or threat to customer safety (With information on traceability available to competent authorities if required). ~Each packaged product should be identified by a code which would ensure that a link between the product and the manufacturing site and date of production is made (with this being communicated to the customer whenever relevant). ~Testing and inspection procedures need to be defined to determine the compliance of the final product with agreed quality and safety standards. Any results of quality testing need to be recorded and saved, according to a pre-defined procedure. ~Procedures should be in place to verify the correct performance of the quality system.</p> <p>Corrective measures to remove any inefficiencies and non-compliance: Documentation: ~Relevant documentation should be kept to enable the identification of the finished products and raw materials that may need to</p> | <p>Notes</p> <p>~Covers production processes used in tissue mills and also covers converting activities ~Guidelines apply to all kitchen towels and napkins made of tissue paper, which may comprise of one of more layers of fibres, which may also come into contact with food.</p> <p>Raw materials -Information contained in the document is mostly good but could use additional information on requirements that supplier must meet (for example having their own GMP and QA systems) and on the quality of the raw materials purchased. Good information on the data required to be supplied with the raw materials and on the importance of producing raw materials by processes that reduce dioxins to levels as low as possible. QA -Detailed information provided but could have emphasized the importance of having communication between suppliers and producers and indicating, to the manufacturer, the end use of the product being manufactured to ensure it is compliant and fit-for-use. QC -Some good information but could usefully have information on corrective measures to remove any inefficiencies and non-compliance encountered and further details on the requirements of documentation</p> <p>Extra comments: ~Kitchen towels and napkins usually are only in contact with food for short periods of time and it has been shown that there is no significant migration from kitchen towels and napkins into food and that consumer exposure is therefore very low. ~Since products have many uses, they are not specifically intended for food contact, they have low migration and low exposure to consumers, these products are merely covered by these guidelines. ~Manufacturing of kitchen towels and napkins requires very small amounts of chemicals and therefore these guidelines do not contain an inventory of chemicals but list the chemical substances that are typically used and those that are not permitted for use in manufacture. Any chemicals that could potentially constitute a risk for consumers undergo specific tests.</p> |
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| ECMA | <p>be involved in the case of recall of defective finished products.</p> <p>Raw materials ~Raw materials must be traceable and certified (based on an independently audited QM system of the manufacturing process) ~Raw materials shall not contain substances classified as CMR (carcinogenic, mutagenic or repro-toxic) or pigment colorants based on certain heavy metals (arsenic, mercury and lead as some examples) ~Raw materials used must be certified as known from previous experience to be compliant for their specific use ~Migration features, detailed information on characteristics, a certification of compliance, their composition and presence of a use of a functional barrier need to be provided by the supplier of raw materials ~Raw materials should be purchased from suppliers with QA systems compatible with the converters' QA system ~Converters need to seek information on the traceability of composition, production method and components' origin. Also require a certificate of compliance of the material being supplied, assurance that no contamination during storage or delivery occurred and information on any raw material change at the earliest possible as well as, lastly, measures on unintentionally added substances ~Only use raw materials known to be organoleptically inert ~Raw material suppliers need relevant information for monitoring the transfer of substances by migration or invisible set-off</p> <p>QA Adequacy of the personnel: ~Board level management team should be fully engaged in implementing and maintaining an appropriate QA to satisfy GMP requirements ~A key responsibility holder and a senior board-level sponsor should be appointed as the core enabling team to take responsibility to ensure that GMP objectives are met. ~Converter should have names of people responsible for each process operation ~All personnel must be informed of the concept of GMP, its objectives and the actions needed to achieve them ~Personnel performing activities affecting compliance should undergo training while personnel performing specific tasks shall be deemed qualified on the basis of relevant education, training or experience ~Training records should be maintained</p> <p>Organisation of the premises and equipment: ~Need suitable storage areas for raw materials, works in progress and finished materials ~QA system is essential for warehousing and transportation controls to ensure incoming materials' safety is not compromised and is instead stored immediately ~Appropriate covering should be used before transport to any print finishing or subsequent processing. All packaging should carry relevant batch numbers/codes and necessary documentation ~Storage requires measures in place to avoid contamination (be it physical, chemical or biological), as does transportation</p> <p>1. Machinery and tools ~Machinery used needs to be in excellent condition ~Always use clean machinery and tools to avoid contamination</p> <p>2. Manufacturing processes ~'Building blocks' concept where evidence of compliance with applicable restrictions for a number of products using similar materials or combinations of materials, are considered to apply. This is seen as the core safety approach carton makers have to implement, with regular compliance testing over time, to guarantee safety ~Avoid contact between raw materials/products with dirt, exhaust gases and vapours ~Ideally the same ink type should be run continually on a press to avoid the need for costly clean-downs and avoid potential contamination. ~Migration test methods can use food simulants to test the migration of substances in the packaging (either laminated or non-laminated paper and board) ~Guidelines concerning inks and varnishes issued by EuPIA are observed and if certain substances have specific migration limits (SML), compliance with these is demonstrated ~Testing should be done on representative samples (with transportation of the substances ensuring that no contamination or loss occurs) and with the samples selected being representative of the whole batch ~Need suitable hazard analysis and risk evaluation to identify dangers at an early stage, which allows causes to be contained and countermeasures to be put in place</p> <p>Presence of pre-established instructions for the procedures: ~This documentation contains a chapter with details concerning ink drying, ink mixing (if mixing of low and higher migration inks occurs), ink film weight and UV curing, which are performed in such a way so as to reduce the likelihood of migration or contamination, as inks and varnishes have been a prime source of food safety incidents</p> <p>QC Monitoring the implementation and achievement of GMP: ~Documented risk assessment needs to be carried out to ensure product is produced with a consistent quality (which includes supplier provided certification confirming suitability of the materials)</p> | <p>-Guide designed for companies that manufacture cartons intended to come into contact with food or that could be the source of chemical migration into food. Windowed and laminated cartons are also in the scope. -Cartons used in dry, fatty and frozen food categories are in, while cartons for liquids are not covered by this document</p> <p>Notes</p> <p>Raw materials -Very detailed information provided QA -Very detailed information. No further information needed. QC -Some information available. Could usefully have information on the importance of having corrective measures in place to deal with any non-compliance or product rejection, as well as some information on documentation required. Lastly, could also include information on the importance of having adequate storage facilities and a system to avoid contamination and to deal with rejected or non-compliant products.</p> <p>Additional information in the document ~GMP guidelines should be implemented by converters who employ an effective, independently audited, quality management system and must be embedded in a system such as ISO 9001, not used as a standalone document ~GMP 'design for compliance' described as the best approach ~This code assures a customer that if used correctly, a packaging material will not give rise to migration of substances at levels of concern to human health due to appropriate manufacturing and materials. However, to ensure compliance of the material remains, the customer must contribute by giving appropriate information and by only using packaging for the purpose it was originally designed and intended ~Suppliers should perform tests and include results on the composition of raw materials, maximum permitted substance quantities and worst case calculation of 100% migration from FCM to food ~Highlights the fact that transfer of substances by migration is a time dependent phenomenon so if migrants exist in the packaging then the risk of unwanted transfer to the food will increase with time, while the opposite is true for volatile products in packaging, which will be lost through evaporation ~Specific chapter in GMP documentation dedicated to inks and varnishes, as these last have been a prime source of food safety incidents due to: -Decomposition products of photoinitiators and non-reacted photoinitiators -Residual monomers that remain in ink film or are absorbed into the substrate -Incomplete reaction of ink components due to inadequate curing</p> |
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| | <p>~Testing the finished or intermediate products using methods appropriate to the specific use of the packaging and food type ~Advisable for all stages of the packaging production chain to mark their products so that individual production batches can be identified, allowing only a couple of batches to be recalled if a product is non-compliant ~QA system should be independently audited and certified periodically and be capable of being verified by or on behalf of customers to check GMP compliance ~Converters should only subcontract manufacture of food contact packaging to converters who are carrying out their work in compliance with GMP Corrective measures to remove any inefficiencies and non-compliance: Documentation:</p> | |
| FPE | <p>Raw materials ~Raw materials shall only be purchased from suppliers who employ their own QA systems and GMP, which meet requirements ~Raw material suppliers must assure complete traceability of the composition and production methods of these materials and intermediates as well as the origin of the components (to assure that sources of possible mishaps can be identified and corrected and also to allow manufacturers to rely on previous steps in the production chain) ~Raw materials and their ingredients should be traceable up to the point where, for the first time in the production chain, the material is decided to be used in food packaging ~Supplier must certify compliance with applicable legislation, recommendations and standards ~Supplier needs to identify and quantify all components that have been allocated an SML, QM or QMA ~Identify and quantify all components that are regulated as direct food additives or flavourings ~Raw materials used must be certified or known from previous experience by the manufacturer to be organoleptically inert (for the specific food and use of the packaging) ~Ensure that during production, handling, storage and transportation of the raw material, it does not become contaminated and maintains desired quality ~Traceability and certification of compliance (obtained through an independently audited quality assurance system of the supplier's manufacturing process) of the raw materials is highly important ~Unless otherwise specified, raw materials are used on a first in first out basis QA Adequacy of personnel: ~A suitable flow of information must occur along the whole supply chain from raw materials to packer/filler and food producer/brand owner so the packaging is designed with compliance in mind Organisation of premises and equipment: ~Rejected, recalled or returned raw materials or packaging shall be stored separately from certified and tested raw and packaging materials as shall materials waiting approval or testing. 1.Machinery and tools 2.Manufacturing processes ~The choice of substrates, inks, varnishes, lacquers, other coatings and adhesives should be based on recommendations from the raw materials suppliers and applied under conditions specified by them ~Application of inks, varnishes and adhesives, as well as production process, must occur in such a way to ensure that chemical cannot undergo an unintended chemical reaction and if a unintended reaction does occur, it does not give rise to potentially hazardous by-products. ~Need to ensure correct setting of production parameters on machines such as drying temperatures and reel tensions ~Final customer will be required to notify manufacturer if there are changes in the use or requirements of the packaging they request in case these changes bring about changes in the product's performance. ~Only inks certified for direct food contact may be used on the food contact surface of the packaging material (and in some EU countries, their use is not even permitted) ~Require identification and control of potential sources of contamination during the production processes, storage and transportation ~Need to keep track of intermediate and finished products until they reach the customer's warehouse ~Potential sources of contamination during manufacture shall be identified and analysed and where appropriate, measures shall be taken to avoid contamination (for example control of pests and rodents or maintaining good hygiene practices in warehouses and modes of transportation) ~Conditions during storage and transportation minimise deterioration of raw materials and packaging products ~Need clear labelling and referral of raw and packaging materials to ensure constant traceability ~Unless otherwise specified, products are sent out on a first produced, first out basis Presence of pre-established instructions for the procedures: QC Monitoring the implementation and achievement of GMP: ~The quality assurance system shall be audited and certified periodically by an independent body</p> | <p>FPE document Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food</p> <p>Notes</p> <p>-GMP document designed for manufacturers of flexible and fibre-based packaging materials intended to come into contact with food (with these packaging materials being made of paper, board, regenerated cellulose, plastic film or aluminium foil or laminates of these materials. They may be printed, varnished, glued or converted (for example made into boxes). -Document covers the preparation of inks, varnishes and adhesives as well as the extrusion of plastic film and the metallizing of paper and plastic film.</p> <p>Raw materials -Very detailed information provided QA -Sufficiently detailed guidance, despite the lack of guidelines on requirement of having pre-established instructions for the procedures or anything on machinery and tools. Very detailed information on contamination prevention and on the importance of critical points being highlighted and controlled to ensure end-product is compliant. Also highlights the importance of communication between manufacturer and supplier. QC -Very detailed information provided. No additional information required.</p> <p>~The GMP document is not a stand-alone document and can only be implemented in businesses that have a good, independently audited, quality assurance system. It must be 'hooked onto' and 'embedded in' a system such as the ISO 9001. ~This GMP document describes itself as 'designing for compliance' and with regard to the packaging products, focuses on the design, development and specification stages to ensure products almost unavoidably meet the criteria of the GMP document. ~This document fills the gap in legislation with respect to multi-material multi-layer packaging and non-plastic materials by indicating where national legislation, standards, recommendations or guidelines from authoritative bodies should be applied. ~This GMP document goes beyond existing legislation as</p> |

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| | <p>~Supplier shall also maintain a quality assurance system (also subject to independent audits) capable of assuring GMP and compliance</p> <p>Corrective measures to remove any inefficiencies and non-compliance:</p> <p>~Complete traceability of the flexible and fibre-based packaging materials produced must be assured</p> <p>~When materials do not meet standards, these materials will be clearly segregated and identified (or disposed of if there is no means of correcting their faults)</p> <p>~A procedure should be in place which enables the manufacturer, in the event of a failure at any stage of the process or a complaint, to find the cause and rectify the problem as quickly as possible and if necessary, make amendments to the manuals or other controls to prevent such a problem repeating itself</p> <p>Documentation:</p> <p>~A written declaration of compliance shall be provided to the customers for all packaging materials (supplier can decide on his own whether he provides a certificate with each delivery or whether documentation is available via a web link for example). Decision on which method is used can be arranged between supplier and customer</p> <p>~Declaration shall be altered when substantial changes in the production bring about changes in the migration or when new scientific data are available</p> <p>~Business operator needs to have documentation to demonstrate that materials and articles, as well as substances intended for the manufacture, comply with regulation and shall be available to competent national authorities upon request. This documentation needs to contain conditions and results of testing, calculation, other analyses and evidence on the safety and compliance of the final product.</p> | <p>flexible and fibre-based packaging materials are often composed of more than only plastics and therefore are not fully regulated by specific EU legislation. This means that manufacturers have no clear rules to abide by, but this document will resolve this issue by demanding compliance with food contact legislation of each component of the packaging material, which fully controls the composition of the FCM</p> |
| <p>PLASTICS</p> <p>PlasticsEurope, EuPC and CEFIC-FCA</p> | <p>Raw Materials</p> <p>~Starting or raw materials are approved using a specific procedure and then only approved materials are used.</p> <p>~Need to handle and store raw materials so as not to mix-them up or contaminate them</p> <p>~Need to be of good technical quality and purity based on their intended final use</p> <p>~Starting materials should be verified for acceptance before use</p> <p>~Materials that do not meet the acceptance criteria are identified and controlled to avoid their misuse</p> <p>~Water coming into contact with FCMs needs to be of suitable quality</p> <p>QA</p> <p>Adequacy of the personnel:</p> <p>~Importance of creating awareness at all levels involved</p> <p>~Management and personnel actively participate in an effective quality assurance system</p> <p>~Management responsibilities for GMP implementation are assigned, defined and documented</p> <p>~The personnel supervising or performing the manufacture or control of FCM should have the education, training and/or experience to perform the assigned tasks</p> <p>~Training of personnel should include a segment on GMP</p> <p>Organisation of premises and equipment:</p> <p>~There is sufficient and well-managed storage for starting and/or raw materials</p> <p>~There are adequate storage facilities to avoid contamination of FCM</p> <p>1. Machinery and tools</p> <p>~Major equipment, transfer lines, containers and tanks that are used for processing, filling or holding FCM are identified either by labelling or using electronic control systems to indicate contents, batch designation, control status and other important information</p> <p>~Silo's and bulk trucks can either be used only for FCM or these can undergo processes that ensure that they do not contain any contaminants or products</p> <p>~The equipment and set-up are adequate to avoid cross-contamination between materials or ingredients for food contact with those for non-food contact purposes. There are also cleaning and buffering procedures in place when transitioning from non-FCM to FCM to avoid contamination</p> <p>2. Manufacturing processes</p> <p>~Require effective contamination prevention and compliance of composition and possible migrants being maintained throughout the production stages</p> <p>~In a factory where FCMs are produced as well as non-FCMs and where there is a risk that cross-contamination could harm the quality of the FCM, then production of FCMs needs to be flagged</p> <p>~There are procedures to ensure traceability from incoming starting material to outgoing FCM, which also take into account the use of raw materials recovered from a production process and the recording and traceability of their use</p> <p>~There is an adequate contamination prevention procedure based on a risk assessment</p> <p>~Raw materials need to be segregated from products ready for release, those awaiting release and those materials that are non-conforming or returns</p> <p>~Starting and/or raw materials should be monitored to verify their compliance and conformance with specifications</p> <p>~Every FCM product has one unique specification</p> <p>~Any work contracted out should be subject to a written contract and should be performed using GMP</p> | <p>Raw materials</p> <p>-Sufficiently detailed information provided. Could use additional information on requirements that supplier must meet (for example QA and GMP systems), though document does mention the importance of carrying out both internal and supplier audits, and specifications ensuring materials are suitable for their intended use and to come into contact with food.</p> <p>QA</p> <p>- Some useful information provided, with all areas if QA system covered. However, there is too little focus on the importance of having good communication between manufacturers and producers to ensure product is suitable for its desired end use and the need to draw attention to critical points of the production process, to ensure that the final product is compliant with legislative and technical requirements. Document does highlight the importance of avoiding contamination (especially when transitioning from non-FCMs to FCMs).</p> <p>QC</p> <p>-Very detailed information. Could maybe use additional information on the importance of ensuring traceability throughout the production chain and information on the importance of documenting compliance of product and GMP of production but good information on the importance of conducting internal and supplier audits which monitor the implementation of GMP and the importance of having a QC department that has the authority to authorise or reject materials and that investigates complaints and product recall.</p> <p>Additional information</p> <p><u>3 main concepts of GMP:</u></p> <p>~Awareness at all levels involved in production</p> <p>~ Effective contamination prevention strategy (which ensures article's composition remains compliant with legislation)</p> <p>~Effective management of change (procedures that monitor change in composition or contamination risk arising, which may</p> |

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| | <p>~Procedures are in place to ensure that transfer, packaging and loading are conducted in such a way so as to avoid product contamination</p> <p>Presence of pre-established instructions for the procedures:</p> <p>~There is a system in which product formulation, operating procedures, operating windows, product release specifications and other critical information shall be documented</p> <p>QC</p> <p>Monitoring the implementation and achievement of GMP:</p> <p>~A quality control department must exist with responsibility and authority to independently approve or reject all materials in the process</p> <p>~Documented specifications exist for starting and/or raw materials and finished products</p> <p>Corrective measures to remove any inefficiencies and non-compliance:</p> <p>~There is a system in place for recording and investigating complaints including product recall if needed and this investigation shall result in recommendations for corrective actions if needed</p> <p>~There is a procedure in place to respond to contamination</p> <p>~There is a procedure in place to ensure that non-conforming or recalled products are not released for food contact use without extensive investigation and proper authorisation</p> <p>~There is a procedure in place to ensure regular internal audits or self-assessments in order to monitor the implementation and respect of GMP</p> <p>Documentation:</p> <p>~There is a management of change procedure in case operating procedures have to be changed. The management of change procedure is capable of detecting and indicating potential changes in the composition or increased risk of contamination</p> <p>~The management of change considers changes in product formulations, starting/raw materials or suppliers of these materials</p> <p>~There are documented procedures to consider the impact of such changes on the final product quality, performance, composition and compliance.</p> | <p>eventually affect composition and migration of FCMs</p> <p>GMP emphasizes:</p> <p>~Personnel being trained on GMP</p> <p>~If a factory produces both FCM and non-FCM, then the production of FCM needs to be flagged</p> <p>~Need physical separation of a control system to segregate raw materials and products that have been released for use/distribution from materials pending release, non-conforming or product returns. There are also measures to ensure that the non-conforming or recalled products are not released for food contact use without investigation or proper authorisation</p> <p>~Packaging, loading and transfer operations are carried out in such a way to avoid contamination (ex. silo's or bulk trucks are only used for FCMs or there are effective measures to ensure these containers do not contain any products or contaminants that would jeopardise the FCMs produced.</p> <p>~Procedures in place to ensure correct labelling</p> <p>~There is a system that records and investigates complaints and product recall.</p> <p>~Procedure in place to ensure that there are regular internal and supplier audits or self-assessments which will monitor the implementation and respect of GMP</p> <p>~Need a quality control department that has the responsibility and authority to independently authorise or reject materials</p> <p>~Need methods to ensure traceability from starting materials to final FCMs</p> |
| EuPIA | <p>Raw materials</p> <p>~Employ a common Exclusion List of raw materials that are to be avoided in the formulation, manufacture and supply of printing inks</p> <p>~Guideline on Printing Inks to the non-food contact surface of packaging materials and articles specifies requirements that raw materials must meet in terms of purity, migration and toxicological properties</p> <p>~There needs to be co-operation with the suppliers of raw materials and knowledge of the needs of the customer</p> <p>~Raw materials are carefully selected to ensure that the components of the food packaging inks are of suitable quality</p> <p>~A name, reference number and batch/delivery number identify each raw material to ensure their traceability</p> <p>~Each raw material has a specification agreed between the supplier and food packing ink manufacturer, which includes physical and chemical properties to maintain agreed upon quality and suitable end use</p> <p>~Where appropriate raw materials are tested in house or alternatively are supported by a certificate of conformity from the supplier</p> <p>~Raw materials should be used on a first-in first-out basis</p> <p>~Raw materials must pass quality control procedures before their use to formulate final product</p> <p>~Inventory list –comprising packaging ink raw materials applied to the non-food contact surface of food packaging (December 2013)</p> <p>~EuPIA Suitability List of Photo-initiators for Low Migration UV Printing Inks and Varnishes</p> <p>~Printing ink industry contribution to German paper, paper converting and food industry initiatives to reduce mineral oil in paper and board packaging</p> <p>QA</p> <p>Adequacy of the personnel:</p> <p>~The entire workforce, including all levels of management, is committed to the objectives of GMP</p> <p>~Training programmes and facilities are established to ensure that all personnel are fully aware of their functions and responsibilities and are competent to carry them out</p> <p>Organisation of the premises and equipment:</p> <p>1. Machinery and tools</p> <p>~The equipment used needs to be suitable to manufacture the products required and maintained in a good state</p> <p>~Equipment needs to be clean and calibrated, where necessary</p> <p>~All measuring equipment is tested and/or calibrated to ensure test results are accurate</p> <p>2. Manufacturing processes</p> <p>~Product is identified with a descriptive title/trade name, reference number and a specific batch number</p> <p>~Where appropriate, each delivery of food packaging inks can be supported by a test certificate confirming that it meets agreed</p> | <p>EuPIA documents</p> <p>Good Manufacturing Practices for the Production of Packaging Inks formulated for Use on the Non-food-contact Surfaces of Food Packaging and Articles Intended to come into Contact with Food</p> <p>EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles</p> <p>Information leaflet: Printing Inks for food packaging</p> <p>Raw materials</p> <p>-Very detailed information, which also highlights the need for an exclusion list of raw materials and highlights the importance of communication between supplier and manufacturer.</p> <p>QA</p> <p>-Very detailed and complete information, which highlights the importance of ensuring that the end-product is suitable for its required use and the need to highlight critical points of the production process and detail any subsequent stages of manufacture required on delivered product. Also emphasizes the importance of correct storage to avoid misuse of non-compliant products and contamination.</p> <p>QC</p> <p>-Very detailed and complete information. Could possibly include information on the correct storage of products based on their compliance tests to prevent their contamination or mix-up.</p> |

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| | <p>specification</p> <p>~Each product has data sheets detailing relevant chemical, physical and safety data and suitable end uses and methods of application</p> <p>~Packaging is selected to protect the food packaging ink during shipment and storage (and must be adequate based on the means of transport used and legal requirements for the nature and use of the product)</p> <p>~All products (including raw materials) are stored in conditions that prevent, as much as possible, their deterioration. Where appropriate a method exists to test products that have been held for some time to ensure their quality still remains adequate</p> <p>~Rejected stock is clearly marked and isolated so that it is not used accidentally</p> <p>~All products are delivered in clean and clearly labelled containers</p> <p>~Traceability of materials is required at all stages (including raw materials)</p> <p>Presence of pre-established instructions for the procedures:</p> <p>~An instruction document (batch card) is issued for each batch of printing ink manufactured, which details the materials, quantities and equipment to be used and highlights any specific precautions to be followed</p> <p>~Product test specifications exist for each food packaging ink manufactured. They list the tests which are required during the manufacture and on completion, to ensure the batch meets the required specification and is fit for intended use</p> <p>~Manufacturing instructions are issued and followed for each batch, giving details of the raw materials, the quantities and the equipment to be used</p> <p>Monitoring the implementation and achievement of GMP:</p> <p>~Implementation and achievement of GMP is regularly monitored by using a GMP-Audit Checklist. Corrective measures are identified to correct any failure to achieve GMP and are implemented without delay.</p> <p>~Requires testing food packaging ink samples at selected stages of the process to establish whether the product is meeting the required quality standard.</p> <p>~Final inspection and testing are key elements too, with specific test methods to be used</p> <p>Corrective measures to remove any inefficiencies and non-compliance:</p> <p>~In the event of non-conformity at any stage in the process or a complaint, a procedure exists to take corrective and preventive action to find the cause, rectify the problem and if needed, make appropriate improvements to the manuals or other controls to prevent a recurrence</p> <p>~A person is appointed to accept responsibility for ensuring that any non-conformity issue is dealt with and corrective action completed.</p> <p>Documentation:</p> <p>~Recording systems ensure that quality relevant stages can be verified for correct action, with these systems having to be documented (covering the operations performed and specifications set out)</p> <p>~The above documentation is available to the authorities on request</p> <p>~Documentation of maintenance is required</p> | <p>Additional information</p> <p>Many inks are blended at converter plants from basic constituents and are labelled, given a brief description and given a reference and a batch number</p> <p>~If inks return from the print operation in their original state, they maintain the same description and batch number. If they are modified they need to be checked for suitability of re-use and if found to be suitable, they are given a new reference and a new batch number but keep their same description. If the inks are re-used or re-handled, modifications should be recorded, the product tested and the new product labelled accordingly</p> |
| CIPCEL | <p>Raw materials</p> <p>~Raw materials used have been demonstrated to be safe for their intended use by reference positive lists or by testing products under laboratory conditions, using mathematical calculations, by dietary exposure, by toxicological analyses or by providing supplier certificates.</p> <p>~Substances used in cellulose casings must be shown to not migrate from casings at levels that could adulterate the food</p> <p>~Basic raw materials used to manufacture cellulose casings are cellulose pulp and sometimes a paper substrate (for reinforced casings)</p> <p>QA</p> <p>Adequacy of the personnel:</p> <p>Organisation of the premises and equipment:</p> <p>1. Machinery and tools</p> <p>2. Manufacturing processes</p> <p>~ Printing inks used by cellulose casing manufacturers are formulated based on EuPIAs 'Exclusion List for Printing Inks and Related Products' and CEPE's 'GMP for the Production of Packaging Inks' for the use on non-food contact surface of food packaging.</p> <p>~Cellulose products also conform to the norm for heavy metals and have a maximum of 100ppm as the total amount of lead, mercury, cadmium and chromium (VI).</p> <p>~It is the responsibility of the manufacturer of the finished packaged food to ensure that all regulatory or legislative limitations and specifications applicable to the packaged food are met.</p> <p>~CIPCEL members guarantee that their products are made of raw materials that have been demonstrated to be safe for their intended use and guarantee that delivered casings are tested under laboratory conditions and/or evaluated through mathematical calculations.</p> <p>~The importance of product traceability is highlighted</p> <p>Presence of pre-established instructions for the procedures:</p> | <p>CIPCEL document</p> <p>Guide to Good Manufacturing Practice for non-edible Cellulose Casings</p> <p>Raw materials</p> <p>-Very detailed information provided.</p> <p>QA</p> <p>-Incomplete information provided. Information is only provided in the GMP guide, which outlines the key procedures involved in manufacturing and some key requirements that products must conform too. Not enough detail about ensuring correct storage to prevent mix-up or contamination, nor enough on the adequacy of the personnel and machinery and tools. Also require more information on the importance of having pre-established instructions for the procedures.</p> <p>QC</p> <p>-Some information provided. Could also include additional information on any required documentation and any corrective measures to deal with any non-compliance that are in place. The document could also specify in more detail, measures in place to prevent contamination or mix-up of products.</p> <p>Additional information</p> <p>Three main principles for the manufacture of cellulose</p> |

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| | <p>~The Guide to Good Manufacturing Practice outlines the key procedures involved in manufacturing regenerated cellulose casings from raw materials through to final product (includes storage and transportation)</p> <p>QC Monitoring the implementation and achievement of GMP: ~Final cellulose casings intended for food contact use are tested under laboratory conditions and/or evaluated through mathematical calculations (with laboratory tests are performed by accredited laboratories and according to specific requirements of migration testing (time and temperature most notably)). ~Traceability of materials and articles intended to come into contact with food need to be in place at all stages to facilitate control to enable the recall of defective products, provision of consumer information and the attribution of responsibility ~Businesses should have in place systems and procedures in order to be able to identify the businesses from which and to which materials are supplied ~Materials placed on the market should also be identifiable, which allows their traceability ~Control programmes are implemented and consist of adequate testing regimes to ensure that all risks and sources are monitored and controlled Corrective measures to remove any inefficiencies and non-compliance: Documentation:</p> | <p>casings: ~Observe, as far as possible, the global migration limit of all substances from FCM into food (as outlined in the Plastics Directive) ~Review all chemicals used and check they appear in approved listings (if there is insufficient toxicity data or where chemicals have not yet been approved for food contact use, either approval must be sought or the use of such materials shall be discontinued) ~Traceability of materials and articles intended to come into contact with food</p> <p>~No harmonised regulation for cellulose casings used as a food contact material (unlike for plastics for example) but their manufacture must be in accordance with GMP and they must not endanger human health</p> |
| <p>RUBBER ETRMA</p> | <p>Raw materials ~ Incoming starting materials need to be supplied with information given by the relevant supplier. This information details the name of the supplier, type (grade) of starting material, location, date and batch number of production, any documents certifying that they comply with any other required legislation (for example for plastics) and documents containing any agreed upon attributes.</p> <p>QA Adequacy of the personnel: ~Personnel employed must be adequately qualified and undergo further training wherever necessary</p> <p>Organisation of the premises and equipment: ~Manufacturing sites should be designed and constructed to permit cleanliness, tidiness and prevent contamination. ~Rubber components, containers and finished products shall at all times be handled and stored so as to prevent contamination. ~Batch segregation needs to be possible during storage.</p> <p>1. Machinery and tools ~Equipment used must perform in accordance with its intended use and must be of appropriate design, adequate size and suitably located to enable its cleaning and maintenance. ~Any measuring equipment needs to be of an appropriate range with adequate precision and needs to undergo calibration on a regular, scheduled basis, with results being recorded. ~Production equipment should not present any hazard to the products and any parts of production equipment that come into contact with the product should not be reactive, additive or absorptive to an extent that would affect the quality of the product.</p> <p>2. Manufacturing processes ~All manufacturing processes need to be clearly defined, systematically reviewed and shown to consistently manufacture rubber products of adequate quality. ~Contamination of a starting material or a product by another material or product (gases, vapours, dust, sprays etc...) needs to be avoided and the successes of methods in place to avoid contamination need to be monitored ~Before starting a new processing operation, steps should be taken to ensure nothing remains from previous operations. ~Any in-process controls carried out should not affect the quality of the product and should be recorded. ~Where appropriate, there needs to be procedures designed to assure that correct labels, labelling and packaging materials are used for rubber products. ~All the necessary precautions are in place to ensure that mix-ups, damage, deterioration and contamination do not occur during the handling stage ~If a product deteriorates over time, it shall be stored in such a manner so as to reduce this deterioration and its condition shall be assessed as appropriate. ~Manufacturing processes are clearly defined and controlled, with all critical processes being validated to ensure consistency and compliance with specifications. ~Suitable storage and transportation facilities are required</p> <p>Presence of pre-established instructions for the procedures: ~Require documentation that defines the specifications for manufacture and control of all materials and components so that personnel know what to do and when it needs to be done, to ensure authorised persons the information to decide whether or not to release a batch of rubber and to provide a trail/traceability in case of defective batches. ~Instructions and procedures are written in clear and unambiguous language ~Records are kept of manufacturing that demonstrates that all steps required in the process are carried out. ~The document available to personnel must be the most up-to-date one</p> <p>QC Monitoring the implementation and achievement of GMP:</p> | <p>ETRMA: ~ETRMA provided the general "Industrial guidelines on traceability of materials and articles for food contact" when contacted by email. Their GMP document that specifically deals with rubber (and lays out the minimum requirements for producing FCM) is included in these industrial guidelines as Part 6 of Annex II. A second document is prepared by the Council of Europe. ~The traceability outlines the key factors involved in ensuring traceability</p> <p>Raw materials -Some information provided but lacking information about the GMP requirements of raw materials suppliers and the purity criteria of raw materials. QA -Very detailed information provided on the key aspects of the QA system. QC -Some information but guidance on documents required is lacking completely and more detailed information on the importance of ensuring mix-up and contamination of products, intermediates and raw materials does not occur. Good information on the importance of traceability and dealing with non-conformant products.</p> |

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| | <p>~Batch identity of raw materials, components, semi-finished products, finished products should be maintained all along the storage and production operations.</p> <p>~Need an adequate traceability system in operation too.</p> <p>~Use of vendor certification, which is a system that assures that a supplier's product is produced under controlled conditions, which results in a product of consistent quality. This system is based on the principle of defect prevention and not defect identification and reduces the need for the final customer to verify the product. This certification system is a supplier-customer partnership, which can only be successful if both are involved.</p> <p>~Records and relevant standard operating procedures should be kept for at least one year after distribution of the batch, or if appropriate, for a year after the expiry date of the product.</p> <p>~The QC system needs to be independent from the manufacturing process</p> <p>~The responsibility for approval of all raw materials, packaging materials and finished products lies within the QC department. It is therefore very important that they perform adequate controls in order to guarantee the quality of the finished product.</p> <p>Corrective measures to remove any inefficiencies and non-compliance:</p> <p>~There needs to be a procedure in place to handle all written and oral complaints regarding a rubber product, which shall be followed whenever necessary.</p> <p>~Any returned rubber products shall be labelled as such, pending a decision on subsequent actions to be taken (destruction, examination, testing etc.) following an investigation of the defects is carried out. Following such an incident, appropriate measures need to be taken to prevent a repeat of the problem.</p> <p>~There is a procedure to recall any batch of rubber product from sale or supply if needed</p> <p>~Traceability of materials and articles should be ensured at all stages in order to facilitate the control, product recall, consumer information and the attribution of responsibility. This means that businesses need to have in place systems that help with the identification of the businesses to and from which materials and articles are supplied to and procured from (with this information being made available to the competent authorities if requested).</p> <p>~Any materials placed on the market shall be identifiable, which allows their traceability.</p> <p>~Upstream producers require the ,manufacturer's name and address, details on the location and date of production, article number or product name and the production date and identification of the product.</p> <p>Documentation: no info</p> | |
| CES | <p>No information on GMP on their website BUT emailed us their GMP document (Good Manufacturing Practices for Organosilicon Materials Intended to Come into Contact with Food)</p> <p>-GMP fact sheet applies to European producers of silanes, siloxanes and silicones.</p> <p>~The document is more of a fact sheet than a guidance document</p> <p>~The document states that typical CES Member Companies' products are not 'materials or articles' but starting materials, which renders them outside the scope of EU Regulation (EC) 2023/2006. However, some article-type products could end up being used in contact with food and then in such cases, these articles are subject to stringent quality control procedures already in place.</p> <p>~If products manufactured are intended for food-contact use, then their compliance with FDA, European or national regulations is systematically ensured.</p> | <p>Raw materials -No information QA -No information QC -No information</p> |
| CEPE | <p>Raw materials</p> <p>~Need complete understanding between the suppliers of raw materials and the needs of the customer</p> <p>~Each raw material is identified by a unique agreed reference number and/or trade name. Each batch is identified by a unique number or the delivery date</p> <p>~Each material has a detailed specification decided upon by the supplier and coatings manufacturer, which should ensure consistency, fitness for use and conformity with appropriate food contact directives</p> <p>~Raw materials should undergo various tests and chemical analyses</p> <p>~Every delivery of raw materials should be tested in-house or be accompanied by a certificate of conformity to ensure it meets required specifications</p> <p>~Random checks of raw materials, without previous notice, should be carried out by the coating manufacturer, possibly coupled with audits of the suppliers testing procedures to check the reliability of data provided by suppliers in the certificates of conformity</p> <p>~Need traceability of raw materials by using delivery/batch reference numbers</p> <p>~Only approved raw materials in the quantities and proportions necessary to obtain the quality of product required are permitted</p> <p>~Raw materials should be stored in appropriate containers in a manner to prevent spillage and contamination and should be clearly marked with a description and or code, which include a reference to the delivery date</p> <p>QA</p> <p>Adequacy of the personnel:</p> <p>~Commitment to GMP by the entire workforce from the most senior manager downward is required</p> <p>~Adequate training programmes and facilities are required in order to ensure that all personnel are fully aware of their function and responsibilities and are able to carry them out competently</p> <p>Organisation of the premises and equipment:</p> | <p>-Code of practice applies to coated articles in contact with food where the food contact layer is derived from a coating</p> <p>-Coatings are prepared by mixing raw materials and then applied to a substrate before being transformed to form the food contact layer (need to distinguish between the coating applied to the substrate and the coating layer in contact with the food)</p> <p>CEPE documents</p> <p>Code of Practice for Coatings on finished light metal packaging articles for direct food contact, [heavy duty objects, sealants and gaskets, pails and drums-to be included at a later date] (Hard copy booklet in GMP file)</p> <p>Good Manufacturing Practices for the Production of Heavy Duty Coatings which come into Contact with Food (Saved in My Documents)</p> <p>Good Manufacturing Practices for the Production of Coatings which come into Contact with Food (Saved in My Documents)</p> |

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| <p>~Ideally the plant used is dedicated to the production of FCM coatings only or production of other similar products</p> <p>1. Machinery and tools</p> <p>~Equipment used is known to be appropriate to perform the task required of it</p> <p>~Equipment is kept in good repair with a documented inspection and maintenance schedule appropriate to the particular piece of equipment</p> <p>~All test equipment is tested and/or calibrated to ensure results are correct with results being recorded (and appropriate action taken to repair or replace equipment where necessary)</p> <p>2. Manufacturing processes</p> <p>~Test methods should be agreed by coating manufacturer and user and should be internationally and industry accepted methods, wherever possible (if tests do not exist, tests used should be fully documented and meet certain reproducible standards)</p> <p>~Every delivery of coating should be supported by a certificate of conformity which lists the tests that have been carried out and their results</p> <p>~Packaging is selected in order to meet national and EU legislation and is appropriate for the product packed and the following means of transport</p> <p>~New containers should be inspected for cleanliness and returned containers cleaned to avoid contamination with another product or foreign bodies</p> <p>~Each container for dispatch should carry labels showing details such as identification, manufacturing date, shelf life/expiry date, gross and net weight etc...</p> <p>~Raw materials and finished coatings should be stored in conditions to prevent, as far as possible, any deterioration of the material</p> <p>~Areas should be allocated to approved materials and when tested in-house, they should be marked as such, while untested materials should be stored separately until approved or rejected and lastly, rejected materials should be marked and segregated to prevent their use in production</p> <p>~Materials should be used on a first-in, first-out basis</p> <p>~A procedure should exist to re-test stock if it is approaching its expiry date or may no longer be acceptable before dispatching to the customer</p> <p>Presence of pre-established instructions for the procedures:</p> <p>~For each stage of the operation, from receipt of the order to delivery of the product, there must be detailed procedures set out in manuals. These are followed and the required actions recorded as being completed, so that there is no doubt about what has been done and what still needs to be done</p> <p>~For each batch of coating manufactured, an instruction document is released which details the actions required by production staff for the manufacture</p> <p>~Any critical feature of the process is highlighted by requiring a specific action by the operator, which is recorded as being completed.</p> <p>~Each coating has a detailed specification (agreed upon between the manufacturer and user) which includes (where appropriate): method of application, solids content, specific gravity etc...</p> <p>~A manufacturing instruction document is issued with each batch giving precise details of the raw materials and quantities to be used, highlights critical points of the process and provides a facility for required actions to be recorded and certified by the operator</p> <p>~Since a variety of coatings are used with many different processes, the production of manufacturing guidelines is inhibited</p> <p>QC</p> <p>Monitoring the implementation and achievement of GMP:</p> <p>~Product test specifications exist for every coating manufactured (they list the tests required during manufacture and on completion to ensure the batch meets the coating specifications and is fit for use).</p> <p>~Need to carry out laboratory tests on raw materials, coatings in production and finished coatings to ensure that the material supplied to the customer is fit for use and compliant</p> <p>~Each delivery of raw materials is tested in-house or compliance and quality is guaranteed with a certificate of conformity accompanied by random in-house testing</p> <p>~Testing samples at selected stages of the process, is performed to determine whether product is meeting required quality parameters</p> <p>~The finished product is tested with particular care taken to monitor that legislative, directive and regulative requirements relevant to product and its end use are met</p> <p>Corrective measures to remove any inefficiencies and non-compliance:</p> <p>~In the event of a failure at any stage of the process or a complaint, an independent procedure exists to find the cause, rectify the problem and if necessary make the appropriate improvements to the manuals or other controls, to prevent repetition.</p> <p>~A person who is independent of the production and quality control functions is appointed and accepts responsibility for the rectification process (and is referred to as the Quality Manager in this document)</p> <p>Documentation:</p> | <p>Guide to Good Hygiene and Manufacturing Practices for Metal Cans, Packaging and Closures for Foodstuffs (Saved in My Documents)</p> <p>Code of Practice for Coated Articles where the Food Contact Layer is a Coating-Working Document (Saved in My Documents)</p> <p>Raw materials</p> <p>-Very detailed information provided. No additional information required.</p> <p>QA</p> <p>-Very detailed information provided. No additional information required.</p> <p>QC</p> <p>-Some information available. Could use information on required documentation and more information is required on methods in place to ensure traceability.</p> |
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| <p>Wood</p> <p>FEDEMCO</p> | <p>Raw materials</p> <p>~Selected according to pre-established specifications that guarantee compliance of the material or object with all applicable regulations</p> <p>~If used to manufacture the end product, they must be stored separately from other materials (waste, by-products, chemicals etc...)</p> <p>to avoid cross contamination</p> <p>~Need their up-to-date details from suppliers for approval and control</p> <p>~Quality and hygiene needs to be agreed upon between supplier and manufacturer</p> <p>~Suppliers must guarantee that raw materials have not been treated or that chemical treatments used were those authorised by health authorities, which can be proven by indication on the delivery note or by presenting declarations of compliance.</p> <p>~Specification of biocides which contain certain chemicals (for example metals, mercury or halogens), which are prohibited in the treatment of wood under all circumstances</p> <p>~Chemicals must always be stored in their original container with their original label and stored safely so as to prevent leakage</p> <p>~Products that do not comply or are rejected, for whatever reason, must be identified, labelled and stored in a specific area set aside for this purpose</p> <p>~Measures must be taken to ensure these errors are not repeated</p> <p>~Specification of dyes used in inks or coatings, which are prohibited (for example dyes containing arsenic, mercury and lead)</p> <p>QA</p> <p>Adequacy of personnel:</p> <p>~The personnel must be informed of their duties and responsibilities in order to guarantee the safety of their products, so they can handle substances correctly and can implement a self-control system.</p> <p>Organisation of premises and equipment:</p> <p>1. Machinery and tools:</p> <p>~Require a Maintenance and Lubrication Programme (with evidence that this programme is being followed) for tools and equipment that require maintenance or lubrication in order to prevent deterioration or faulty operation</p> <p>~Manuals or technical instructions for machines and equipment must be made available</p> <p>~Oils or lubricants used, that could come into contact with food when it is packed, must be suitable for this purpose and the industry must have the appropriate declarations of compliance.</p> <p>~Special care must be given to the sharpening of saws and blades to avoid remains of chemicals and metal particles on the blades</p> <p>~Excess grease must be removed each time the equipment or tools are lubricated</p> <p>~Equipment needs to be regularly checked to ensure that grease is not leaking from maintenance equipment or the circuit conveyor belt</p> <p>~Compressed air that comes into contact with the product must be filtered</p> <p>2. Manufacturing processes:</p> <p>~Need a flow chart to describe the production process, which contains information on raw materials (the format in which they are received, their characteristics, storage conditions etc...), details of the process and storage conditions and delivery of the final product</p> <p>~Need procedures in place to ensure that the processes and equipment used always produce legal and safe products that meet required quality standards.</p> <p>~Contamination with oil grease must be avoided during all stages of production</p> <p>~During assembly of the product, metal parts must be used correctly and therefore machines must be checked, adjusted and repaired on a regular basis</p> <p>~Specific instructions concerning staples to be used for wooden boxes for fruits and vegetables and stapling angles are adhered to, to maximise adherence</p> <p>~Need a simple end control to be carried out and documented on a daily basis by workers in charge of the palletisation of products</p> <p>~ The finished product must be inert, clean and in good condition</p> <p>~Inks and marks must not be found on the inside of the finished product that will come into contact with the food</p> <p>~Finished product needs a declaration of compliance with appropriate regulations must be enclosed</p> <p>~If necessary, documents or technical files describing technical characteristics of the product, production, packaging, delivery method, storage, instructions of use and safety and maintenance must be enclosed.</p> <p>Presence of pre-established instructions for the procedures:</p> <p>QC</p> <p>Monitoring of the implementation and achievement of GMP:</p> <p>~Establish procedures that guarantee the traceability of materials and products</p> <p>--> -Personnel must be aware of the benefits of traceability and the consequences of non-compliance</p> <p>~Industry must insist that their suppliers label and identify all of their products with a batch number and/or manufacturing date</p> <p>~Products must be stored with information on the date they were received, the supplier, the batch number etc...</p> <p>~Finished product must be labelled with the batch number and/or manufacturing date</p> | <p>FEDEMCO document</p> <p>Guide to Good Hygiene and Manufacturing Practices for the Sector of Wooden Packaging and their Components Intended to come into Contact with Food</p> <p>-GMP legislation is aimed at industries that manufacture lightweight wooden crates and packaging and their components (sawn timber, boards, half-finished products etc...) which are intended to come into contact with food</p> <p>Raw materials</p> <p>-Detailed information provided, with specifications applicable to wood highlighted.</p> <p>QA</p> <p>-Some good information provided. Need further information or specifications on the importance of having pre-established instructions for the procedures and more information on the communication between manufacturer and customer. Guidance does detail points of importance specific to wood manufacture and contact with food.</p> <p>QC</p> <p>-Some good information provided. Could usefully have more information on the importance of checking the conformity of the finished product using information on raw materials and any production processes which could both have implications on the final suitability of the product. Could also usefully highlight the importance of periodically monitoring whether GMPs are being employed and could equally highlight the fact that only the QC system is allowed to authorise the use of any rejected materials or those pending further control.</p> |
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| | <p>~A record must be kept of rejections or unsatisfactory products ~A record must be kept of the customers to whom the finished products are supplied ~Carry out audits that verify the effectiveness of the system ~Quality system must be checked yearly ~Person who is carrying out internal self-assessment procedure must be qualified to do so and have had training or experience in this sector</p> <p>Corrective measures to remove any inefficiencies and non-compliance: ~Establish procedures to deal with non-compliance, incidents and complaints, which will be taken as soon as possible to reduce inefficiency and the emergence of new non-conformities (with results being used as suggestions for improvement)</p> <p>Documentation: ~Need to provide a statement from the management or provide a quality policy that confirms their commitment to guarantee the quality and food safety of their products ~Need internal documents to prove the system has been introduced and is being complied with (for example quality manuals, instructions etc...)</p> <p>~Record of the most important manufacturing operations concerning the compliance and safety of the material or finished product ~Results of the quality control system</p> | |
| <p>CEI Bois WOOD</p> | <p>QC Corrective measures to remove any inefficiencies and non-compliance: Following the process described in chapter 3, the crates shipped to fillers are fully traceable. If a problem is identified at retail level requiring the recall of crates, using upstream traceability documentation the problem component can be identified and a decision taken on problem crate withdrawal. The process would be: a) If there are no markings on the crate b) If the GROW license and the production date or lot number are printed on the crate.</p> | |

Annex 6. Hurdles in compilations of information on national rules.

Typical difficulties/hurdles were summarised in the box below for materials specific legislation:

a) Missing unequivocal identification numbers: Very often in national legislation, lists of substances are found only with the chemical names of the substances, but no CAS number, PM Ref. number, FCM number, EC inventory number, or other univocal identification number. In some cases the CAS number reported in the original source legislation was incorrect (e.g. typos), and thus also sometimes incorrect in the ESCO lists. An example is the French "Arrêté du 9 novembre 1994 relatif aux matériaux et objets en caoutchouc au contact des denrées, produits et boissons alimentaires", where some CAS numbers (e.g. 1709-10-2 or 2212-82-9) were incorrectly reported.

b) Mixed nomenclature: Substances were not always reported according IUPAC rules or CAS nomenclature. This aspect added to the lack of an identification number, made verifications very difficult. It is thus possible that a substance is listed several times under different names.

c) Lack of proper chemical names: Sometimes cumulative descriptions were given instead of names. For example, restrictions for rubbers can be found formulated as such as "Solvents" or "Polyesters produced by reacting acetic acid, acrylic acid, adipic acid, azelaic acid, caprylic acid, crotonic acid, phthalic acid, fumaric acid, coco fatty acids, tall oil fatty acids, itaconic acid, maleic acid, palmitic acid, sebacic acid and stearic acid with 2,2-bis(4-hydroxyphenyl)-propane, butanediols, butanols, cyclohexanol, n-decanol, hexanediols, glycerol, mono-, di- and polyethyleneglycols, mono, di- and polypropyleneglycols, isodecanol, 2,2-dimethyl-, 1,3-propanediol, pentaerythritol and sorbitol", or "reaction product of styrene and/or alpha methyl styrene and/or alkenes (C3-C12) with phenol and/or methy phenol". Another example is the CoE ResAP2004 which states "Salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of authorised acid, alcohol or phenol shall be automatically authorised. Salts of acids and bases that have been evaluated separately and are assigned to any of SCF lists 1 to 4 are also authorised. The restrictions should be the same as those of the individual acid and/or base." These types of descriptions can be difficult to interpret and to translate into substances that can be added to a positive list to be easily identified.

d) Lack of specificity in the chemical name: several names of substances are generic (e.g. "Hexanediol" or "Tartaric acid") and do not give further information to identify which one of the isomers (1,6-Hexanediol, or 1,2-Hexanediol, or 1,5-Hexanediol, etc.) or enantiomers (L-(+)-Tartaric acid, D-(-)-Tartaric acid, etc.) the legislator wanted to authorise. The different isomers or enantiomers have different CAS number and different characteristics. This lack of specificity, together with the lack of identification number makes the unequivocal identification of the substance impossible.

e) Multiple substances in one cell or line: There are many cases where a national measure or an ESCO file unifies in one cell more different substances. Lacking identification numbers it is often impossible to know if the legislators referred to a mixture, to reaction product(s) or to the single substances. In the context of this study, when the ESCO group added CAS numbers of the single substances this study interpreted as if they were referring to single substances and the cells were split. Where the ESCO group did not do so, it was not possible to know to what the legislators were referring to.

f) Verification of sources: In the CoE ResAP2004 on rubbers an extra column specified the country (by its name acronym) that was the source of the restriction, but without a reference to a measure. This made it very difficult to impossible to verify the information and check whether the legislative reference was amended or repealed. In some cases the cited MS does not have legislation on FCM other than the transposition of EU legislation (e.g. UK), so it is not clear where the information reported came from.

g) Generic reference to other materials: Mostly for adhesives and rubbers, some sources refer also to the substances authorised for other materials (e.g. plastics), but without giving any other additional information on eventual restrictions.

Annex 7. Frameworks and other documents for adhesives

The documents found are summarised below:

Overview of national measures or sources of information in the EU MSs related to adhesives:

| MS | Legislation | materials applicable for adhesives | Restrictions on composition | Positive/negative list Residual/QM/ OM/SML | Basis for enforcement/ test conditions |
|----|---|---|--|--|--|
| HR | NN125-2009 | - in polymers, including polyvinyl chloride (PVC), regenerated cellulose (RC), polyethylene (PE), polypropylene (PP), polystyrene (PS), polycarbonate (PC), polyethylene terephthalate (PET), polyamide (PA), melamine, silicones, polyurethanes (PU) and elastomers - in tableware, kitchenware, equipment or appliances (Članak 15, 32-71 and 92). | - connecting tubes for liquid food should be based on same polymeric material as tubes - solvent must not remain in tubes - polyurethane - adhesives may be used as glue e.g. multi-layer foils, if meet requirements (Članak 62-64). | Positive list: yes Residual QM SM: yes migration (Članak 15, 90, 94 in conjunction with Članak 32-71 and Prilog II, III, IV, V, VI, VII, and Članak 62-64) | Yes - (Članak 15., 90, 94 in conjunction with Članak 32-71 and DODATAK 5., Tablica 4 – 7a, Prilog II, III, IV, V, VI, VII). |
| FR | "Instructions" e.g. 30/11/87 30/05/89, circulaire 1982 DGCCRF. Note d'information n. 2012-93. (3.2.3.1) | - in P&B: dispersing agent in bactericidal mixes, preservatives - as direct contact meat and vegetable and fruits - In wood: substances authorised in Reg EU 10/2011. Other substances if not CMR or toxic cat. 1 or 2 if swallowed in Reg EC 1272/2008 | Individual substances | Yes: e.g. sodium lignosulfonate, sodium lauryl ether sulphate (5%); 1,2-benzisothiazolin-3-one (0.03%). | Not specified |
| DE | BfR Rec XXVIII BfR Rec LII (fillers and filler additives) | - in polyurethanes (PU) adhesives - in cross-linked PU (as adhesive layers for food packaging materials) - in temperature resistant polymer coating systems for frying, cooking and baking utensils - in linear PU for paper coatings, - in commodities from natural and synthetic rubber and from silicones. | Individual substances | <u>BfR XXVIII</u> - maximum amounts for substances and of PU adhesive per adhesive layer <u>BfR Rec II:</u> - maximum amount of filler /additives - purity criteria for fillers heavy metals | |
| IT | D.M. 20/03/1973 (+ amendmts) | ?? n/a? | positive list for adhesives (Titolo II, Capo III, art. 23, Allegato II, Sezione 3, Parte D), | - purity criteria of the waxes in adhesives | method for purity criteria (Allegato IV, Sez 4, pt. 1) |
| NL | Commodities Act Reg. 14/03/2014 | - in glues and fibre binding agents for P&B (Chapter II, 1.2.2), - in adhesives and thickening agents for wood and cork (Chapter IX, 2.1) - in adhesives for coatings without binding resin for polytetrafluorethene coatings (Chapter X, 11.2.2). | depending on use of substance / end use of adhesive | Yes, positive list | n/a |
| ES | R.D. 847/2011. (Art.+Anexo I) | polymeric adhesives, | - list of substances t in the preparation of polymeric adhesives (Art. 4, Anexo I). - Art. 12: sanctions based on R.D. 1945/1983 | - Art. 7 AnI: OML for polymeric waxes - Art. 7-8: SMLs - restrictions on content (Anexo I). | - Art. 9:basic information on verification of compliance with ML (based on Reg. 10/2011) |

Standards

There was little information found on standards for adhesives in the context of FCMs. A standard is available in the drinking water area and is presented below:

| standard name and source | standard title and contents |
|---|--|
| EN 12873-2:2005 (CEN/TC 164 water supply) | Influence of materials on water intended for human consumption - Influence due to migration - Part 2: Test method for non-metallic and non-cementitious site-applied materials (transport and storage of water). It covers the extraction by water of constituents from these materials after their application on site. It is applicable to materials whose physical or chemical properties alter during or after on-site application, such as coatings, paints, and adhesives. (Some greases or lubricants are also included). |
| AS 2400.14-1985 (AS (AU)) | Packaging – Adhesives: It provides guidance on the adhesives used in the manufacture of packaging materials and for assembling and sealing packages, or securing of unit loads. (It seems to include information on adhesives for Packaging of Food and Beverages) |

Substances in common for 3 or more MSs

Only 9 substances are in common by 3 countries of more.

Substances considered in common across three or more MS for adhesives:

| Name | HR 125/2009 | IT DPR n.777, 23/08/1982 (and its amendment) | NL X | ES No. 847/2011 Annex 1 | DE BfR XXVIII, and / or LII |
|-----------------------------------|--|--|--|--|---|
| Carboxymethyl cellulose | Art 61: Allowed only as coatings for paper as starting substances for silicone resins/masses Annex III: incomplete list of additives which may be used in the manufacture of plastic materials and articles | production of coupling adhesives for use with plastics, paper and paperboard (regenerated cellulose) | NL X, Ch. II 1. 2.2h: as glues and fibre binding agents for paper and cardboard (cellulose derivatives) NL X, Ch. IX 2.1c: for adhesives and thickening agents for wood and cork | n/a | n/a |
| cellulose acetate | n/a | production of coupling adhesives for plastics, paper and paperboard (regenerated cellulose) | NL X, Ch. IV 2.2g: according to NL X Ch. I, as starting materials and auxiliaries in organic coatings for metals | as monomer, additive and other substance | n/a |
| Cellulose acetate butyrate | Annex III: incomplete list of additives which may be used in the manufacture of plastic materials and articles | production of coupling adhesives for use with plastics, paper and paperboard (regenerated cellulose) | NL X, Ch. IV 2.2g: containing no auxiliary materials other than those permitted in NL X Ch. I, as starting materials and auxiliaries in organic coatings for metals | as monomer, additive and other substance | n/a |
| cellulose nitrate | Art. 62- polyurethane must prevail in blend, as starting substances in polyurethane polyether polyols Annex II: list of monomers and their starting substances | n/a | NL X, Ch. IV 2.2g containing 10.8- 12.4% nitrogen, as starting materials / auxiliaries in organic coatings for metals | n/a | DE BfR XXVIII, 2-a): according to DIN 53 179, as starting materials for cross-linked polyurethanes adhesive layers |
| ethyl cellulose | Annex III: incomplete list of additives which may be used in plastic materials/articles | n/a | NL X, Ch. IV 2.2g: polymers for organic coatings (metals) NL X, Ch. IX 2.1c: in adhesives and thickening agents for wood and cork | as monomer, additive and other substance | n/a |
| formic acid | Annex III | n/a | n/a | as monomer, additive, other substance | DE BfR LII, 2.2.4: EU2, as additives for fillers |
| phosphoric acid | Annex II: list of authorised monomers and their basic starting substances Annex III: incomplete list of additives which may be used in the manufacture of plastic materials and articles | n/a | NL X, Ch. IV 2.2g: as starting materials /auxiliaries in organic coatings for metals NL X, Ch. X 11.2.2a: in adhesives for coatings without binding resin | n/a | DE BfR LII, 2.2.4: EU2, as fillers (additives) in the preparation of film-forming as processing aids for glass fibres, carbon fibres and glass microballs |
| polyurethane | Art. 62 - < 10g/m2 after elimination of solvents - as adhesives, starting substances in polyurethane polyether polyols | n/a | NL X, Ch. IV 2.2g: according to NL X Ch. I, as starting materials/auxiliaries in organic coatings for metals NL X, Ch. IX 2.1c: according to NL X Ch.I, in adhesives /thickening agents for wood / cork | n/a | DE BfR LII, 2.2.2: - in compliance with BfR XXXIX, as additives for fillers |
| polyvinyl alcohol | Art. 61: as starting substances for silicone resins/masses | only as coatings for paper, coupling adhesives for use in plastics, paper and paperboard | NL X, Ch. IV – 2.2 g) viscosity of the 4% solution in water at 20 °C at least 5 mPas, as starting materials and auxiliaries in organic coatings for metals | n/a | n/a |

Annex 8. Frameworks and other documents for printing inks

National /supra national sources

In terms of the regulatory frameworks there are 4-5 MSs with positive list (+ CoE). An overview of national or supranational documents on printing inks for FCMs is shown below.

Overview of national sources in the EU MSs on printing inks

| MS | Legislation | Positive lists / negative lists + other comments | Restrictions : Residual/QM/OM/SML Basis for enforcement / test conditions if any |
|-----|---|---|---|
| COE | PS Inks 2007 | <p>PS Inks 2007: packaging inks applied to the non-food contact surface of FCM</p> <p>ResAP (2005)2: packaging ink applied to the non-food contact surface of FCM</p> <ul style="list-style-type: none"> - Tech. doc No 1: selection of raw materials, - Tech. doc No 2: GMPs for production of inks (part1) and Code for GMPs for flexible and fibre-based packaging for food | <ul style="list-style-type: none"> - SMLs for additives / binders in inks already assessed by SCF/EFSA (Tech. doc No1) - non-detectable SML (< 0.01 mg/kg food or food simulant, analytical tolerance included) for substances not yet assessed by SCF/EFSA with no SMLs. <p>It recalls "all restrictions (e.g. SML) of substances in the Inventory list, in all EU regulations or CoE resolutions must be observed" (Tech. doc No. 1 Sect. 4.2)</p> <p>Test conditions:</p> <ul style="list-style-type: none"> - recalls standards OM/SM (EN1186/13130/14338) - instructions / recommendations on sampling and selection of test foods. |
| | ResAP (2005)2 | <ul style="list-style-type: none"> - Tech. doc No 3: guide on test conditions - Positive lists (Tech. doc 1) - Negative lists: exclusion criteria to evaluate which substances cannot be used in printing inks (Tech. doc 2) | <ul style="list-style-type: none"> - Reference to EU Reg. plastics for simulants and t/T (Ch.4.1, 4.2, Tech. doc 3) |
| COE | PS tissue paper (2004) | <ul style="list-style-type: none"> - printing inks can be used for tissue paper, kitchen towels and napkins. "Should be formulated using raw materials with a description of substances typically used in printing inks for kitchen towels and napkins." | <p>restrictions for constituents of inks used for tissue paper, kitchen towels and napkins:</p> <ul style="list-style-type: none"> - limits for Sb, As, Cd, Cr(VI), Pb, Hg, Se, PCBs, primary aromatic amines (PAAs) in colorants - limits for Pb, Cd, Hg, PCP in paper (Ch.4, App 2). - SML for Ba from inks used for tissue paper, kitchen towels and napkins (Appendix 2). |
| HR | NN125-2009 | bans the use of naphthylamine, benzidine and 4-aminodiphenyl | fixes purity criteria for dyes |
| CZ | Vyhláška č. 38/2001 | <ul style="list-style-type: none"> - bans the use of colouring agents based on Sb, As, Cr(VI), Cd, Pb, Hg and Se) (Part 1, section 6, §3) - imposes conditions for azo-dyes/diazodyes and carbon black | <ul style="list-style-type: none"> - limits for substances in inks (dyes, pigments, fillers) (Příloha 1, 1-2), - purity requirements on elements soluble in acid such as Ba, Cr, Cd, Se, Hg, Sb, As, Pb, - limits on PAAs (0.05% PAAs with content of benzidine, beta-naphthylamine and 4-aminobiphenyl < 0,001%) - limits on extracted PCBs (0.005% as decachlorobiphenyl) |
| FR | Avis DGCCRF du 10 juin 2010 | <ul style="list-style-type: none"> - On MW <1000 Da - specifies that the producers of inks have to provide all the necessary documentation for converters to verify the compliance | <ul style="list-style-type: none"> - QMLs - SMLs - general limits for subst. not risk assessed (Ch. 4)- (MW <1000 Da) |
| FR | BOCCRF n°9 12/05/1999 + another | Authorising some solvents for inks for P&B Positive list for solvents in inks for FCMs | <p>n/a</p> <ul style="list-style-type: none"> - maximum amount of a pigment and - general purity criteria for pigments in FCM inks - SMLs for solvents to be used in FCM inks |
| FR | Instruction 30/11/1987 | substances to be used in inks | <ul style="list-style-type: none"> - maximum content of metals in 1 ink substance - limits for total extractable from polymers in inks (5h reflux, simulants/ solvents) |
| FR | Lettres-circ. 8/11/1984 16/12/1983 | <ul style="list-style-type: none"> - pigment (aminobenzamide) - 5-(6-methyl-2-oxobenzimidazol-5-yl)azo]perhydropyrimidine-2,4,6-trione | n/a |
| DE | Law UNDER PREPARATION | <p>Positive list:</p> <ul style="list-style-type: none"> - 90-95% of substances as in the CH ord. - monomers / additives of Reg. EU 10/2011 - includes monomers for polymers, additives, colorants, solvents and photoinitiators with risk assessment or sufficient toxicological information - provisional list for pigments (4 years) - other substances for inks <u>not</u> intended for direct food contact, if not CMR (no direct contact with food under foreseeable conditions of use) (draft 21st amendment Art.1 No.2 and No.7 + §4 BedGgstV) - DoC and supporting documents for printed FCMs, inks and raw materials for inks + instructions on information required in the DoC. States when a DoC is not required (draft 21st amdt Art.1 No.4/No.7 + §10 BedGgstV) - sanctions for non-compliance (draft 21st amendment Art.1 No.5 + §12 BedGgstV) | <ul style="list-style-type: none"> - purity criteria (§4(5), Anlage 14, BedGgstV) - SMLs or SML(T) organics, metal ions and PAAs (§8(5,6) Anlage 14, BedGgstV) - migration of substances not in the positive list and pigments in provisional positive list must be non-detectable (LOD of 0.01 mg/kg food applied, except for nanomaterials (§8(7) BedGgstV). - substances of Reg. EU 10/2011, keep their SMLs (see draft for 21st amdt Art. 1 No. 3 and No. 7 + §8 BedGgstV) |
| DE | BfR Opinion No. 028/2008 | <ul style="list-style-type: none"> - isopropyl thioxanthone (ITX) can be used - presents a risk assessment on potential migration of photoinitiators used in inks | - migration of isopropyl thioxanthone (ITX) must not exceed 50 microgram ITX per kilogram food |
| IT | DPR n.777, 23/08/1982 (and its amendment) | n/a establishes the obligation for the producer to have a DoC for printing inks (Art. 4.5-4.6, Art. 5-bis.2) and sanctions for non-compliance (Art.3, 5-bis, 6) | n/a |
| NL | Commodities Act (Packagings and Consumer | substances in colorants and pigments (Ch. 0, 0.3 and Ch. XI, 2) | <ul style="list-style-type: none"> - limits for metals, PAAs from colorants/pigments - total limits for soot (furnace black /channel black) and other carbon products (Ch. 0, 0.5.1-0.5.4; Ch. XI, 3-4) - SMLs for ingredients of colorants and pigments. (Ch. 0, |

| MS | Legislation | Positive lists / negative lists + other comments | Restrictions : Residual/QM/OM/SML Basis for enforcement / test conditions if any |
|----|--|--|--|
| | Articles) | | 0.5.1-0.5.4, 0.6; Ch. XI, 3-4) |
| RO | Order 869 of 17/07/2006 | - requires a declaration of compliance and specifies documents (Annex, Art.5-7) | - maximum amount for Pb, As, Hg, Cd, Zn, Se, Ba for inks (Annex, Art.2) |
| SK | Foodstuffs Code 1799/2003 | - it reports the restrictions on components of dyes and pigments | - requirements (purity criteria) (§6, Prilohe č. 2) - maximum amounts for substances (PAAs, PCB derivatives) that can be used for inks (Prilohe č. 2) |
| CH | Ordinanza DFI del 23/11/2005 SR 817.023.21 | positive lists for substances in inks. - list A of evaluated substances - list B of non-evaluated substances - Inks for direct food contact regulated as food additives revision (2013): list A >340 substances, includes binders, dyes and pigments, solvents, additives, photoinitiators List B >4000 substances - notification process with direct market entry for new substances | - List A : SML, maximum amounts in inks, - list B: SML "non-detectable" (set as 10µg/kg including analytical tolerance) |

Standards

Standards for printing inks exist and are presented below.

| source | standard name | standard title |
|------------|-----------------|---|
| AFNOR (FR) | NFQ 64 020:1981 | Graphic Technology - Printing And Printing Inks - Determination Of The Likelihood Of Colour Migration From A Print Into Edible Oils |
| AFNOR (FR) | NF Q64-017:1981 | Graphic technology. Printing and printing inks. Determination of the likelihood of colour migration from print to water |
| AFNOR (FR) | NFQ 64 021:1981 | Graphic technology. Printing and printing inks. Determination of the likelihood of colour migration from a print into a solution of lactic acid |
| AFNOR (FR) | NFQ 64 018:1981 | Graphic technology. Printing and printing inks. Determination of the likelihood of colour migration from a print into a saline solution |
| AFNOR (FR) | NFQ 64 019:1981 | Graphic technology. Printing and printing inks. Determination of the likelihood of colour migration from a print into a sugar solution |

Note: **India** (Bureau of Indian Standards) has a standard on Printing Inks (BIS IS 15495:2004, Printing Ink for Food Packaging - Code of Practice) – no description available.

Sectorial guidance

See in text- situation limited to mainly two MSs, but large number of substances

Annex 9. Frameworks and other documents for ion exchange resins

National /supra national sources

Overall 3 MSs have mentions to resins in their frameworks (France, The Netherlands, Spain), in addition to a CoE Policy statement at supranational level. The main input at national level are found in France (overall) and Spain (polymeric ones only). An overview of the sources at national level is presented. From a general standpoint, IERs are regulated under the concept of positive lists with residual /contents, purity criteria, overall and specific limits imposed using a process of authorisation of substances.

Overview of national sources in the EU MSs on Ion exchange resins:

| MS | Measure | Information on GMP, DoC& supporting documents, sanctions and enforcement | Positive lists / negative lists | Restrictions - Residual/QM/OM/SML Basis for enforcement/ test conditions |
|-----|---|---|--|---|
| CoE | PS ion exchange and adsorbent resins (IERs) | States that IERs should be manufactured in accordance with a certified Quality Assurance System (Appendix, 2) | - gives a positive list (list 1) of substances for IERs - Reports a list (List 2) of substances used in IERs, but should not be used for FCM | - Reports restrictions for authorised substances, OMLs and SMLs - Provides information on the assessment of migration from IERs (Appendix, 2) |
| FR | Arrêté du 19 octobre 2006 | States the need for regular checks of the IERs listed to ensure that they do not release or leave toxic substances into food in quantities which may endanger human health (Art. 1 with Annex II No. IV) | Provides a positive list for processing aids including for IERs (Art. 1 in conjunction with Annex I B). It also refers to a list of authorised food additives and authorises their use as additives, dispersants or dilutants for processing aids (including IERs) | - Defines general purity criteria for processing aids (including IERs, Art. 1 in conjunction with Annex II No. III) - Sets limits for the maximum residual amount of four IERs and it limits the use of two other IERs to the strictly necessary and technically inevitable amount (Art. 1 with Annex I B) |
| FR | Décret no 2011-509 | n/a | n/a | Defines purity criteria for processing aids for the content of Pb, As, Hg and Cd (Art. 4 I), which include IERs |
| ES | Real Decreto 847/2011 | States that failure to comply with law would imply sanctions based on the Real Decreto 1945/1983 provisions (Art. 12) | Reports a list of substances that can be used in preparation (Art. 4, Anexo I) | - Establishes restrictions on content of some substances (Anexo I) - Reports OM (art 7) and SMLs for substances (Art. 7, 8, Anexo I) - Provides some very basic information on the verification of compliance with migration limits (Art. 9) |
| NL | Commodities act | It sets rules for compliance with limits (migration conditions, methods, detection, calculation of results) and for the assessment of substances not included in the EU list. (Ch. 0, 0.7, 0.8, 4.1, 4.2, 5, 6, annex I-IV; Ch. II, 1, annex I) It establishes the obligation of DoC in (chapter 0, 0.9, annex I) | It provides a very generic positive list for substances that can be used or be present in all packaging and consumer articles (Annex Part A, Ch. 0, 0.3), thus it is considered to include also IERs | It fixes limits for the specific migration of substances in all packaging and consumer articles (Annex Part A, Chapter 0, 0.5.1, 0.6), and for overall and residual content for the migration of substances in all packagings and consumer articles (CH. 0, 0.5.2-0.5.4, 0.6) |

Standards

Standards for IERs exists and are presented below:

| standard code and source | standard title |
|--------------------------------------|--|
| EN 12873-4:2006-06 (CEN/TC 164) | Influence of materials on water intended for human consumption : - Influence due to migration Part 3: Test method for ion exchange and adsorbent resins |
| NFT 90 601:2011 (AFNOR (FR), T90M ?) | Ion Exchange Resins - Test Release <i>"Le présent document spécifie une méthode permettant de déterminer le relargage de substances organiques à partir des résines adsorbantes et échangeuses d'ions utilisées en contact avec l'eau destinée à la consommation humaine ou les denrées alimentaires. Ces résines comprennent des matériaux macromoléculaires organiques synthétiques. Le présent document s'applique aux résines échangeuses d'ions (anioniques, cationiques) ; les résines adsorbantes</i> |

CEN/TC 164 - water supply; T90M - Effets des matériaux en contact avec l'eau potable

Annex 10. Frameworks and documents on varnishes and coatings

An overview of the sources available at national level is presented. It does not include measures for Bisphenol A since those are under discussion at EU level.

Overview of national sources in the EU MSs on varnishes and coatings

| MS | Legislation | Positive list or negative list End use if applicable | Restrictions - Residual/QM/OM/SML Basis for enforcement/ test conditions if any |
|------|---|---|--|
| Co E | PS coatings (2009) | <ul style="list-style-type: none"> - monomers and additives from 2002/72/EC, - two additional lists of substances not assessed but approved by MSs or FDA - restrictions: (Tech. doc. No. 1, annex 4, part B, List 1 of monomers, List 1 of additives) (Appendix to framework resolution, 3.2, Technical document No. 1, 1., List 1 of monomers, Temporary appendix to list 1 of monomers, List 1 of additives, Temporary appendix to list 1 of additives) | <ul style="list-style-type: none"> - OML (Appendix to framework resolution, 3.3, Technical document No. 1, 1.). It also indicates specific migration limits for monomers and additives (Technical document No. 1, 1.4, List 1 of monomers, List 1 of additives). It recommends that coatings should be manufactured in accordance with guidelines on GMP for coatings intended to come into contact with foodstuffs (Appendix to resolution, 3.2) - test conditions not specified |
| BE | DRAFT "Arrêté royal concernant les vernis et revêtements destinés à entrer en contact avec les denrées alimentaires" | <ul style="list-style-type: none"> - enables the use of all substances authorised in Reg. (EU) 10/2011 under specified conditions. - draft and as of 05.12.2015 had been suspended | <ul style="list-style-type: none"> - QM L for substances in final material (Art. 4). - OML (Art. 5) - SMLs (Art. 6) Test conditions: <ul style="list-style-type: none"> - methods of analyses (Annex, Ch. 1+2) - stipulates the necessity of providing a declaration of compliance (Annex, Ch. 3) |
| CZ | Vyhláška č. 38/2001 | -list of substances that can be used in the preparation of coatings (binders, plasticisers, ingredients/excipients, stabilisers, emulsifiers and protective colloids) (Příloha 10, 11). | -SMLs for coatings and -limits on substances in preparation. - BADGE in migrates and extracts (nd, LOD: 0.02mg/kg or 0.004 mg/dm ²) (Příloha 11). - test conditions not specified |
| DE | (measures depending on end materials) BfR Rec. LI coatings for frying, cooking and baking utensils BfR Rec. LII fillers BfR Rec. XVIII outer hollow glassware coatings BfR Rec. XLI linear polyurethanes for paper coatings | <p>BfR Rec LI: substances for the preparation of temperature resistant <u>coatings</u> for frying, cooking and baking utensils</p> <p>BfR Rec LII. Fillers lists for fillers and filler additives that may, among other applications, be used in the manufacture of cross-linked polyurethanes (incl for temperature resistant polymer <u>coating</u> systems for frying, cooking and baking utensils, in the manufacture of linear polyurethanes for paper <u>coatings</u>)</p> <p>BfR Rec. XLVIII substances for <u>coating</u> the outside of hollow glassware</p> <p>BfR Rec. XLI - substances for polyurethane paper coatings - dispersion preservatives Restrictions: as nd in finished products - that formaldehyde in extracts from the inside surface of the product - isocyanate groups and aromatic amines</p> | <p>BfR Rec LI: - residual limits for substances in the finished coatings, -SMLs - reports test conditions for SM tests</p> <p>BfR Rec LII: - maximum amounts of some filler additives based on the filler as well as purity criteria for fillers regarding contamination with heavy metals</p> <p>BfR Rec. XLVIII - purity criteria for substances in coatings of hollow glassware</p> <p>BfR Rec. XLI -limits for substances for polyurethane paper coatings - limits for dispersion preservatives</p> |
| EL | Greek food code | <ul style="list-style-type: none"> - substances that can be used in the manufacture of coatings (Table 1) - states necessity of supporting documentation and gives instructions on what it has to contain (Article 28, 2.g) | <ul style="list-style-type: none"> - OML for the final coated material (10 mg/dm² or in some cases 60 mg/kg food)(Table 1) - SMLs for substances (Table 1) - Maximum content in final product - test conditions not specified |
| ES | Real Decreto 847/2011 | <ul style="list-style-type: none"> - substances that can be used in the preparation of <u>polymeric</u> varnishes/coatings (Art. 4, Anexo I). - sanctions for failure to comply based on Real Decreto 1945/1983 (Art. 12). | <ul style="list-style-type: none"> - Limits on content of some substances (Anexo I). - OML (Art. 7, Anexo I) - SMLs (Art. 7, 8, Anexo I). - Verification of compliance with MLs (Art. 9). |
| FR | BOCCRF n°17 du 15/09/1998 n°08 du 24/05/1996 Instruction du 30/11/1987 | <p>In varnishes – individual substances</p> <ul style="list-style-type: none"> - as fungicide (n°17 du 15/09/1998) - in printing (n°08 du 24/05/1996) - in cellulose derivatives (Inst. 30/11/1987) | <ul style="list-style-type: none"> - BOCCRF n°17-15/09/98: authorises 3-iodo-2-propynyl butylcarbamate (IPBC) as fungicide and fixes its maximum content in varnishes. - BOCCRF n°08-24/05/96: positive list for solvents to be used in varnishes for printings on food packaging materials + SMLs Instruction du 30/11/1987: - maximum content of heavy metals in mixtures - amount of total extractables in two derivatives of cellulose (test conditions specified as : 5h reflux, food simulants/solvents) |
| FR | Lettre-circulaire (LC) et circulaire (C) | <p>List positive: (authorisation)</p> <p>LC 16/12/1983: 5-(6-methyl-2-oxobenzimidazol-5-yl)azo]perhydroprymidine-2,4,6-trione</p> <p>C 29/05/1978: - 2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole + QM - polyphenylene sulphide for non-stick coatings for cooking utensils (+ max temperature of use) - ammonium bis(N-ethyl-2-perfluoroalkyl sulfonamide ethyl) phosphate as grease-proofing of P&B (+QM)</p> <p>C 02/04/1969: substances for varnishes + purity criteria + SML for zinc carbonate.</p> | <p>See previous column when applicable</p> <ul style="list-style-type: none"> - test conditions not specified |

| MS | Legislation | Positive list or negative list End use if applicable | Restrictions - Residual/QM/OM/SML Basis for enforcement/ test conditions if any |
|----|--|---|--|
| | | <i>C n°175 du 25/03/1959</i> : plasticisers and stabilisers in varnishes and specifies + QM <i>C n°165 du 12/01/1954</i> <i>C n°162 du 25 avril 1952</i> <i>C n°159 du 23 juin 1950</i> <i>Arrêté du 03/09/1959</i> : antioxidants added to coating + QM (Art. 3). <u>Negative list:</u> <i>C n°172 du 26/06/1956</i> : bans diethylene glycol | |
| FR | DGCCRF Note d'information n°2012-93 : coatings for wood (section 3.2.3.1). | - substances from Reg. EU 10/2011 for varnishes, lacquers, paints, surface coatings and adhesives in wooden FCM - substances in lists 0-4 of the SCF - substances in CoE ResAP (2004)1 part A: List 1 of monomers and part B: List 1 of additives - other substances if not CMR or toxic cat. 1 or 2 if swallowed in Reg. (EC) 1272/2008 | Not specified? |
| HR | NN125-2009 | Positive list: substances /compounds as <u>binders</u> (Članak 81-83) Negative list: bans BFDGE and novolac glycidyl ethers for coatings (Članak 81-83). | - SMLs - extractable amounts for substances from varnishes and coatings (Članak 82, 84) -test conditions for SM and OM tests (Članak 25). |
| IT | D.M. 21/03/1973 (and amendments) DPR n°777 of 23/08/1982 (amended) | - substances Reg. 10/2011 may be also used for surface coatings, resins, varnishes, multimaterials (Allegato II). | - residual content - OML - SMLs Reg. 10/2011 (Allegato II). DPR n°777: - content of Pb of the internal coating/varnish of metal containers + sanctions (Art. 2-bis) Nota del Ministero della Salute n°20072 of 20/05/2014: - migration tests (contact conditions). - metals other than the regulated Pb and Cd (e.g. nickel) might migrate from porcelain enamels: test used for Pb and Cd can be used and the results evaluated case-by-case |
| NL | the Commodities Act (Packagings and Consumer Articles) Regulation for coatings | substances for <u>dispersions</u> of: - macromolecular substances in water, - paraffins and waxes in water, - macromolecular substances in an organic liquid or a mixture of organic liquids, substances for <u>solutions</u> of: - macromolecular substances in water, - in an organic solvent, solvent-free material based on waxes or macromolecular substances, other solvent-free materials, layers applied through evaporation of metal to an existing substrate, polytetrafluorethene (Ch. 0, 0.3; Ch. X, 3-11). - <u>For enamels</u> : "the base materials and auxiliary materials used in the manufacture of enamels must be of high technical quality. The auxiliaries must not be used in larger quantities than strictly necessary for the manufacture of the final product". - <u>For coatings</u> it includes lists of authorised substances. (Ch. 0, 0.3; Ch. X, 3-11). | - OML - SMLs from enamels and coatings (Ch. 0, 0.5.1-0.5.4, 0.6; Ch. X, 12; Ch. VI, 2). - Quantity in material for some substances For enamels,: test only with 3 % acetic acid using test conditions referred to in subsection 4.1.1.2(3) of Annex B, Chapter I, Results in mg/dm ² must be divided by 10 and then assessed against the limits mentioned in subsection 2.3.3 (Ch. VI, 2). |
| SK | Foodstuffs Code 1799/2003 | substances and materials for coatings, varnishes and enamels. (§10-13, Prílohe č. 4) | - it provides maximum allowed amounts for substances and materials that can be used for coatings, varnishes and enamels (Prílohe č. 4). |

Standards

Standards found related to varnishes and coatings are presented.

| standard name and source | Standard title and content |
|-----------------------------------|--|
| EN ISO 9233-1:2013 9233-2:2013 | Cheese, cheese rind and processed cheese - Determination of natamycin content – Part 1: Molecular absorption spectrometric method for cheese rind: Specifies a method for the determination in cheese rind of natamycin mass fraction of above 0,5 mg/kg and surface-area-related natamycin mass of above 0,03 mg/dm ² . Part 2: High-performance liquid chromatographic method for cheese, cheese rind and processed cheese: Specifies a method for the determination of natamycin mass fraction of above 0,5 mg/kg and of the surface-area-related natamycin mass in cheese rind of above 0,03 mg/dm ² . |
| CEN/TS 13130-20:2005 | Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 20: Determination of epichlorohydrin in plastics: This document, part of EN 13130, specifies an analytical procedure for the determination of residual epichlorohydrin in coatings |
| EN 15136:2006 | Materials and articles in contact with foodstuffs - Certain epoxy derivatives subject to limitation - Determination of BADGE, BFDGE and their hydroxy and chlorinated derivatives in food simulants. It describes the determination in food simulants distilled water, 3 % w/v aqueous acetic acid, 10 % v/v aqueous ethanol solution and olive oil or sunflower oil. A high performance liquid chromatography (HPLC) method is employed based on reversed phase HPLC and fluorescence detection. Substances are indicatively confirmed. |
| CEN EN 15137:2006 | Materials and articles in contact with foodstuffs - Certain epoxy derivatives subject to limitation - Determination of NOGE and its hydroxy and chlorinated derivatives Describes the determination of NOGE components with more than two aromatic rings (the two-ring NOGE is equal to BFDGE = Bis(2-hydroxyphenyl)methane bis(2,3-epoxypropyl)ether) and at least one epoxy group as well as their derivatives containing chlorohydrin functions and a molecular mass <1000 Daltons in can coatings. |
| CEN/TS | Materials And Articles In Contact With Foodstuffs - Polymeric Coatings On Paper And Board - Guide To The Selection Of |

| standard name and source | Standard title and content |
|----------------------------|---|
| 14234:2002 | Conditions And Test Methods For Overall Migration. It provides test methods for 'alternative tests' and 'substitute tests' performed with volatile test media, iso-octane and a volume fraction of 95 % aqueous ethanol, for the determination of overall migration from polymeric coatings on paper and board intended to come into contact with fatty foodstuffs. |
| CEN/TS 14235:2002 | Materials And Articles In Contact With Foodstuffs - Polymeric Coatings On Metal Substrates - Guide To The Selection Of Conditions And Test Methods For Overall Migration. It provides guidelines for the selection of the appropriate conditions and test methods for the determination of overall migration into food simulants and test media from polymeric coatings on metal substrates which are intended to come into contact with foodstuffs and a test method for overall migration into aqueous simulants by article filling from polymeric coatings on food and beverage cans and non-stick coatings. |
| DVS (DE) 2317:2008-01 | Use of thermally sprayed coatings for products in contact with food - Proof of harmlessness |
| CEN EN 16058:2012 | Influence Of Metallic Materials On Water Intended For Human Consumption - Dynamic Rig Test For Assessment Of Surface Coatings With Nickel Layers - Long-Term Test Method Describes a procedure to determine the release of nickel from nickel layers or a coating containing nickel on inner surfaces of products which are intended to come into contact with drinking water. |
| CEN EN 12873-4:2006-06 | Influence of materials on water intended for human consumption - Influence due to migration Part 4: Test Method For Water Treatment Membranes * |
| EN 15768:2015 | Influence of materials on water intended for human consumption. GC-MS identification of water leachable organic substances Describes the analytical procedures based upon gas chromatography and mass spectrometry (GC-MS) to screen migration waters for organic substances derived from finished products such as pipes, protective coatings, membranes, etc.* |
| AFNOR (FR) NFA 36 713:2004 | Unpackaged Steels - Flat Steel Products Intended For Contact With Foodstuffs, Products And Beverages For Human And Animal Consumption - Steel With Organic Coating |
| GB/T 5009.68-2003 | Method for analysis of hygienic standard of perchlorovinyl-coating for inner wall of food container: Specifies: a vinyl chloride resin as the main raw material, together with pigments and additives composition paint the health indicators analysis. This standard applies to: a vinyl chloride resin as the main raw materials, together with pigments and additives composition paint the health indicators analysis. |
| GB/T 5009.69-2008 | Method for analysis of hygienic standard of epoxy phenolic coatings for inner wall of food cans: Specifies the method for the analysis of health indicators canned food inside wall epoxy phenolic coatings. |
| GB/T 5009.70-2003 | Method for analysis of hygienic standard of epoxy coating for inner wall of food container: Specifies epoxy amide curing agent of epoxy coating health indicators analytical methods. This standard applies to: touch wine, soy sauce, fermented foods, preserved foods and edible oil storage, the tank used as a preservative, such as the inner wall polyamide epoxy coating health indicators analysis. |
| GB/T 5009.80-2003 | Method for analysis of hygienic standard of polytetrafluoroethylene coating for inner wall of food container: Specifies: food container wall Teflon coating hygiene standards analytical methods, This standard applies to: PTFE as the main raw material, together with certain additive composition Teflon coating, coating on aluminium wood, iron and other metal surfaces, sintered at high temperature, as a contact non-acidic food containers release coating. Temperature limits below 250 iæ. |
| GB 9682-1988 (SAC CN) | Hygienic standard for internal coating of food cans: Specifies the requirements of food hygiene stripping paint cans inside wall. This standard applies to ethylene (bis)stearamide canned food for the inner wall of mold release agent coating. This coating printed on tin plate, high temperature baking to film, can be used for the inner wall of canned luncheon meat and other meat products. |

CEN/TC 194 - Utensils in contact with food; CEN/TC 164 - water supply; *: note: might be applicable to rubbers; CEN/TC 302 - Milk and milk products - Methods of sampling and analysis;

Substances with convergence for 3 or more MSs.

Substances commonly considered included oils and waxes. Waxes include for example bees, carnauba, Montane²¹¹. Oils were considered in some cases with fatty acids, and hydrogenated form as well. Examples included such as castor, coconut, cotton seed, corn, poppy seed, pumpkin seed, rapeseed, safflower, sesame, sunflower, tall/pine resin, tallow, and walnut. Substances commonly considered by three or more MSs also included paraffin resins, shellac oil, and lanolin. The main countries for the convergence for oils and waxes in varnishes and coatings were Spain, CoE and Greece.

The second source of convergence is found for substances acids or salts, esters, or sugars and derivatives. It was estimated that about 23 substances which do not seem to present a particular issue and are allowed but not restricted for the most part. These substances may be specified based on the nature of their use (monomer, additives, and agents, starting substance) and/or by the end materials for which their use is intended since they are intermediates. Examples of restriction on end use include for example as monomer/starting substance or additive based on permission for use as in Reg. (EU) No 10/2011. It can also be further defined either generically e.g. auxiliary agent, processing aid, or more function oriented such as for example (depending on the chemical nature of the substance) plasticiser, film-forming agent, antistatic finish, protective colloid or thickening agent, filler, binder, emulsifier, antioxidant, reduction agent, neutralising agent. Most often substances from this category are already allowed in the plastics Regulation 10/2011. Examples of acids include mild acids such as acetic acid (FCM 115), citric acid (FCM139), tartaric acid or of stronger acids such as formic acid, hydrochloric acid, nitric acid, and phosphoric acid. Examples of regulated substances that are polysaccharides/carbohydrates in nature included cellulose and derivatives (acetate, acetate-butyrate, acetate-propionate, ethylcellulose), dextrin, saccharose, starches. They are also glycerol ester (glycerol monostearate, monooleate, triacetate, lecithin), or fatty acids such as stearic acid,

²¹¹ montanic acids C26-C32; esters with ethylene glycol and/or 1,3-butylene glycol and/or calcium salts)

A few are inorganic such as cobalt salts of tall oil fatty acids or lithopone which is a mixture of barium sulphate and zinc sulphide where a restriction may exist such as for cobalt salts of tall oil with an SML(T)=0.05 mg/kg (expressed as cobalt together with all cobalt compounds) expressed convergently by Spain CoE and Greece. Additional substances considered commonly by three or more MSs for coatings and not restricted are 1,2-propanediol, wheat protein, triethylamine, triethylene glycol. However a salt such as ammonium chloride can be found restricted to 20% by Germany (BfR) LII but not by Greece, CoE, Spain or the Netherlands. Substances for which convergence exists in the nature and limits are presented below.

Substances with convergence across three or more MSs both in nature and in relative limits considered

| Substance and CAS | NL X | EL Dec. 446/98 | ES 847/2011 | CoE |
|--|---|---|--|---|
| Chlorobenzene 108-90-7 | as other auxiliary substance in polysulphones - use EP to max 140 °C | as additive SML=36 mg/kg | as monomer, additive and other substance - SML=36 mg/kg | n/a |
| Diethyleneglycol monobutyl ether 111-76-2; 112-34-5 | monomer, additive, other substance SML(T)=3 mg/kg (sum 15780/16993/16996/17002/48030/48050/53765) | as additive SML=3 mg/kg (all ethyleneglycol and diethylene glycol ethers) | n/a | as additive SML = 3 mg/kg ADI/TDI=0.5mg/kg bw |
| Dimethylamine 124-40-3 | as reducing agent | as monomer or starting mat., as additive; SML=0.06 mg/kg | as monomer, additive and other substance; SML=0.06 mg/kg | n/a |
| Ethylene glycol, monoethyl ether 110-80-5 -- monobutyl ether 111-76-2 | n/a | as monomer or starting mat., as additive SML=3 mg/kg (together with all ethers of ethylene and diethylene glycol) | as monomer, additive or other substance; SML=3 mg/kg (sum of 15780/16993/16996/17002/48030/48050/53765) | as monomer and additive; SML = 3 mg/kg |
| Lithium (LI) hydroxide 1310-65-2 | | as additive, SML=0.6 mg/kg (expressed as Li) | as monomer, additive or other substance SML=0.6 mg/kg (expressed as Li) | as additive |
| Manganese salts of resin acids and rosin acids 9008-34-8 | n/a | as additive SML=0.6 mg/kg (expressed as Mn) | as monomer, additive or other substance; SML=0.6 mg/kg (expressed as Mn) | as additive SML(T) = 0.6 mg/kg (as Mn) for sum of PM/REF 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440, 73120 |
| methyl ethyl ketone 78-93-3 | | as monomer or starting mat., as additive | as monomer, additive or other substance; SML= 5 mg/kg | as monomer; SML= 5 mg/kg |
| Methyl isobutyl ketone 108-10-1 | as defoaming agent | as additive SML= 5 mg/kg | as monomer, additive or other substance; SML= 5 mg/kg | n/a |
| n-octanoate cobalt 6700-85-2 | n/a | as additive SML=0.05 mg/kg (expressed as Co) | as monomer, additive or other substance SML(T)=0.05 mg/kg (as Co) | as additive SML(T)=0.05 mg/kg (as Co); sum PM/REF 44960, 68078, 69160, 82020, 89170 |
| Polytetrafluorethylene 9002-84-0 * | as (EU) No10/201: melting p > 320°C, melt viscosity at 380°C > 50 Pa.s. | n/a | n/a | n/a |
| Toluene 108-88-3 | n/a | n/a | as monomer, additive or other substance; SML=1.2 mg/kg | as additive SML = 1.2 mg/kg |
| 2,2,4-trimethylhexane-1,6-diisocyanate 16938-22-0 2,4,4-trimethylhexane-1,6-diisocyanate 15646-96-5 | as monomer or starting mat. (iso)cyanate groups: SML(T)= ND (DL=0.05 mg/kg) | as monomer or starting mat.; QM: 1 mg/kg in final product (expressed as NCO) | as monomer, additive or other substance QM=1 mg/kg in PT (expressed as NCO); SML=0.01 mg/kg (expressed as NCO) | as monomer: QM(T)=1 mg/kg in PT (as NCO) sum REF: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240, 25270 |
| Toluene diisocyanate 26471-62-5 | | as monomer or starting mat.; QM=1 mg/kg in final product (expressed as NCO) | as monomer, additive or other substance QM=1 mg/kg in PT (expressed as NCO); SML=0.01 mg/kg (expressed as NCO) | as monomer: QM(T)=1 mg/kg in PT (as NCO) sum REF: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240, 25270 |
| N-vinyl pyrrolidone 88-12-0 | as film-forming agent; as monomers | | as monomer, additive or other substance; SML=ND (DL=0.01 mg/kg) | as additive SML = ND (DL = 0.01 mg/kg) |
| Xylene 1330-20-7 | | as monomer or starting mat. | as monomer, additive or other substance SML=1.2 mg/kg | as monomer / additive SML=1.2 mg/kg |

*BfR LI/LII: as NL/EU 10/2011

Substances for which convergence exists in the nature but should be given attention in terms of improved mutual recognition are presented in **Error! Reference source not found.** The table

illustrates substances for which the convergence is only on the nature of the substance restricted but that the restrictions themselves present discrepancies across MSs.

Substances warranting attention whilst considered by three or more MSs.

| Substance/ CAS | Legislation | Restrictions/remarks |
|---|---------------------------------|---|
| 1,2-Benzisothiazol in-3-one 2634-33-5 | NL X 3g, 6g | SML = 30 mg/kg as preservative |
| | EL Dec. 446/98 | SML= 1.2 mg/kg as additive |
| | CoE PS coatings 2009 | SML = 0.05 mg/kg as monomer when used for the surface treatment of materials |
| | ES No. 847/2011 | SML=0.05 mg/kg as monomer, additive and other substance. (only for use in aqueous dispersions and polymer emulsions at concentrations that do not result in an antimicrobial effect of the polymer surface or food) |
| 2 and 3-tert-butylhydroxy anisole (BHA) 25013-16-5 635 | NL X 3j, 4d, 9b; 8b | as antioxidant; as additive; monomethyl-hydroquinone ether content of mixture max 0.05%; hydroquinone and derivatives: SML(T)=0.6 mg/kg (as hydroquinone) |
| | EL Dec. 446/98 | as additive SML=30 mg/kg. antioxidants in coatings, varnishes or covering mat. |
| | FR Arrêté 3/09/1959 | max 0.125 % weight content |
| di(2-ethylhexyl) phthalate 117-81-7 | FR Circ. 165/1954 | in the composition of coatings for containers |
| | FR Circ. 175/1959 | as plasticiser |
| | NL X 9d | as auxiliary agent |
| | EL Dec. 446/98 | as additive SML=3 mg/kg |
| [1,4-Cyclohexane dimethanol] 105-08-8 | NL X 7a | as monomer |
| | DE BfR XLI | as chain extender for polyurethanes for paper coatings, max. 25% |
| 1,2-ethanediol 107-21-1 | EL Dec. 446/98 | as monomer or starting mat., as additive; SML=30 mg/kg (with diethyleneglycol) |
| | DE BfR XLI | as starting materials for polyurethanes for paper coatings |
| | EL Dec. 446/98 | as monomer or starting mat., as additive; SML=12 mg/kg |
| Ethylene diamine 107-15-3 | NL X 7a | as monomer |
| | EL Dec. 446/98 | as monomer or starting mat., as additive; SML=12 mg/kg |
| Hexamethylen e tetramine 100-97-0 | NL X 3g, 6l, 7i | as preservative, as wet-strengthening agent, as auxiliary agent |
| | FR Circ. 159/1950 | as stabiliser |
| | EL Dec. 446/98 | as monomer or starting mat., as additive; SML=15 mg/kg (as formaldehyde) |
| Iron(II) diammonium bisulphate 10045-89-3 | NL X 3c, 6c | as reducing agent |
| | EL Dec. 446/98 | as additive |
| | CoE PS coatings 2009 | as additive |
| | ES No. 847/2011 | as monomer, additive or other substance; SML=48 mg/kg (expressed as iron) |
| n-octanoate lithium 16577-52-9 | ES No. 847/2011 | as monomer, additive or other substance |
| | ES No. 847/2011 | as monomer, additive or other substance, SML=0.6 mg/kg (expressed as Li) |
| | CoE PS coatings 2009 | as additive SML(T) = 0.05 mg/kg (as Li); SML(T)24886, 38000, 42400, 62020, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725 |
| n-octanoate manganese 6535-19-9 | EL Dec. 446/98 | as additive SML=0.6 mg/kg (expressed as Li) |
| | ES No. 847/2011 | as monomer, additive or other substance; SML(T)=0.6 mg/kg (expressed as Mn) |
| | CoE PS coatings 2009 | as additive SML(T) = 0.05 mg/kg (as Mn); SML(T) 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120 |
| Phthalic acid, dicyclohexyl ester 84-61-7 | EL Dec. 446/98 | as additive SML=0.6 mg/kg (expressed as Mn) |
| | NL X 3k, 5d, 7h | as plasticizer |
| | EL Dec. 446/98 | as additive SML=6 mg/kg |
| Polyethylenegl ycol 2,4,7,9-tetramethyl-5-decyn-4,7-diol ether 9014-85-1 | CoE PS coatings 2009 | as additive (1) |
| | NL X 11.2.2b | as emulsifier - SML = 0.05 |
| | CoE PS coatings 2009 | as additive |
| Polyvinylalcoh ol 9002-89-5 | ES No. 847/2011 | as monomer, additive or other substance |
| | NL X 3e, 4e, 6e; 4b, 5a, 7c, 9a | as protective colloid or thickening agent; as macromolecular substance, as antioxidant; viscosity of a 4% solution in water at 20°C not less than 5 mPa.s |
| | CoE PS coatings 2009 | as additive Weight average molecular weight should not be less than 2500 Da. |
| Sodium aluminate 1302-42-7 [or 11138-49-1 anhydrous] | CoE PS coatings 2009 | (1) As monomer |
| | NL X 6n | as other auxiliary substance |
| | CoE PS coatings 2009 | as additive ADI/TDI=1 (as Al) mg/kg bw |
| | EL Dec. 446/98 | as additive |
| Tin chloride ^(IV) 7646-78-8 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive |
| Triethanolami ne 102-71-6 | NL X 3m | as auxiliary agent |
| | ES No.847/2011 | as monomer, additive, other substance; SML=0.05mg/kg incl. hydrochloric adduct |
| | CoE PS coatings 2009 | As monomer (1) |
| Urea 57-13-6 | NL X 6i | as liquefying agent |
| | FR Circ. 175/1959 | as stabiliser |
| | EL Dec. 446/98 | as monomer or starting mat. |
| | SK 1799/2003 | as viscosity adjuster - an aggregate quantity of not more than 0.1% |
| Zinc powder [or zinc dust, or zinc] 7440-66-6 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive SML(T) = 25 mg/kg (as Zn); SML(T) 81515, 96190, 96240 and 96230 and of salts (including double and acid salts) of Zn of authorised acids, phenols or alcohols. The same restriction for Zn applies to the names containing —...acid(s), salts which appear in the lists, if corresponding |

| Substance/ CAS | Legislation | Restrictions/remarks |
|---------------------------------------|----------------------|---|
| Zinc hydroxyl phosphite 55799-16-1 | | free acid(s) is/are) not mentioned |
| | NL X 6j | as filler |
| | EL Dec. 446/98 | as additive |
| | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive SML(T) = 25 mg/kg (as Zn); SML(T) 81515, 96190, 96240 and 96230 and of salts (and same note as for Zinc powder) |
| | EL Dec. 446/98 | as additive |

Overall substances in common for 3 or more MSs

List: Colour coding: blue: qualitative restrictions; light orange: restriction but low fit between limits, dark orange: common restrictions and better fit.

| Substance and CAS | Legislation | Restrictions/remarks |
|--|---|---|
| 1,2-Benzisothiazolin-3-one 2634-33-5 | NL X 3g, 6g | SML = 30 mg/kg as preservative |
| | EL Dec. 446/98 | SML= 1.2 mg/kg as additive |
| | CoE PS coatings 2009 | SML = 0.05 mg/kg as monomer when used for the surface treatment of materials |
| | ES No. 847/2011 | SML=0.05 mg/kg as monomer, additive and other substance. (only for use in aqueous dispersions and polymer emulsions at concentrations that do not result in an antimicrobial effect of the polymer surface or food) |
| Acetic acid 64-19-7 | DE BfR LII | as neutralising agent, permitted as an additive in compliance with Reg. (EU) No 10/2011 |
| | EL Dec. 446/98 | as monomer/starting material, as additive |
| | NL X 3i | as film-forming agent |
| Ammonium chloride 12125-02-9 | DE BfR LII | as, antistatic finish, permitted as an additive in compliance with Regulation (EU) No 10/2011. The total amount used, based on solids content of the processing aids, must not exceed 20 % |
| | EL Dec. 446/98, CoE PS coatings 2009 | as additive |
| | ES No. 847/2011 | as monomer, additive and other substance |
| | NL X 6n | as auxiliary agent |
| Bees wax 8012-89-3 | FR Circ. 162/1952 | |
| | DE BfR XLVIII | as basic substance for outside of hollow glassware |
| | EL Dec. 446/98 | as additive |
| 2 and 3-tert-butylhydroxy anisole (BHA) 25013-16-5 | NL X 3j, 4d, 9b; 8b | as antioxidant; as additive; monomethyl-hydroquinone ether content of the mixture max 0.05%; hydroquinone and derivatives: SML(T) = 0.6 mg/kg (as hydroquinone) |
| | EL Dec. 446/98 | as additive SML=30 mg/kg. antioxidants is authorised in coatings, varnishes or covering materials |
| | FR Arrêté 3/09/1959 | max 0.125 % weight content |
| carnauba wax 8015-86-9 | FR Circ. 162/1952 | -- |
| | DE BfR XLVIII | as basic substance for outside of hollow glassware |
| | EL Dec. 446/98 | as additive |
| Castor oil 8001-79-4 | NL X 8b | as auxiliary agent of food quality |
| | FR Circ. 159/1950 | as plasticiser |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| Castor oil fatty acids 61789-44-4 | EL Dec. 446/98 | as monomer or starting mat. |
| | ES No. 847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| | ES No. 847/2011 | as monomer, additive or other substance |
| castor oil, fatty acids hydrogenated (61789-45-5, 8001-78-3) | EL Dec. 446/98 | as additive |
| | CoE PS coatings 2009 | as monomer |
| | DE BfR LII | Permitted as an additive in compliance with Reg. (EU) No 10/2011 |
| Cellulose 9004-34-6 | EL Dec. 446/98 | as monomer or starting mat., as additive |
| | NL X 3e, 4e | as protective colloid or thickening agent |
| | HR 125/2009 Art. 81, par.a | as starting substance |
| Cellulose acetate 9004-35-7 | ES No. 847/2011 | as monomer, additive or other substance |
| | EL Dec. 446/98 | as monomer or starting mat. |
| | CoE PS coatings 2009 | -- |
| Cellulose acetate-butylate 9004-36-8 | NL X 7c, 9a | as macromolecular compound, as antioxidant |
| | ES No. 847/2011 | as monomer, additive or other substance |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| Cellulose acetate-propionate 9004-39-1 | NL X 7c, 9a | as macromolecular compound, as antioxidant |
| | ES No. 847/2011 | as monomer, additive or other substance |
| | EL Dec. 446/98 | as monomer or starting mat. |
| | CoE PS coatings 2009 | as monomer |
| Chlorobenzene 108-90-7 | NL X 11.2.1.2f | as other auxiliary substance in polysulphones - use EP to max 140 °C |
| | EL Dec. 446/98 | as additive SML=36 mg/kg |
| | ES No. 847/2011 | as monomer, additive and other substance - SML=36 mg/kg |
| Citric acid | DE BfR LII | as neutralising agent, permitted as an additive in compliance with Reg. (EU) No 10/2011 |

| Substance and CAS | Legislation | Restrictions/remarks |
|---|-------------------------------|---|
| 77-92-9 | NL X 3j, 3m | as antioxidant; as auxiliary agent |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| Coconut oil 8001-31-8 | ES No. 847/2011 | as monomer, additive and other substance |
| | EL Dec. 446/98 | as monomer or starting mat. |
| | CoE PS coatings 2009 | as monomer |
| Coconut oil fatty acids, hydrogenated 68938-15-8 | ES No. 847/2011 | as monomer, additive and other substance |
| | EL Dec. 446/98 | as monomer or starting mat. |
| | CoE PS coatings 2009 | as monomer |
| Cottonseed oil 8001-29-4 | ES No. 847/2011 | as monomer, additive and other substance |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| | CoE PS coatings 2009 | as monomer |
| Cottonseed oil fatty acids No CAS | ES No. 847/2011 | as monomer, additive and other substance |
| | EL Dec. 446/98 | as monomer or starting mat. |
| | CoE PS coatings 2009 | as monomer |
| Dextrin 9004-53-9 | CoE PS coatings 2009 | as additive. In compliance with the FCC specifications |
| | NL X 3e, 4e, 6e | as protective colloid or thickening agent |
| | EL Dec. 446/98 | as additive |
| di(2-ethylhexyl) phthalate 117-81-7 | FR Circ. 165/1954 | in the composition of coatings for containers |
| | FR Circ. 175/1959 | as plasticiser |
| | NL X 9d | as auxiliary agent |
| | EL Dec. 446/98 | as additive SML=3 mg/kg |
| Diethyleneglycol monobutyl ether 111-76-2 112-34-5 | ES No. 847/2011 | as monomer, additive and other substance SML=3 mg/kg (group of 15780/16993/16996/17002/48030/48050/53765) |
| | CoE PS coatings 2009 | as additive SML = 3 mg/kg ADI/TDI=0.5 mg/kg bw |
| | EL Dec. 446/98 | as additive SML=3 mg/kg (for all ethyleneglycol and diethyleneglycol ethers) |
| 1,4-di (hydroxymethyl) cyclohexane [1,4-Cyclohexane dimethanol] 105-08-8 | NL X 7a | as monomer |
| | DE BfR XLI | as chain extender for polyurethanes for paper coatings max. 25% (as chain extender) |
| | EL Dec. 446/98 | as monomer or starting mat. |
| Dimethylamine 124-40-3 | NL X 3c, 4c, 6c | as reducing agent |
| | EL Dec. 446/98 | as monomer or starting mat., as additive SML=0.06 mg/kg |
| | ES No. 847/2011 | as monomer, additive and other substance SML=0.06 mg/kg |
| 1,2-ethanediol [ethyleneglycol] 107-21-1 | NL X 6h | as softener |
| | EL Dec. 446/98 | as monomer or starting mat., as additive SML=30 mg/kg (together with diethyleneglycol) |
| | DE BfR XLI | as starting materials for polyurethanes for paper coatings |
| Ethyleneglycol, monoethyl ether 110-80-5 | ES No. 847/2011 | as monomer, additive or other substance SML=3 mg/kg (group of 15780/ 16993/16996/17002/48030/48050/53765) |
| | EL Dec. 446/98 | as monomer or starting mat., as additive 3 mg/kg (together with all ethers of ethyleneglycol and diethyleneglycol) |
| | CoE PS coatings 2009 | as monomer and additive SML = 3 mg/kg |
| Ethyleneglycol, monobutyl ether 111-76-2 | ES No. 847/2011 | as monomer, additive or other substance SML=3 mg/kg (group of 15780/ 16993/16996/17002/48030/48050/53765) |
| | EL Dec. 446/98 | as monomer or starting mat., as additive 3 mg/kg (together with all ethers of ethyleneglycol and diethyleneglycol) |
| | CoE PS coatings 2009 | as monomer SML = 3 mg/kg |
| Ethyl cellulose 9004-57-3 | HR 125/2009 Art. 81, par.a | as starting substance |
| | DE BfR LI | as processing aid |
| | ES No. 847/2011 | as monomer, additive or other substance |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| Ethylene diamine 107-15-3 | NL X 8a | as starting substance max. 50% of coating (starting substance) |
| | DE BfR LI | as processing aid |
| | EL Dec. 446/98 | as monomer or starting mat., as additive; SML=12 mg/kg |
| Formic acid 64-18-6 | NL X 7a | as monomer |
| | DE BfR LII | as neutralising agent, permitted as an additive in compliance with Reg. (EU) No 10/2011 |
| | EL Dec. 446/98 | as monomer or starting mat., as additive SML=15 mg/kg |
| | ES No. 847/2011 | as monomer, additive or other substance |

| Substance and CAS | Legislation | Restrictions/remarks |
|---|---|--|
| Glycerol monostearate 31566-31-1 | ES No.847/2011 | as monomer, additive or other substance |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| | CoE PS coatings 2009 | as monomer and additive |
| | NL X 6a | as monomer or starting mat. |
| Glycerol monooleate 25496-72-4 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive |
| Glycerol triacetate 102-76-1 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive |
| Hexamethylene tetramine 100-97-0 | NL X 3g, 6l, 7i | as preservative, as wet-strengthening agent, as auxiliary agent |
| | FR Circ. 159/1950 | as stabiliser |
| | EL Dec. 446/98 | as monomer or starting mat., as additive SML=15 mg/kg (expressed as formaldehyde) |
| Hydrochloric acid 7647-01-0 | DE BfR LII | as neutralising agent, permitted as an additive in compliance with Reg. (EU) No 10/2011 |
| | NL X 3m, 6n | as auxiliary agent |
| | EL Dec. 446/98 | as additive |
| Iron(III) diammonium bisulphate 10045-89-3 | NL X 3c, 6c | as reducing agent |
| | EL Dec. 446/98 | as additive |
| | CoE PS coatings 2009 | as additive |
| | ES No. 847/2011 | as monomer, additive or other substance SML=48 mg/kg (expressed as iron) |
| Lanolin 8006-54-0 | ES No. 847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive |
| Lecithin, soybean 8002-43-5 | NL X, 3f 11.2.2b | as emulsifier |
| | EL Dec. 446/98 | as additive |
| | DE BfR LI | as emulsifying agent |
| Lithium hydroxide 1310-65-2 | ES No. 847/2011 | as monomer, additive or other substance SML=0.6 mg/kg (expressed as lithium together with all lithium compounds) |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive, SML=0.6 mg/kg (expressed as lithium) |
| Lithopone 1345-05-7 | NL X 6j, 7g | as filler |
| | EL Dec. 446/98 | as additive |
| | CoE PS coatings 2009 | as additive |
| | ES No. 847/2011 | as monomer, additive or other substance - Free of water soluble barium |
| Maize (corn) oil 8001-30-7 | ES No.847/2011 | as monomer, additive and other substance |
| | EL Dec. 446/98 | as monomer or starting mat. |
| | CoE PS coatings 2009 | as monomer |
| Maize (corn) oil fatty acid | ES No. 847/2011 | as monomer, additive and other substance |
| | CoE PS coatings 2009 | as monomer |
| | EL Dec. 446/98 | as monomer or starting mat. |
| Manganese salts of resin acids and rosin acids 9008-34-8 | ES No. 847/2011 | as monomer, additive or other substance SML=0.6 mg/kg (expressed as manganese together with all Mn compounds) |
| | CoE PS coatings 2009 | as additive SML(T) = 0.6 mg/kg (as Mn) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF N°: 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120 ADI/TDI= 0.01 (as Mn) mg/kg bw |
| | EL Dec. 446/98 | as additive SML=0.6 mg/kg (expressed as manganese) |
| methyl ethyl ketone 78-93-3 | ES No.847/2011 | as monomer, additive or other substance SML= 5 mg/kg |
| | CoE PS coatings 2009 | as monomer SML= 5 mg/kg |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| Methyl isobutyl ketone 108-10-1 | NL X 4f, 6f | as defoaming agent |
| | EL Dec. 446/98 | as additive SML= 5 mg/kg |
| | ES No. 847/2011 | as monomer, additive or other substance SML= 5 mg/kg |
| Montane wax, consisting of: montanic acids C26-C32; esters with ethylene glycol and/or 1,3- | NL X 3m, 4a; 6h; 7c, 8a, 9a; 5e, 7f, 9c; 3l | as paraffin or wax, plasticizer, macromolecular or starting substance, as lubricant or releasing agent, as antioxidant product meets the purity requirements specified in Part B (Methods of Test); |
| | FR Circ. 175/1959 | as plasticiser - maximum of 3 % |
| | EL Dec. 446/98 | as additive |

| Substance and CAS | Legislation | Restrictions/remarks |
|--|-------------------------------------|--|
| butylene glycol and/or calcium salts 8002-53-7 | | |
| Nitric acid 7697-37-2 | NL X 3m | as auxiliary agent |
| | EL Dec. 446/98 | as additive |
| | CoE PS coatings 2009 | as additive |
| | ES No. 847/2011 | as monomer, additive or other substance |
| n-octanoate cobalt 6700-85-2 | ES No. 847/2011 | as monomer, additive or other substance SML=0.05 mg/kg (expressed as cobalt together with all cobalt compounds) |
| | CoE PS coatings 2009 | as additive SML(T) = 0.05 mg/kg (as Co) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF N°: 44960, 68078, 69160, 82020 and 89170 |
| | EL Dec. 446/98 | as additive SML=0.05 mg/kg (expressed as cobalt) |
| n-octanoate lithium 16577-52-9 | ES No. 847/2011 | as monomer, additive or other substance SML=0.6 mg/kg (expressed as lithium together with all lithium compounds) |
| | CoE PS coatings 2009 | as additive SML(T) = 0.05 mg/kg (as Co) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF N°: 24886, 38000, 42400, 62020, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725 |
| | EL Dec. 446/98 | as additive SML=0.6 mg/kg (expressed as lithium) |
| n-octanoate manganese 6535-19-9 | ES No. 847/2011 | as monomer, additive or other substance SML=0.6 mg/kg (expressed as manganese together with all manganese compounds) |
| | CoE PS coatings 2009 | as additive SML(T) = 0.05 mg/kg (as Co) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF N°: 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120 |
| | EL Dec. 446/98 | as additive SML=0.6 mg/kg (expressed as manganese) |
| Paraffin oil 8012-95-1 | FR Circ.159/1950 | as plasticiser |
| | NL X 3l, 4a, 4c, 5e, 7c, 7f, 8a, 9a | as dispersion, flotation or defoaming agent, as starting, macromolecular or other auxiliary substance or as paraffin, wax or lubricant, as antioxidant specifications: colour < Standard Saybolt 30; virtually no odour; UV extinction of hexane extract <0,10/cm at 260-350 nm |
| | CoE PS coatings 2009 | as additive (1) |
| Phosphoric acid 7664-38-2 | DE BfR LII | as neutralising agent, permitted as an additive in compliance with Reg. (EU) No 10/2011 |
| | FR Circ. 2 /04/1969 | |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| Phthalic acid, dicyclohexyl ester 84-61-7 | NL X 3m | as auxiliary agent |
| | NL X 3k, 5d, 7h | as plasticizer |
| | EL Dec. 446/98 | as additive SML=6 mg/kg |
| Poppy(seed) oil 8002-11-7 | CoE PS coatings 2009 | as additive (1) |
| | ES No.847/2011 | as monomer, additive or other substance |
| | EL Dec. 446/98 | as monomer or starting mat. |
| Polyethyleneglycol 2,4,7,9-tetramethyl-5-decyn-4,7-diol ether 9014-85-1 | NL X 11.2.2b | as emulsifier - SML = 0.05 |
| | CoE PS coatings 2009 | as additive |
| | ES No. 847/2011 | as monomer, additive or other substance |
| Polytetrafluoroethylene 9002-84-0 | NL X 11.2.1.1a | According to (EU) No10/201; polymer meets the following specification: melting point at least 320°C, melt viscosity at 380°C at least 50 Pa.s. |
| | DE BfR LII | melting viscosity at 380 °C is more than 50 Pa.s |
| | DE BfR LI | melting viscosity at 380 °C is more than 50 Pa.s and melting point higher than 320°C |
| Polyvinylalcohol 9002-89-5 | NL X 3e, 4e, 6e; 4b, 5a, 7c, 9a | as protective colloid or thickening agent; as macromolecular substance, as antioxidant viscosity of a 4% solution in water at 20°C not less than 5 mPa.s |
| | CoE PS coatings 2009 | as additive Weight average molecular weight should not be less than 2500 Da. |
| | CoE PS coatings 2009 | (1) As monomer |
| 1,2-propanediol [propylene glycol] 57-55-6 | DE BfR XLI | as starting materials for polyurethanes for paper coatings |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| | FR Circ. 159/1950 | as plasticiser |
| Wheat Protein | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive |
| Pumpkin seed oil 8016-49-7 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| | EL Dec. 446/98 | as monomer or starting mat. |

| Substance and CAS | Legislation | Restrictions/remarks |
|--|--|--|
| Rapeseed oil, refined 8002-13-9 | NL X 4c | as dispersion, flotation or defoaming agent |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive |
| | ES No.847/2011 | as monomer, additive or other substance |
| Resins, natural: shellac 9000-59-3 | NL X 7c, 9a | as macromolecular substance, as antioxidant |
| | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer and additive |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| | HR 125/2009 Art. 81 par.a; Art.83, par.a | as starting substances, as binders |
| DE BfR XLVIII | as basic substance for outside of hollow glassware | |
| Saccharose [or sucrose] 57-50-1 | NL X 3c, 4c | as reduction agent |
| | ES No.847/2011 | as monomer or starting mat., as additive |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| Safflower oil 8001-23-8 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| | EL Dec. 446/98 | as monomer or starting mat. |
| Sesame oil 8008-74-0 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| | EL Dec. 446/98 | as monomer or starting mat. |
| Sodium aluminate 1302-42-7 [or 11138-49-1 anhydrous] | NL X 6n | as other auxiliary substance |
| | CoE PS coatings 2009 | as additive ADI/TDI=1 (as Al) mg/kg bw |
| | EL Dec. 446/98 | as additive |
| | ES No.847/2011 | as monomer, additive or other substance |
| Stannous / (Tin) chloride (IV) 7646-78-8 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive |
| Starches | NL X 3e, 4e, 6e, 8a | as starting substance, as protective colloid or thickening agent According to requirements, specified in Chapter 10 (Coatings) of the Dutch FCM regulations; max 50% in surface coating; max 1 mg/kg in EP (epichlorohydrin); SML = 1 (as boron); formaldehyde, glyoxal and hexamethylenetetramine: in total SML = 15 mg/kg (as formaldehyde) |
| | EL Dec. 446/98 | as additive |
| | SK 1799/2003 | as binder |
| Stearic acid 57-11-4 | DE XLVIII | as additive for outside of hollow glassware |
| | FR Circ. 2/04/1969 | |
| | EL Dec. 446/98 | as monomer or starting mat., as additive |
| Sunflower oil 8001-21-6 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| | EL Dec. 446/98 | as monomer, additive or other substance |
| Sunflower oil fatty acids | ES No.847/2011 | as monomer, additive or other substance |
| | EL Dec. 446/98 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| Tall/ pine resin oil 8002-26-4 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| | EL Dec. 446/98 | as monomer, additive or other substance |
| Tall oil fatty acids cobalt salts | ES No.847/2011 | as monomer, additive or other substance SML=0.05 mg/kg (expressed as cobalt together with all cobalt compounds) |
| | CoE PS coatings 2009 | as additive SML(T) = 0.05 mg/kg (as Co) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF N°: 44960, 68078, 69160, 82020 and 89170 |
| | EL Dec. 446/98 | as additive SML=0.05 mg/kg (expressed as cobalt) |
| Tallow 61789-97-7 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive |
| | EL Dec. 446/98 | as additive |
| Tartaric acid 526-83-0 | DE BfR LII | as neutralising agent, permitted as an additive in compliance with Reg. (EU) No 10/2011 |
| | NL X 3m | as auxiliary agent |
| | EL Dec. 446/98 | as additive |
| Toluene 108-88-3 | ES No.847/2011 | as monomer, additive or other substance SML=1.2 mg/kg |
| | CoE PS coatings 2009 | as additive SML = 1.2 mg/kg |
| | EL Dec. 446/98 | as monomer or starting mat., as additive SML=1.2 mg/kg |
| Toluene | NL X 6a | as monomer or starting mat. (iso)cyanate groups: SML(T) = ND (DL = 0.05 mg/kg) |

| Substance and CAS | Legislation | Restrictions/remarks |
|--|-------------------------|---|
| diisocyanate 26471-62-5 | CoE PS coatings 2009 | as monomer QM(T)=1 mg/kg in PT (as NCO) The restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as PM/REF N°: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270 |
| | EL Dec. 446/98 | as monomer or starting mat. 1 mg/kg in final product (expressed as NCO) |
| | ES No.847/2011 | as monomer, additive or other substance QM=1 mg/kg in PT (expressed as NCO); SML=0.01 mg/kg (expressed as NCO) |
| Triethanolamine 102-71-6 | NL X 3m | as auxiliary agent |
| | ES No.847/2011 | as monomer, additive or other substance SML=0.05 mg/kg (including hydrochloric adduct) |
| | CoE PS coatings 2009 | As monomer (1) |
| Triethylamine 121-44-8 | NL X 3m, 11.2.2g, 3l | as other auxiliary substance |
| | DE BfR LI | as processing aid |
| | CoE PS coatings 2009 | as additive (1) |
| Triethylene glycol 112-27-6 | NL X 7i | as auxiliary agent |
| | FR Circ. 159/1950 | as plasticiser |
| | EL Dec. 446/98 | as monomer or starting mat. |
| 2,2,4- trimethylhexane- 1,6-diisocyanate 16938-22-0 | ES No.847/2011 | as monomer, additive or other substance QM=1 mg/kg in PT (expressed as NCO); SML=0.01 mg/kg (expressed as NCO) |
| | CoE PS coatings 2009 | as monomer QM(T)=1 mg/kg in PT (as NCO) The restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as PM/REF N°: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270 |
| | EL Dec. 446/98 | as monomer or starting mat. 1 mg/kg in final product (expressed as NCO) |
| 2,4,4- trimethylhexane- 1,6-diisocyanate 15646-96-5 | ES No.847/2011 | as monomer, additive or other substance QM=1 mg/kg in PT (expressed as NCO); SML=0.01 mg/kg (expressed as NCO) |
| | CoE PS coatings 2009 | as monomer QM(T)=1 mg/kg in PT (as NCO) The restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as PM/REF N°: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270 |
| | EL Dec. 446/98 | as monomer or starting mat. 1 mg/kg in final product (expressed as NCO) |
| Urea 57-13-6 | NL X 6i | as liquefying agent |
| | FR Circ. 175/1959 | as stabiliser |
| | EL Dec. 446/98 | as monomer or starting mat. |
| | SK 1799/2003 | as viscosity adjuster - an aggregate quantity of not more than 0.1% |
| N-vinyl pyrrolidone 88-12-0 | NL X 3i, 6a | as film-forming agent; as monomers |
| | CoE PS coatings 09 | as additive SML = ND (DL = 0.01 mg/kg) |
| | ES No.847/2011 | as monomer, additive or other substance SML=non detectable (DL=0.01 mg/kg) |
| Walnut oil 8024-09-7 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| | EL Dec. 446/98 | as monomer or starting mat. |
| Walnut oil fatty acids | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as monomer |
| | EL Dec. 446/98 | as monomer or starting mat. |
| Xylene 1330-20-7 | ES No.847/2011 | as monomer, additive or other substance SML=1.2 mg/kg |
| | CoE PS coatings 2009 | as monomer and additive SML=1.2 mg/kg ADI/TDI=0,02 mg/kg bw |
| | EL Dec. 446/98 | as monomer or starting mat. |
| Zinc powder [or zinc dust, or zinc] 7440-66-6 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive SML(T) = 25 mg/kg (as Zn) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF N°: 81515, 96190, 96240 and 96230 as well as of salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. The same restriction for Zn applies to the names containing —...acid(s), salts which appear in the lists, if the corresponding free acid(s) is (are) not mentioned |
| | NL X 6j | as filler |
| | EL Dec. 446/98 | as additive |
| Zinc hydroxyphosphite 55799-16-1 | ES No.847/2011 | as monomer, additive or other substance |
| | CoE PS coatings 2009 | as additive SML(T) = 25 mg/kg (as Zn) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as PM/REF N°: 81515, 96190, 96240 and 96230 as well as of salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. The same restriction for Zn applies to the names containing —...acid(s), salts which appear in the lists, if the corresponding free acid(s) is (are) not mentioned |
| | EL Dec. 446/98 | as additive |

Annex 11. Frameworks or other documents for waxes

A tabulation of the measures or instructions at national level is described below.

| MS | Measure | Field of application Positive lists / negative lists | Restrictions Residual/QM/OM/SML |
|----|---|--|---|
| DE | BfR Rec. XXV | <ul style="list-style-type: none"> - reports a list of substances that can be used in the preparation of microcrystalline waxes ("micro waxes"), paraffins and beeswaxes used in the manufacture of cheese coatings not meant to be eaten - regulates hard paraffins, microcrystalline waxes and mixtures of these with waxes, resins and plastics | <ul style="list-style-type: none"> - reports the maximum amounts of substances that can be used in the production of microcrystalline waxes and for paraffins and beeswaxes - includes physicochemical parameters (e.g. solidification temperature, kinematic viscosity, alkaline / acidic impurities) - limits contents of 3,4-benzopyrene, antioxidants (BHA, BHT), and tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinamate)]methane |
| ES | Real Decreto (R.D) 847/2011 | establishes a list of substances that can be used in the preparation of polymeric materials and articles (having waxes under its scope for polymeric waxes,) | <ul style="list-style-type: none"> - OMLs + SMLs (Art. 7, 8, Anexo I) - information on the verification of compliance limits (Art. 9) - Restrictions apply in particular to synthetic, hydrocarbon, paraffin, microcrystalline, and spermaceti wax (provisional list). Their use is limited to migration <ND (0.01 mg/kg) - sanctions based on the Real Decreto 1945/1983 (Art. 12) |
| FR | Avis BOCCRF n° 17 du 15/09/98 | - It authorises a substance to be used as fungicide in waxes | - it fixes the maximum content of a substance used as fungicide in varnishes and waxes |
| NL | Commodities Act | -positive list for wax, intended as dispersions in water of paraffins and waxes, and materials based on waxes or macromolecular substances. (Chapter 0, 0.3; Chapter X, 2, 4, 8) | - includes limits for the substances that can be used in the preparation of waxes. (Chapter X, 2, 4, 8) |
| CH | Ordinanza 817.023.21, as of 01 April 2013 | <ul style="list-style-type: none"> - paraffins and waxes for direct packaging must not contain carcinogenic substances (section 8, art. 25) - List includes Beeswax, Candellila, Japan, Carnauba, Montan, polyethylene, polypropylene waxes | <ul style="list-style-type: none"> - paraffins and waxes for direct food packaging must comply with requirements set in the Pharmacopoeia Helvetica - waxes that are paraffinic, refined, derived from petroleum or synthetic hydrocarbon feedstocks are restricted to 0.05 mg/kg and not to be used for FCMs with fatty foods |

Annex 12. Frameworks or other documents for ceramics

National restrictions for heavy metals (beyond Dir. 84/500/EEC amended by Dir. 2005/31/EC, and limits for rim can be found below.

Overview for national sources on ceramics

| MS | Legislation | Restrictions: Residual/QM/OM/SML Other requirements | Test conditions |
|----|---|--|--|
| AT | BGBI 893-1993 | - limits according to EU legislation on ceramics, - adds limits for Zinc (Zn) 3mg/L, Antimony (Sb) 1mg/L, and Barium (Ba) 1mg/L (Anlage 1) - requires FCM operators to provide a DoC, not only with respect to release of Pb and Cd as requested in EU legislation but also with respect to release of Zn, Sb and Ba (§3(1)) | n/a |
| HR | NN125-2009 | - implements the EU legislation - adds the contribution of the rim to the calculation of migration (Članak 28, 30) | uses standards for - ceramics ware, glass-ceramic ware and glass dinnerware (EN 1388-1/2 and ISO 6486-1/2) - cookware (ISO 8391-1/2) - glass hollowware (ISO 7086-1 /2) |
| CZ | Vyhláška č. 38/2001 | - limits of Pb and Cd based on EU provisions - adding also rim test (Příloha 9, Oddíl 1) - information on how to prepare a DoC for the release of Pb and Cd from the body and from the rim (Příloha 9, Oddíl 3) | provides information on how to assess migration of Pb and Cd (Příloha 9, Oddíl 2) |
| DK | BEK nr 822 of 26/06/2013 | - release limits on Pb and Cd, based on 84/500/EEC - adding limits also for rim (Kapitel 4, §16, Bilag 4) | n/a |
| FI | Decision 268/92 | gives limit values for Pb, Cd, Cr and Nickel (Ni) for all materials with the exception of Pb and Cd release from ceramics (i.e. limits for Cr and Ni for ceramics) | n/a |
| DE | ASU nach §64 LFGB, BVLB80.03-4:2008-10 DIN51032:1986-02 | sets limits for the release of Pb (max. 2.0 mg/article) and Cd (max. 0.20 mg/article) from the rim (20 mm) | - states that the rim test described for glassware can be used for ceramics - copy of EN 1388-2:1995 - test conditions in DIN 51031, replaced by DIN EN 1388-1 and -2 |
| NL | Commodities Act (Packagings and Consumer Articles) | - OML (Chapter VI, 2.3) - SMLs for additional metals beyond Pb and Cd, such as Arsenic (As), Barium (Ba), Boron (B), Chromium (Cr), Cobalt (Co), Mercury (Hg), Lithium (Li), Rubidium (Rb), Selenium (Se) and Strontium (Sr) (Chapter 0, Chapter 0, 0.3; Chapter VI, 2.3) | describes the methods for the determination of specific migration (Annex B, Chapter I, 4.1.1.2 (1),(3)) |
| NO | Regulation 1381-1993 | - provides limits of migration for Pb, Cd and Ba (Kapittel VI, Vedlegg III) - requirement for DoC and includes the type of information that it has to contain (§ 25a) | n/a |
| PL | PN-B-13210:1997 | - gives limits of Pb and Cd - also from the rim area from ceramic ware | n/a |

Standards

Standards at CEN and ISO are illustrated below.

| source | standard name | Standard title and contents |
|---------|---------------------|---|
| CEN | EN 1388:1995 | Part 1: Determination of the release of Pb and Cd from ceramic ware Part 2: Determination of the release of Pb and Cd from silicate surfaces other than ceramic ware |
| CEN | CEN/TS 12983-2:2005 | Part 2: Further general and specific requirements for ceramic, glass and glass ceramic cookware |
| ISO | EN ISO 4531:1998 | Vitreous and porcelain enamels: Release of Pb and Cd from enamelled ware in contact with food: Part 1: Method of test Part 2: Permissible limits |
| ISO | EN ISO 6486:1999 | Ceramic ware, glass ceramic ware and glass dinnerware in contact with food: Release of Pb and Cd Part 1: Test method Part 2: Permissible limits |
| ISO | EN ISO 7086:2005 | Glass hollowware in contact with food : Release of Pb and Cd Part 1: Test method Part 2: Permissible limits |
| ISO | ISO 8391:1986 | Ceramic cookware in contact with food : Release of Pb and Cd Part 1: Method of test limits Part 2: Permissible limits |
| CEN/ISO | EN ISO 8442:19997 | Cutlery and table and decorative metal hollow-ware Part 1: Requirements for cutlery for the preparation of food Part 2: Requirements for stainless steel and silver-plated cutlery Part 3: Requirements for silver-plated table and decorative hollowware Part 4: Requirements for gold-plated cutlery Part 5: Specification for sharpness and edge retention test of cutlery Part 6: Lightly silver plated table hollowware protected by lacquer Part 7: Specification for table cutlery made of silver, precious metals and their alloys Part 8: Specification for silver table and decorative hollowware |

Non EU frameworks

The United States of America uses the Federal Food, Drug, and Cosmetic Act, FDA compliance Policy Guide section 545.400 (CPG 7117,06) 1995 – Cadmium and 545.450 (CPG 7117,07) 1995 – lead. It implements the act using the AOAC²¹² test method section 973.32 or ASTM²¹³ C 738-94 (2011). The lip rim is also tested with limits for lead (4 mg/kg) and cadmium (0.4 mg/kg) according to the standard ASTM C927-80 (2009). In addition, the Consumer Product Safety Commission (CPSC) has established a Consumer Product Safety Improvement Act of 2008 (CPSIA) which introduces a requirement for children's products made from ceramic, crystal and other siliceous materials. Any product designed or intended primarily for children 12 years of age or younger was banned if it contained more than 600 mg/kg total lead content by weight, reduced to a limit of 300 mg/kg in 2009, and further reduced to 100 mg/kg in 2011. The document HR 2715 reformed CPSIA (August 2011, effective February 2013) stipulates that products manufactured after this date must have a periodic testing plan at a CPSC accredited, independent 3rd party laboratory for conformity certification. Retesting is required when a material change occurs. For children's products, a CPSIA Test Method is required²¹⁴. Products may be voluntarily labelled to show that the product complies with the conformity certification requirements, "Meets CPSC Safety Requirements." Tracking labels have been required for children's products manufactured after August 2009.

Canada applies the Canada Consumer Product Safety Act of 2011 as well as the glazed ceramics and glassware regulation of 1998 (SOR/98-176). It implements it using ISO 6486-1:1999 and ASTM C927-80 (test, reapproved in 2014).

Australia uses the Customs Act 1901 and Regulation 1956 as amended, Regulation 4E and for testing schedule 7 BS 4860 (articles of glazed ceramic ware) and AS4371:2012 (ceramic tableware). For Mercosur, the GMC/Res No55/1992 regulates ceramics, glass packages and glass equipment in contact with foods for lead and cadmium. It is also used by Argentina and Brazil. Colombia applies the Resolution No 190 21/7/08 together with standard NTC 3536:93 (limits and test, corresponding to ISO 7086-1 and ISO 7086-2), NTC 4634:1999 (test, corresponding to ISO 6468-1) and NTC 916:1999 (limits). Ecuador uses its resolution No 077-2008 21/8/2008 and implements it using NTE INENE 1 802:2006 (test) and 802:2006 (limits). India uses its Prevention and Food Adulteration Act of 1954 and rules as well as a standard 9806:2001 for tests and limits. Indonesia uses a Food Act 1996 and SNI 13-6697-2002 (fine pottery tableware) and 7275:2008 (ceramics). Israel uses its SI 1003:199 and amendment 1:2011 for tableware, ornamental ware and cooking /bakeware. Japan uses its specifications, standards and testing methods for foodstuffs implements containers and packaging toys detergents 2008 (2009) and announcement No 370 ministry of health and welfare of 21/07/2008 (revision). In China, the Food Safety Law 2009, Art. 99 is applied together with the standards GB/T 3534:2002 (test) and GB 12651:2003 (limits) for ceramic articles (daily-use decoration products, special use decoration products, ceramic ware, glass ceramics ware and glass dinnerware). For ceramic containers, the standards GB/T 5009.62:2003 (test) and GB 13121:1991 (limits) are applied, whereas for ceramic packaging vessels the GB 14147:1993 is applied and the GB 8058:2003 (test and limits) is applied for cookware. Additional standards exist for specialty regional products (e.g. Guangdong on-glaze decoration porcelain, zisha ware, celadon porcelain). For the Customs Union of RUSSIA Belarus and Kazakhstan, the Uniform Sanitary and Epidemiological and Hygienic Requirements for goods is applied subject to sanitary and Epidemiological Supervision (control) Chapter II section 16. Countries applying the EU principles (limits) from Directives 84/500/EEC and 2005/31/EEC include for example Armenia, Bosnia-Herzegovina, Ethiopia, and implement these using ISO standards 6486, 7086 and 8391 both for limits (for same ones) and tests. Croatia applies the CEN standards 1388 and ISO standards 6486, 7086 and 8391. There are additional countries with provisions which were reported in the Publication by CERAM.

²¹² AOAC: American Official Chemists' Association

²¹³ American Society for Testing and Materials

²¹⁴ CPSC-CH-E1002-08 Standard Operating Procedure for Determining Total Lead in Non-Metal Children's Products, 2009 and/or CPSC-CH-E1002-08.1 Lead Content in Children's Non-Metal Products, 2011.

Annex 13. Frameworks and other documents for glass

An overview of the measures or sources available at national level is described below:

| MS | Measures | Positive list / negative list; Restrictions - Residual/QM/OM/SML Basis for enforcement/ Test conditions DoC/ GMP/ sanctions If any |
|------|--|--|
| Co E | PS concerning Pb leaching from glass | - limits from ISO 7086-2 and ISO 6486-2 for Pb in different glass FCM (Chapter 9.3.1, 9.3.2). - levels are not necessarily intended to be regarded as the maximum amount of these metals to which exposure can be considered safe, but somewhat harmonised levels consistent with GMP in the respective industries |
| BE | Arrêté royal du 11 mai 1992 | - positive list for substances allowed in the treatment of external surfaces of glass FCM (Annex 6) - OML + SMLs for Pb and Cd from glass FCM (Annex 6, II) |
| BG | Ordinance N° 3 from 4.06.2007 | - limits release Pb and Cd from glass/glass ceramics same as for ceramics (Section III, Art. 8-10) - method for testing same as that for ceramics in EU legislation (Art. 9 + Annex 3) |
| HR | NN125-2009 | - bans the use of glass wool in the production of glass containers (Članak 114) - limits of migration for Pb and Cd (Članak 31, 111) |
| CZ | Vyhláška č. 38/2001 | - migration limits of Pb and Cd for glass, based on the EU provisions for ceramics - adding also rim (Příloha 9, Oddíl 1) - rules for verifying migration of Pb and Cd (Příloha 9, Oddíl 2) |
| DK | BEK nr 822 of 26/06/2013 | - release limits on Pb and Cd, based EU provisions for ceramics - includes the rim (Kapitel 5, §16, Bilag 4) - migration testing also include the rim (§27; Bilag 10) |
| FR | DGCCRF Note d'information 2004/64 | - limits for release of Pb/Cd, including for the rim - testing, methods, expression of results for Pb, Cd, Cr _{VI} (from EU 80/778/EEC) (Ch. glass) |
| FR | Arrêté du 15/11/1945 | - maximum amounts of some substances used in glass |
| DE | ASU nach §64 LFGB, BVL B 80.03-4:2008-10 | - test for the release from glass, including from the rim - copy of EN 1388-2:1995 |
| IT | D.M. 21/03/1973 (and its amendments) | - types of glass for contact with foods (Titolo II, capo V, art. 34; Allegato II, Sezione 5) - release limit for Pb (Allegato II, Sezione 5) - overall and specific release test methods for compliance (Titolo II, art. 35, Allegato IV as amended by and D.M. 26/04/1993, D.M. 22/7/1998 n 338 and D.M. 28/3/2003 n. 123) - obligation for the producer to have a declaration of compliance for glass FCM. (Titolo I, art. 6, 7, as amended by D.M. 3 agosto 1974; D.M. 26/04/1993, Annex III, Section 1, Part B, point 4) |
| NL | Commodities Act (Packagings and Consumer Articles) | - states that mercury compounds must not be used (Chapter V, 3.2) - states that " The base materials and auxiliary materials used in the manufacture of glass and glass ceramics must be of high technical quality" - OMLs (Chapter 0, 0.3; Chapter V, 4) - SMLs for Sb, As, Ba, B, Cd, Cerium (Ce), Cr, Fluorine (F), Co, Li, Pb, Manganese (Mn), Ni, Rb, and Zirconium (Zr) (Chapter 0, 0.3; Chapter V, 4) - auxiliaries must not be used in larger quantities than strictly necessary for the final product" (Chapter V, 3) |
| NO | Regulation 1381-1993 | - limits for Pb and Cd from glass FCM, - including from the rim (§26a, Vedlegg IV) - instructions on tests and analytical methods for Pb and Cd (§26, Vedlegg VI, Vedlegg V) |
| SK | Foodstuffs Code 1799/2003 | - substances for the treatments of the external surface of glass FCM (§36 (3)) - limits of migration of Pb and Cd (§37) - states that glass FCM have to be manufactured according to GMP (§36 (1)) |
| CH | Ordinanza DFI del 23/11/2005 | - fixes limits of migration (as those for ceramics) for Pb and Cd (Section 5, art. 20, Annex 4) |

Standards

Standards are available for glass and are reported below:

| standard name (and committee) | standard title and contents |
|-------------------------------|--|
| CEN/TS 12983:2005 | Cookware - Domestic cookware for use on top of a stove, cooker or hob Part 2: Further general and specific requirements for ceramic, glass and glass ceramic cookware |
| EN ISO 6486:1999 | Ceramic ware, glass ceramic ware and glass dinnerware in contact with food - Release of Pb and Cd Part 1: Test method -- Part 2: Permissible limits |
| EN ISO 7086:2005 | Glass hollowware in contact with food - Release of Pb and Cd Part 1: Test method -- Part 2: Permissible limits |
| Standard DIN 51032:1986-02 | - limits for the release of Pb and Cd from glass - includes limits of release from the rim. - states that the release of Pb and Cd from glassware (except lead crystal) can only be due to contaminations and therefore < limit of detection (LOD (Pb): 0.05 mg/l, LOD (Cd): 0.005 mg/l). - For glassware with inside decorations, the limits set in 84/500/EEC for Pb and Cd applies |
| PN-B-13210:1997 | Glassware And Ceramic Ware In Contact With Food - Permissible Limits Of Release Of Pb and Cd |
| UNE 126301:2003 AENOR (ES) | Glassware in contact with food. Release of Pb and Cd. Test method and permissible limits. |

Note: India (Bureau of Indian Standards) has a standard on Glass (BIS IS 9806:2001, Methods Of Test For And Permissible Limits Of Toxic Materials Released From Ceramic ware, Vitreous Enamelware, Glassware And Glass-ceramic): This standard prescribes the methods of test for and permissible limits of toxic materials released from ceramic ware, vitreous enamelware, glassware and glass-ceramic ware used in preparation, storage, cooking or serving of food and beverages.

Annex 14. Frameworks or other documents for metals and alloys

National /supra national sources

An overview of the measures or sources available at national level is described

| M S | Legislation | Positive list / negative list Restrictions - Residual/QM/OM/SML Basis for enforcement / Test conditions | DoC / supporting documents / GMP/ other info |
|---------|---|---|--|
| Co E | Guide on Metals and alloys used in FCM | - restrictions in the composition of stainless steel (Ch. 2) - SRLs for release from metals and alloys , including rationale behind each value (Ch. 1, 1.4, 2.1, 2.2, Ch. 2) - tests for release and analytical methods, as well as sampling procedures and schemes for enforcement (Ch. 1, art. 5, Ch. 3) | - DoC and SDs are necessary to demonstrate compliance (Ch. 1, 3.2, Ch. 4) - metallic FCMs should be manufactured as per Reg. (EC) No. 2023/2006 (Ch. 1, 3.1) |
| No rden | Nordic guidance for authorities, industry and trade | (FCMs – metals and alloys) - guidance values for release limits of 24 metals (Summary, table 1, Ch.3,3.2) - principles of migration/release testing of FCMs composed of metals and alloys , but does not list specific methods (Annex II) | DoC and SD should be made available to authorities upon request (Ch. 2, 2.1, 2.1.3) |
| N O | Reg. 1381-1993 | - limits for release of Pb and Cd from metal FCM and non-ceramic without enamel coating, including release from rim (§26a, Kapittel VIa, Vedlegg IV) - instructions on release tests and analytical methods for Pb and Cd (§26, Vedlegg VI, Vedlegg V) | n/a |
| AT | BGBI. Nr. 258/1960 | - bans the use of Pb, Cd and Zn, alloys containing As or Sb, and metals and alloys containing Beryllium (Be) in dishes and other FCM (§2 (1-4)). - bans the use of tin for certain food contact applications and in particular tin containing Sb (§4(1-4), §5(1)a, §5(2)) - limits for release of Ba, Zn, Sb and Pb for coatings other than enamels (§3a) - limits for the amount of Mn in metals and alloys and defines purity criteria for Sn and Cu to be used in FCMs (§2(1) No.4, §4(1)b, §4(4), §6(1)) - test conditions (time, temperature, simulant) for release tests (§3a) | n/a |
| BE | Arrêté royal du 11 mai 1992 | - maximum amounts of Sn, Sb, As, Bi, Cd, Cu, Fe, Pb, Ni+Co, S, Zn, Ag in tin and tin alloys (Annex 2, II) | n/a |
| H R | NN125-2009 | - bans the use of Cu or Zn, except in alloys , for flatware and utensils for preparing and serving meals and it states that coil-coated nickel may not be used in contact with food. The cap which decorates the neck of the bottle with a cork must not be made of alloys containing Pb (Članak 19, 88, 112) - limits for the specific release of Pb, Cd, As, Zn, Cr and Ni from metal FCMs in general (Članak 17, 19) - establishes the maximum amounts of content in Pb, As, Cd, Zn, Cu, Sb and Fe for different types of metalware (Članak 16, 22, 88, 112) - limits for the specific release of Cr, Ni and Mn for articles made of stainless steel (Članak 19) - test conditions with time temperature /solvent (Članak 17, 19) - for articles made of stainless steel , it describes corrosion and release tests - establishes test conditions (time, temperature, simulant) for release tests of metal pipes/parts and metal fittings for domestic drinking water installations (Članak 20) and for a corrosion test on coated metalware (Članak 21) | n/a |
| CZ | Vyhláška č. 38/2001 | - list of substances that can be used in metals and alloys (Příloha 8) - limits for those substances (Příloha 8) | n/a |
| EL | Greek food code | - positive lists for products in aluminium and aluminium alloys, stainless steel , tin, copper and zinc (Article 22) - fixes maximum allowed quantities in these products (Article 22) | n/a |
| FR | Arrêté du 28 juin 1912 | - fixes limits for As and Pb contents (Art. 3-5, applicable also to metallic FCMs) | n/a |
| FR | Arrêté du 15/11/1945 | - list of authorised substances for the production of metal FCM in general - fixes limits for the impurities that can be present (Art. 1 and 3) | n/a |
| FR | Arrêté du 13/01/1976 | fixes the list of authorised substances in the production of steel FCMs | n/a |
| FR | Arrêté du 27/08/1987 | lists some elements that can be added to aluminium (Art. 3) | n/a |
| FR | DGCCRF Note d'information 2004-64 | - sets a limit of 10 mg/dm ² or 60 mg/kg food and analytical tolerances for the overall migration/release from articles made of steel, stainless steel, aluminium or cast iron and covered with an organic coating - regarding the specific migration of epoxy derivatives from organic coatings of steel, stainless steel and aluminium articles, it states that the limits set in EU legislation on plastics apply - sets a limit for the specific release of Zn from articles made of zinc and for several metals (Ni, Cr, Zn, Pb, Cd) from the metallic coating of steel, stainless steel , cast iron or whitened metals intended for other food contact applications than packaging materials - for steel/stainless steel, aluminium or cast iron covered with an organic coating and intended for other food contact applications than packaging materials, it recalls the specific release limit for Cr (VI) defined in BOCCRF No 8 of 24/05/1996 - for tin and tin alloys , it recalls the specific release limit for Sb as defined in CSAH of 02/12/1999 - - states that tests for overall and specific release from zinc, whitened metals, steel, stainless steel, aluminium or cast iron , uncoated or covered with an organic or metallic coating shall be performed as described in EU legislation on plastics. This includes time-temperature conditions and the simulants that should be used depending on the intended food contact application of the sample, except for tests modelling the contact with acidic food (pH ≤ 4.5) | requires a DoC and supporting documents for aluminium (in non-coated or coated form) and for the organic coating intended to be applied on steel, stainless steel, aluminium or cast iron |

| MS | Legislation | Positive list / negative list Restrictions - Residual/QM/OM/SML Basis for enforcement / Test conditions | DoC / supporting documents / GMP/ other info |
|----|--|--|---|
| | | where other simulants (i.e. 10% ethanol (v/v), 5% citric acid (w/v)) are defined differently than those mentioned in the EU legislation on plastics - international standards EN 1186 and CEN/TS 14235 should be respected in the determination of the overall migration from steel, aluminium and cast iron covered with an organic coating | |
| IT | D.M. of 21/03/1973 (and its amendments) | - positive lists for FCM manufactured in stainless steel , tinplate, tin free steels (Titolo II, Capo VI, art. 36, as amended by D.M. n.140 11/12/2013, D.M. n.405 13/07/1995, D.M. n.243 01/06/1988, D.M. 18/02/1984) - reports specific release limits for some metals (chrome, Ni, Mn) in stainless steel FCM (Titolo II, Capo VI, as amended by D.M. n.140 11/12/2013) - reports restrictions and protocols to perform a correct sampling, to conduct overall / specific migration and to analyse the extracts (Titolo II, Capo VI, amended by D.M. n.140 11/12/2013, D.M. D.M. n.123 28/03/2003, D.M. n.338 22/07/1998, D.M. n.405 13/07/1995, D.M. n.220 26/4/1993, D.M. n.243 01/06/1988, D.M. 18/02/1984) | stipulates the obligation for the producer to have a DoC for stainless steel FCM (Titolo I, art. 6 e 7) |
| IT | D.M. 18/02/1984 | - limits for Pb in varnished tin free steel FCM (Art. 2, Allegato II) - establishes control criteria such as sampling, overall migration test and analytical method for the release of Pb into foods (Art. 3, Allegato III-A, III-B, III-C; articolo 1, comma 3,4,5 and Allegato I of Decreto n.405 13/07/1995) | n/a |
| IT | Decreto n. 243 01/06/1988 | - establishes limits for the quantities of chrome (Art. 2, Allegato II) and Fe (Art. 2, Allegato III) in varnished tin free steel FCM - establishes sampling, overall migration test and analytical method for chrome and Fe (Art. 3, Allegato III-A, III-B, III-C) | states that varnished tin free steel FCM must be produced according to GMP (no further details, Art. 1, Allegato I) |
| IT | Nota n. 20072 del 20/05/2014 | n/a - summarises the migration test to be performed on steel FCM | n/a |
| IT | Nota n. 12174 del 23/04/2010 | - stipulates that tin free steel and tinplate FCM have to be produced according to GMP and have to be accompanied by a DoC and reports a list of information that have to be included | - indicates the legislative frames that introduce sanctions for non-compliance with legislation - reports the responsible body for controls on tin free steel and tinplate FCM |
| IT | D.M. n.76 18/04/2007 | reports the purity criteria for aluminium (Al) and aluminium alloys FCM (Art. 3-4, Allegato I, II, III) | states that a DoC is compulsory for the producer of aluminium and aluminium alloys and for the company that uses the FCM from a producer (Art. 8, 9) |
| IT | DPR n.777 23/08/1982 and its amendment | establish some restrictions on the content of Pb, Zn, Sn, and As in metals and alloys (Art. 2-bis) | - establish the obligation for the producer to have a DoC (Art. 4.5-4.6, Art. 5-bis.2) - establish fines for not respecting the legal provisions (Art. 2, 2-bis, 3, 4, 5-bis, 6) |
| IT | Nota n. 22887 del 26/06/2012 | n/a | - clarifies laws to be applied when controls are performed - states that operators must show the Competent Authority DoC and SD, including the text of the laws applied in the MS of origin of the materials |
| NL | Commodities Act (Packagings and Consumer Articles) | - establishes a list of substances that can be used in the manufacturing of metals used for packaging materials and for consumer articles - establishes limits for base materials, metallic coatings, greasing agents, rolling oils, lubricants for pounding and pulling, non-metallic joint sealants, adhesive tapes for covering the lengthwise joint, sealant lids and bottom seams, organic coatings in metals used for packaging materials and limits for base materials, solders, welding materials, metallic coatings, organic coatings in consumer articles (Ch. 0, 0.3; Ch. IV, 2, 3) - establishes OML and SMLs (Ch. 0, 0.5.1-4, 0.6; Ch. IV, 4) | n/a |
| SK | Foodstuffs Code 1799/2003 | - indicates the allowed surface treatments and the substances that can be used for the manufacturing of metal FCM (§9, 11, 12, 13, Príloha č. 3) reports maximum allowed amounts for some of the substances that can be used for the manufacturing of metal FCM (Príloha č. 3) | n/a |
| CH | Ordinanza DFI del 23/11/2005 | - bans the use of Pb, Cd, Zn and their alloys in FCM (Section 2, art. 4 and 5) - fixes the amounts of Sn, Pb and Cd in tin FCM (Section 2, art. 4 and 5) - stipulates limit of migration of Al for FCM intended for fruit and vegetable juices (Section 2, art. 4) | n/a |

Standards

Standards exist both at EU level and at national levels, usually published in categories that represent different metals as the primary driver, and a second classification that may target specific uses. The (non-exhaustive) information is summarised.

Examples of standards in the sector of metals and alloys

| source | standard title |
|-------------|---|
| CEN | EN 610: 1996 - Tin and tin alloys. Ingot tin |
| Codex | Codex Standard 193-1995. Codex General Standard for Contaminants and Toxins in Food and Feed; Adopted 1995; Revised 1997, 2006, 2008, 2009; Amended 2009, 2010. (tin in canned foods) |
| CEN/ ISO | Materials and articles in contact with foodstuffs – cutlery and table hollow-ware – EN ISO 8442-1:1997 Part 1: Requirements for cutlery for the preparation of food EN ISO 8442-2:1997 Part 2: Requirements for stainless steel and silver-plated cutlery EN ISO 8442-3:1997 Part 3: Requirements for silver-plated table and decorative hollowware EN ISO 8442-4:1997 Part 4: Requirements for gold-plated cutlery |

| source | standard title |
|-----------------|--|
| | EN ISO 8442-5:2004 Part 5: Specification for sharpness and edge retention test of cutlery EN ISO 8442-6:2000 Part 6: Lightly silver plated table holloware protected by lacquer EN ISO 8442-7:2000 Part 7: Specification for table cutlery made of silver, other precious metals and their alloys EN ISO 8442-8:2000 Part 8: Specification for silver table and decorative holloware |
| CEN | EN 10333 Steel for packaging – Flat steel products intended for use in contact with foodstuffs, products and beverages for human and animal consumption – Tin coated steel (tinplate). |
| CEN | EN 10088-1:2005 Stainless steels. List of stainless steels |
| EN | Aluminum and aluminium alloys. EN 601:2004 - Castings. Chemical composition of castings for use in contact with foodstuff EN 602:2004 - Wrought products. Chemical composition of semi-finished products used for the fabrication of articles for use in contact with foodstuff |
| NF A(FR) | French standard NF A 36-711(2002)-Stainless steel intended for use in contact with foodstuffs, products and beverages for human and animal consumption; |
| DIN (DE) | DIN - 18865-1:2003-05 - Equipment for commercial kitchens - Food distribution equipment - Part 1: Dimensions, requirements, testing. DIN - 18865-2:2004-11 - Equipment for commercial kitchens - Food distribution equipment - Part 2: Heated service counters DIN - 18865-3:2003-05 - Equipment for commercial kitchens - Food distribution equipment - Part 3: Service tables (neutral counters) DIN - 18865-4:2001-02 - Equipment for commercial kitchens - Food distribution equipment - Part 4: Top shelves heated or not heated DIN - 18865-5:2003-05 - Equipment for commercial kitchens - Food distribution equipment - Part 5: Tray slides DIN - 18865-6:2003-05 - Equipment for commercial kitchens - Food distribution equipment - Part 6: Dispensers DIN - 18865-7:2003-05 - Equipment for commercial kitchens - Food distribution equipment - Part 7: Cold storage DIN - 18865-8:2003-05 - Equipment for commercial kitchens - Food distribution equipment - Part 8: Top shelves refrigerated DIN - 18865-9:1997-03 - Equipment for commercial kitchens - Food distribution equipment - Part 9: Equipment-insides in basic and hygiene version DIN - 18865-10:2004-12 - Equipment for commercial kitchens - Food distribution equipment - Part 10: Cash module - Requirements and testing DIN - 18866:2003-06 - Equipment for commercial kitchens - Convection ovens and convection steamers - Requirements and testing |
| BSI (UK) | BS 1746:1987-Specification for domestic pressure cookers; BS 5577:1984- Specification for table cutlery; BS 5312:1996 - Specification stainless steel catering containers and lids Stainless steel tubes and fittings for the food industry and other hygienic applications including: BS 4825 pipes and fittings for the food industry: stainless steel tubes fittings for the food industry and other hygienic applications BS 4825-1 Specification for tubes; BS 4825-2 Specification for bends and tees; BS 4825-3 Specification for clamp type couplings; B S 4825-4 Specification for threaded (IDF type) coupling; BS 4825-5 Specification for recessed ring joint type couplings. |

Annex 15. Frameworks or other documents for cork and wood

Cork

The overview of the **measures or documents** at national level for cork is presented.

| MS | Measure | Positive list - Negative list Composition and/or other guidance | OM - SML/QM Methods test conditions |
|-----|--|---|---|
| CoE | PS cork stoppers and other cork materials | - presents lists of substances (monomers, starting agents, additives, and processing aids) that can be used in the manufacturing of cork as well as a list for substances that are not assessed for being used in cork. - cork FCM should be manufactured according to the CE Liege guidance "Code of cork stoppers manufacturing practice" | - OM by ISO 10106 for cork stoppers - maximum quantity of PCP in cork - SMLs for PCP and trichlorophenols - information on test conditions and on analytical methods for cork FCM, - EU legislative reference - Lists relevant international standards |
| CZ | Vyhláška č. 38/2001 | list of substances that can be used in the preparation of cork | - migration limits (Title VII, Section 24, Annex -Příloha- 14). |
| HR | NN125-2009 | n/a | -OM (determined as non-volatile residue of migration into 15% ethanol (v/v) and 3% acetic acid (v/v) - OM test conditions (Članak 112). |
| FR | Instruction du 11 Avril 1990 | - authorises some polydimethylsiloxane silicone oils for cork stoppers (excluding fatty contact) - specifies the purity and physical characteristics of the authorised polydimethylsiloxane silicone oils | n/a |
| NL | Commodities Act (Packagings and Consumer Articles) | - includes the lists of substances that can be used for base materials, preserving agents, <i>adhesives</i> and thickening agents, finishing and impregnating agents, softeners, solvents, colorants and pigments, other auxiliaries. (Chapter 0, 0.3; Chapter IX, 2.1) - restricts the use of preserving agents (IX.2.1-b), adhesives and thickening agents (IX.2.1-c), finishes and impregnating agents (IX.2.1-d), softeners (IX.2.1-e), solvent (IX.2.1-f), colourants and pigments (IX.2.1-g), and other auxiliaries (IX.2.1-h) | - OMLs and maximum quantity - SMLs (Chapter 0, 0.5.1-4, 0.6; Chapter IX, 3) |
| SK | Foodstuffs Code 1799/2003 | - establishes a positive list for cork. (§41, Príloha č. 13) - basis was the former measure in Czechoslovakia | - maximum amounts for some substances in cork - SMLs for substances (Príloha č. 13) |

Standards for cork exist and are represented below.

| standard source | standard title |
|-----------------|---|
| ISO 22308:2005 | Cork stoppers -- Sensory analysis: Defines a test method for detecting, qualifying and eventually evaluating the exogenous odours/flavours of cork stoppers, and is applicable to all kinds of cork stoppers, ready for use, designed to be in contact with alcoholic drinks. |
| ISO 10106:2003 | Cork stoppers -- Determination of global migration; Specifies a test method to measure the global migration of cork stoppers. It is applicable to all types of cork stoppers that are ready to use. |
| ISO 21128:2006 | Cork stoppers -- Determination of oxidizing residues -- Iodometric titration method Specifies an iodometric titration method for determining the oxidizing residues released by cork stoppers ready to use. |
| ISO 20752:2014 | Cork stoppers -- Determination of releasable 2, 4, 6-trichloroanisole (TCA) Specifies a test method to determine releasable 2,4,6-trichloroanisole (TCA) from cork stoppers. It is applicable to all types of cork stoppers and all their cork constituents. |
| UNE 56930:2005 | Cork stoppers: Determination of releasable 2,4,6-Trichloroanisole (TCA). |
| UNE 56929:2004 | Cork stoppers. Quantitative determination of the oxidising residues. Test methods and specifications. |
| UNI 11311:2009 | Food Packaging - Requirements Of Synthetic Corks Intended For The Conditioning Of Food Beverages And Liquids |

The main **professional associations** for the sector of cork consist in the "Confederation

Wood

The overview of the measures or documents at national level for wood is presented.

| MS | Measure | Positive list - Negative list Composition and/or other guidance | OM - SML/QM Methods test conditions |
|----|-------------------------------------|--|--|
| FR | DGCCRF Note d'information n°2012-93 | - list of wood species admitted for contact with all types of food (section 3.2.1). other wood species can be used provided that they comply with Reg. (EC) 1935/2004 Art. 3 (section 3.2.1). This list only contains substances evaluated by the Conseil Supérieur d'Hygiène Publique de France (CSHPF) or those from Directive 98/8/EC Annex I or Reg. (EC) 1451/2007 Annex II (section 3.2.2). - - It bans the use of antifungal treatment for any kind of wood for food contact applications, except temporary antifungal treatment of wood intended for the manufacture of containers for fruits and vegetables (section 3.2.2 + Annexe) - It bans the use of other antifungal treatments for any wood for FCM applications (section 3.2.2) - restrictions in Reg (EC) 1907/2006 (entry 19, 23, 31) are applied (sections 4.1 and 4.2) | - Limit for dose antifungal substance applied per m ² of treated wood - limits for residual content of PCP, PCB - limits for Pb, Cd and Hg in wood. - SMLs for As, Cr, Cd and creosote - SMLs for substances (section 4.3 + Annexe) - SML for formaldehyde in food/simulants (section 4.2) - cites reference methods - does not exclude the use of other suitable validated method for compliance (section 5). - methods include general migration and extraction procedures, specific methods for the determination of PCP, PCBs and heavy metals and for organoleptic tests |
| FR | Avis DGCCRF du 17/01/2002 | Authorises one substance for wood treatment | specifies its maximum amount |
| FR | Note 31/05/2001 | Authorises one substance as fungicide for wood | specifies its maximum concentration |
| FR | Avis 9/11/1999 | Authorises one substance as fungicide for wood | n/a |

| MS | Measure | Positive list - Negative list Composition and/or other guidance | OM - SML/QM Methods test conditions |
|----|--|---|--|
| FR | Avis 14/09/1999 | authorises the use of alpha-ter-butyl-alpha-(para-chlorophényl)-1H-1,2,4-triazole-1-éthanol ou tébuconazole used for wood treatment | fixes the maximum amount and migration limit |
| FR | BOCCRF n° 17 du 22/01/1997 | Authorises substances for treating wood | fixes their maximum amounts and limits of specific migration |
| FR | BOCCRF n° 16 du 15/12/1995 | Authorises substances for treating wood | sets their limits |
| FR | BOCCRF n° 10 du 24/06/1994 | Authorises some substances as wood fungicides | sets their maximum amount |
| FR | BOCCRF no 22 du 18/12/1992 | authorises the use of one substance as fungicide bans the use of another one | n/a |
| FR | Arrêté du 15/11/1945 | specifies types of wood that can be used for weighing tools intended for food contact | n/a |
| HR | NN125-2009 | n/a | -SMLs for formaldehyde, Pb, Cd, Cr (VI) cations, Hg and PCP for smoking foods - tests for SM testing (Članak 72, 117) |
| NL | Commodities Act (Packagings and Consumer Articles) | - substances for base materials, preserving agents, adhesives / thickening agents, finishing / impregnating agents, softeners, solvents, colorants / pigments, other auxiliaries (Ch. 0, 0.3; Ch. IX, 2.1) - states that preserving agents bis(tributyl tin)oxide, copper naphthenate and zinc naphthenate are only permitted in the country of origin of the base materials | - OMLs (Ch. 0, 0.5.1-4, 0.6; Ch. IX, 3). -SMLs (Ch. 0, 0.5.1-4, 0.6; Ch. IX, 3). |

Substances in common for three or more MSs and including CoE.

For the 168 substances, commonalities could be found in 19 substances corresponding to The Netherlands, Czech Republic, and Slovakia but not with France.

Substances considered by three or more MSs for cork and wood:

| Substance/ CAS | NL IX 2.1h (wood and cork) NL IX 2.1c (wood & cork) | CZ 38/2001 A. 14 SK 1799/2003 A. 13 (cork) | CoE P.S. cork stoppers |
|---|---|---|---|
| Benzoic acid , 65-85-0 | as other additive | and its Ca, K and Na salts, <0.2% (w/w) for cork treatment | n/a |
| Carboxymethyl cellulose, 9000-11-7 | as adhesive or binder | as binder | n/a |
| Colophonium [or rosin /rosin gum/ colophony]; 8050-09-7 | According to paper and board - as adhesive or binder | as binder | as monomer and starting substance and as additive |
| Dextrin; 9004-53-9 | as adhesive or binder | as binder | n/a |
| Ethyl cellulose; 9004-57-3 | as adhesive or binder | as binder | n/a |
| Formaldehyde; 50-00-0 | As other additive SML=15, together with hexamethylene tetramine, CZ 0.1 mgCH ₂ O/dm ² (0.01 mg/dm ²) | for treatment of cork | n/a |
| Glycerol; 56-81-5 | as other additive | for treatment of cork | as aid to processing |
| Hexamethylenetetramine; 100-97-0 | SML=15, together with formaldehyde - as other additive (also NL IX 3.2) | for treatment of cork | n/a |
| Hydrogen peroxide; 7722-84-1 | n/a | for treatment of cork | - as processing aid - as FCC specif. |
| Hydroxyethyl cellulose; 9004-62-0 | as adhesive or binder | as binder | n/a |
| Hydroxypropylmethyl cellulose or synonyms; 9004-65-3 | as adhesive or binder | as binder | n/a |
| Methylcellulose; 9004-67-5 | as adhesive or binder | as binder | n/a |
| Paraffin, liquid (refined mineral oil) 8012-95-1 | - as other additive; specification: colour weaker than Standard Saybolt 30, odour nearly absent and whose absorption of UV light as in Annex B (Assessment Methods) | no specifications for CZ and SK - for treatment of cork | n/a |
| Polyethyleneglycol; 25322-68-3 | MW> 200 - as other additive | MW> 200 - cork treatment | as monomer and starting substance |
| Polyurethane; 65916-86-1 | according to (EU) no 10/2011 - as adhesive or binder | as binder | n/a |
| Polyvinyl acetate; 9003-20-7 | according to (EU) no 10/2011 - as adhesive or binder | as binder - Unplasticised (Section 10 Impl. Decree) - | In compliance with FCC specif. |
| Sorbic acid and its sodium and/or potassium salts | as other additive | not more than 0.2 % by weight - for treatment of cork | n/a |
| Sulphur dioxide; 7446-09-5 | n/a | for treatment of cork | Food additive (E 220) |
| Triethylene glycol; 112-27-6 | as other additive | for treatment of cork | n/a |

Annex 16. Frameworks or other documents for paper and board

National /supra national sources

There are 10 MSs (Belgium, Czech Republic, Estonia, Greece, Germany, France, Croatia, Italy, The Netherlands, Slovakia) with national legislation or instructions on P&B FCMs. In addition, the CoE published two resolutions on P&B FCMs. The overview at national level for paper and board is presented.

Overview of measures available at national level for paper and board (P&B)

| MS | Measure | Positive list / Negative list | Restrictions / QM / OM / SML | Basis for enforcement Test conditions Other (e.g. DoC, sanctions) |
|-----|---|--|---|---|
| BE | Arrêté royal du 11 mai 1992 | - establishes the list of substances that can be used for the preparation of FCM (Annex 4, III) | - sets maximum allowed quantities of some substances (Annex 4, III) - sets an OML (Annex 4, II) - sets SMLs for substances (Annex 4, III) | n/a |
| COE | PS concerning P&B materials and articles | - suggests positive lists for P&B and gives some indications on the types of recycled materials that can be used (Resolution ResAP (2002)1, 1.1, 2, 3.1-3.6, 3.10, 3.11, Tech. Doc No. 1, 1., 2., List 1, temporary appendix (App) to list 1, App. A, App. B, App. C, Tech. Doc No. 3, 3., 3.1-3.3, Table 2) | - indicates restrictions for residual contents of some substances - provides SMLs (Resolution RESAP (2002)1, 2., 3., Tech. Doc No. 1, 1., 2., List 1, App. A, Tech. Doc No. 3, Table 2) | - information on migration tests and analytical methods to assess compliance (Resolution ResAP (2002)1, 3.7, 3.8, Tech. Doc No. 2, 1.-4., 6., 7., App. A, Tech. Doc No. 3, Table 2) |
| COE | PS concerning tissue paper kitchen towels and napkins | - suggests lists of substances (including raw materials, dry strengths, fixating agents, laminating glues, dyes, pick-up and tail seal glues, wet strengths, fluorescent whitening agents, softeners, debonders, absorbency aids) that can be used in the manufacturing of tissue paper, kitchen towels and napkins (Ch.s 1.2, 4, 5.1, 5.2, 7.1, 7.2, App. 1, 1, 2) - suggests a list of substances that should not be used in the manufacturing of tissue paper, kitchen towels and napkins and some restrictions in the use of recovered raw materials (Ch. 7.2.2, App. 1, 3) | indicates restrictions for residual contents of substances or components (Ch. 1.2, 4, App. 1) and suggests specific migration limits (App. 1) | - information on test conditions, methods of analysis, reference to existing standards for kitchen towels and napkins, - specific migration testing method for tissue paper, - method to determine 1,3-dichloro-2-propanol and 3-chloro-1,2-propanediol in an aqueous extract of paper (Ch. 1.2.3, 6, App. 3, App. 4) |
| HR | NN125-2009 | states that P&B packaging coming into direct contact with fats or fatty food, meat and meat products, dairy products and egg powder must not contain magnesium chloride (Članak 107) | - any other chloride can contain max. 2 %, expressed as NaCl (Članak 107) - imposes limits for residual contents of some constituents of P&B products (Članak 101, 102, 104, 106, 107) - sets migration limits for some substances from P&B, P&B impregnated with paraffin, wax, or coated with a protective varnish or polymer materials and from recycled P&B. (Članak 100, 101, 104, 105, Tablica 9) | - provides some general information on how to perform the migration tests for specific types of P&B packaging (high temperature contact, and filters for oil or high volumes) -It also states that paper and board intended to come into contact with food must be produced in accordance with the rules of good manufacturing practice (Članak 100) |
| CZ | Vyhláška č. 38/2001 | - establishes a list of substances that can be used in the preparation of P&B for dry contact and for filters for hot or cold liquid contact (raw materials, additives, fillers, processing/production aids, retention aids, slimicides, preservatives, lubricants) - defines substances that can be used for coatings, colorants, whitening agents (Příloha 12) | sets limits for residual contents of the substances allowed (including for P&B used for hot and cold filtration, raw materials, auxiliary production substances, and special materials for finishing paper) | n/a |
| EE | Käskkiri No. 54 of 09.03.2015 | n/a- not a measure- only a non binding Decree of the general director of the Veterinary and Food Board | - sets a limit of 0.6 mg/kg for the specific release of three different photoinitiators (namely benzophenone, 4-methyl benzophenone, 4-hydroxy benzophenone) into food (Lisa 3, section 10) | - instructions on how to perform the sampling of P&B samples for official control - parameters (photoinitiators) to be analysed in samples for compliance (Lisa 3) |
| FR | DGCCRF Note d'information 2004/64 | n/a | - sets limits for the extractable amount of PCP, PCBs and heavy metals (Pb, Cd, Hg, Cr VI) as well as for the dosage of formaldehyde and glyoxal (section 4 and summary table) - limits the overall release from papers for hot filtering obtained by hot water extraction (section 4) - sets limits for the specific migration of formaldehyde and glyoxal (section 4) | - states which reference test methods shall be used for compliance testing (section 5 and summary table) |
| FR | BOCCRF n° 9 du 12 mai 1999 | authorises the use of some whitening agents for P&B | fixes their maximum allowed amounts | n/a |
| F | BOCCRF n° | authorises the use of a substance as | fixes its maximum allowed amount | n/a |

| M S | Measure | Positive list / Negative list | Restrictions / QM / OM / SML | Basis for enforcement Test conditions Other (e.g. DoC, sanctions) |
|-----|--|--|--|--|
| R | 15 du 3 octobre 1996 | additive for paper | | |
| FR | BOCCRF n° 16 du 15/12/1995 | authorises the use of glutaraldehyde as bactericide for paper pulp | fixes its limit | n/a |
| FR | BOCCRF n° 20 du 27 octobre 1994 | authorises the use of a perfluoroalkyl methacrylate for the coating of paper intended for food contact | fixes a limit for the residual amount of a methacrylate compound (N,N-dimethylaminoethyl methacrylate) in coatings and the maximum amount of coating to be applied on paper | n/a |
| FR | Instruction 30/11/1987 | authorises the use of substances in the treatment of P&B | fixes their maximum content in heavy metals | n/a |
| FR | L. Circ. du 28 octobre 1980 | authorises the use of some substances for the impermeabilising and bactericidal treatments of P&B | fixes the maximum allowed amounts of some substances for the impermeabilising and bactericidal treatments of P&B | n/a |
| FR | L. Circ. du 4/01/1982 | authorises a preparation as bactericide in P&B | fixes the limits for a preparation used as bactericide in P&B | n/a |
| FR | Circulaire du 29 mai 1978 | authorises a perfluorinated grease-proofing agent for P&B | establishes its maximum amount | n/a |
| DE | BfR Rec. XXXVI | <ul style="list-style-type: none"> - establishes lists of substances for raw materials (fibrous materials, fillers), for production aids and for paper refining agents for P&B intended for use at temperatures up to 90°C - bans the use of certain azo dyes in the manufacture of food-contact paper and paper board | <ul style="list-style-type: none"> - sets maximum amounts in which some substances can be used in the manufacture of P&B and fixes maximum amounts for impurities (PCP, toxic metals) - sets release limits for extraction tests on some substances used as production aids and on impurities - states that colorants and optical brighteners must not be transferred to foodstuffs - establishes migration limits for contaminants from recycled fibres | n/a states that finished articles must not have a preserving effect on foodstuffs |
| DE | BfR Rec. XXXVI/1 | establishes lists of substances for the raw materials and for the overall production aids and defines maximum amounts | <ul style="list-style-type: none"> - establishes purity criteria for some substances that can be used in the manufacture of papers - sets limits for the total dry residue and the total nitrogen content in hot and cold water extracts of paper, following extraction procedures described in EN 647 and EN 645, respectively - sets a limit for the migration of some substances used as defoamers as well as for the amount of formaldehyde found in cold water extracts of paper | extraction procedures described in EN 647 and EN 645 |
| DE | BfR Rec. XXXVI/2 | establishes lists of substances for the raw materials (for fibrous materials, fillers) and for production aids | <ul style="list-style-type: none"> - sets limits for the maximum amounts of substances to be used in the manufacture of papers for baking purposes - sets limits for release of some substances in hot water extraction tests, following given extraction procedures | gives extraction procedures states that the finished articles must not have a preserving effect on foodstuffs |
| DE | DE BfR Rec. XXXVI/3 | establishes lists of substances for fibrous materials and for production aids | sets limits for the maximum amounts of substances to be used in the manufacture of absorber pads and fixes limits for the release of some production aids and impurities in cold water extraction tests, following the extraction procedure described in EN 645 | extraction procedure described in EN 645 states that finished articles must not have a preserving effect on foodstuffs |
| EL | Greek food code (Article 24) | <ul style="list-style-type: none"> - states that paper that comes from pure chemical pulp cannot contain barite (barium sulfate), calcite or salts of heavy metals (not as list) - provides very basic information on what can be used for the manufacturing of P&B intended for contact with milk, fruit juices and other liquid foods (not a list) | fixes limits for Cd, Pb, Hg and PCP in P&B for food contact | n/a |
| IT | D.M. of 21/03/1973 (and its amendments) | establishes lists of substances authorised for the manufacturing of P&B FCM | sets the maximum amounts for some of the substances, and specific migration limits for others (Titolo II, Capo IV, as amended by D.M. n.217 25/09/2007, D.M. n.74 04/04/2012) | reports the migration tests and analytical methods to be used (Titolo II, Capo IV, as amended by D.M. n.217 25/09/2007, Allegato IV) |
| IT | DPR n.777 23/08/1982 (and its amendment) | n/a | n/a | <ul style="list-style-type: none"> - establishes the obligation for the producer to have a declaration of compliance (Art. 4.5-4.6, Art. 5-bis.2) - establishes sanctions for contravening to the law (Art. 3, 5-bis, 6) |
| NL | Commodities Act (Packaging) | establishes a list of substances that can be used in the preparation of P&B (for general use, and for use as | - provides specifications on composition and purity of the substances that can be used in the preparation of P&B (base materials, | n/a |

| M S | Measure | Positive list / Negative list | Restrictions / QM / OM / SML | Basis for enforcement Test conditions Other (e.g. DoC, sanctions) |
|-----|---------------------------------|---|---|---|
| | s and Consumer Articles) | cooking packaging and for filtering of beverages were at temperatures higher than 80 °C), dividing them into categories.(Ch. 0, 0.3; Ch. II, 1., 1.2, 2, 2.2.2) | auxiliary materials and refining agents) and sets limits for residual contents of some substances. (Ch. II, 1, 1.2, 2, 2.2.2) - sets total migration limits for P&B (for general use, and for use as cooking packaging and for filtering of beverages were at temperatures higher than 80 °C) (Ch. 0, 0.5.1-0.5.4, 0.6; Ch. II, 1., 1.3, 2, 2.3) and it sets specific migration limits for P&B (for general use, and for use as cooking packaging and for filtering of beverages were at temperatures higher than 80 °C), (Ch. 0, 0.5.1-0.5.4, 0.6; Ch. II, 1., 1.3, 2, 2.3) | |
| P L | Polska Norma PN-P-50430 of 1998 | n/a (note: this seems a standard, but national legislation of limits was not available) | describes the limits for the migration of Cu, Fe, Zn, Cd, Pb, phenol, and formaldehyde in P&B | describes the method for the determination of Cu, Fe, Zn, Cd, Pb, phenol, and formaldehyde in P&B |
| S K | Foodstuffs Code 1799/2003 | reports the allowed starting materials and additives that can be used in the manufacturing of paper FCM | sets the maximum allowed quantities of some of the starting materials and additives that can be used as well as limits of migration for of some of the substances (Priloha č. 8) | n/a |

Standards

Standards for P&B exist to a limited extent they are reported.

| standard code and source | standard title |
|------------------------------|--|
| EN ISO 15318:1999 (ISO/TC 6) | Determination of 7 specified polychlorinated biphenyls (PCB) Gives guidance on a test method which permits the determination of seven specified PCBs in pulp, P&B |
| ISO 9197:2006 (ISO/TC 6) | Paper, board and pulps -- Determination of water-soluble chlorides Specifies a method for all types of paper, board and pulp. The lower limit of the determination is 20 mg of chloride ion per kilogram of dry sample. |
| ISO 15320:2011 (ISO/TC 6) | Pulp, P&B – Determination of pentachlorophenol (PCP) in an aqueous extract it was developed for P&B intended to come into contact with foodstuffs, but applicable to all types |
| ISO 11480:1997 (ISO/TC 6) | Pulp, P&B – Determination of total chlorine and organically bound chlorine. It is applicable to all types of pulp, P&B. The lower limit of the determination is about 20 mg/kg. |
| ISO 9198:2001 (ISO/TC 6) | Paper, board and pulp – Determination of water-soluble sulphates For all types of pulp, P&B. |
| ISO 5647:1990 (ISO/TC 6) | P&B -- Determination of titanium dioxide content Specifies a method for all types of P&B, in particular coated or filled products. It comprises two procedures for the final determination of titanium based on spectrophotometry and flame atomic absorption spectrophotometry, respectively. The limits of determination depend on the amount of sample taken. Titanium present in other forms will not interfere in the determination. |
| ISO 17812:2007 (ISO/TC 6) | Paper, board and pulps -- Determination of total magnesium, total calcium, total manganese, total iron and total copper. Specifies the procedure by atomic absorption spectrometry or by plasma emission spectrometry. The total content comprises the acid-soluble part of the element plus the acid-insoluble part of the element. It is applicable to all types of paper, board and pulps. |
| ISO 12830:2011 (ISO/TC 6) | Paper, board and pulps -- Determination of acid-soluble magnesium, calcium, manganese, iron, copper, sodium and potassium. Specifies the procedure by atomic absorption spectrometry or by plasma emission spectrometry. The acid-soluble element comprises the acid-soluble part of the incineration residue, i.e. that part of the ignition residue obtained after incineration which is soluble in hydrochloric acid. In the case where the residue is completely soluble, the result obtained by the procedure specified in this Standard is a measure of the total amount of each element in the sample. It is applicable to all types of P&B and pulps. The limit of determination depends on the element and instrument used. |
| ISO 10775:2013 (ISO/TC 6) | Paper, board and pulps -- Determination of cadmium content -- Atomic absorption spectrometric method Specifies a method for the determination of traces of cadmium in all types of paper, board and pulp, including products containing recycled fibre that can be wet-combusted in nitric acid. |
| EN 647:1993 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Preparation of a hot water extract Describes the preparation of a hot water extract for certain extractives in P&B for food contact |
| EN 645:1993 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Preparation of a cold water extract Describes the preparation of a cold water extract for certain extractives in P&B for food contact |
| EN 646:2006 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Determination of colour fastness of dyed P&B Describes procedures for the testing of dyed P&B intended to come into contact with foodstuffs. Two procedures are given. Procedure A for contact of long duration (e. g. food packaging) and procedure B for contact of short duration (e. g. napkins, kitchen papers, household papers). |
| EN 648:2006 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Determination of the fastness of fluorescent whitened P&B Two procedures are given, procedure A for contact of long duration (e. g. food packaging) and procedure B, for contact of short duration (e. g. napkins, kitchen papers, household papers). |
| EN 920:2000 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Determination of dry matter content in an aqueous extract. The test method is applicable to P&B intended for boiling or filtering of foodstuffs. |
| EN 1541:2001 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Determination of formaldehyde in an aqueous extract |
| EN 14338:2003 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Conditions for determination of migration from P&B using modified polyphenylene oxide (MPPO) as a simulant; Specifies a method to assess the transfer or migration of specific volatile and semivolatile substances from P&B. This test method is developed for P&B intended to come in contact with dry, non fatty foodstuffs and P&B for baking purposes. In the last case the modified polyphenylenoxide (MPPO) can be seen as a substitute simulant for fatty contact. |
| EN 1104:2005 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Determination of the transfer of antimicrobial constituents Specifies a method for the determination of transfer of antimicrobial constituents from P&B materials and articles intended for food contact. |
| EN 15519:2007 | P&B intended to come into contact with foodstuffs - Preparation of an organic solvent extract |

| standard code and source | standard title |
|---|---|
| (CEN/TC 172) | Specifies a test method for the assessment of substitute tests performed with volatile test media for the determination of migration from P&B for fatty food contact at all temperatures and for any period of time. |
| CEN/TR 15645-1-2-3:2008 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Calibration of the odour test - Part 1: Odour -- Specifies a written protocol to prepare calibration samples for assessment of odour released by a paper or board sample, and how to train the panel in the use of these calibration samples Part 2: Fatty food -- Specifies a written protocol to prepare calibration samples for assessing off-flavour (given by benzaldehyde) in a test substance representative of fatty food products (coconut oil). Essentially, this is meant to simulate the transfer of off-flavours from P&B to a fatty food product. Part 3: Dry food -- Specifies a written protocol to prepare calibration samples for assessment of off-flavour (given by benzaldehyde) in a test substance representative of dry food products (icing sugar). Essentially, this is meant to simulate the transfer of off-flavours from P&B to a dry food product. <i>This Technical Report also specifies how to train the panel in the use of the calibration samples.</i> <i>The general outline of the testing procedure consists of sensory assessment of the odour samples without formal training by a selected panel, followed by training of the panel, and finally sensory assessment of the odour samples after training by the same sensory panel. (technical report)</i> |
| EN 1230-1:2009 EN 1230-2:2009 (CEN/TC 172) | P&B intended to come into contact with foodstuffs - Sensory analysis - Part 1: Odour -- Specifies the test method for assessment of the odour released by a paper or board sample. It is applicable to all kinds of P&B, including coated and/or printed material, intended to come into direct or indirect contact with foodstuffs. Part 2: Off-flavour (taint) -- Specifies whether a paper or board sample contains substances which may be trans-mitted through the air space to a test substance and affect its taste. It is applicable to all kinds of P&B, including coated and printed material, intended to come into contact with foodstuffs. |
| EN 15845:2010 (CEN/TC 172) | P&B - Determination of the cytotoxicity of aqueous extracts This test method is intended to assess wet contact with food simulant. |
| EN 16453:2014 (CEN/TC 172) | Pulp, paper and paperboard - Determination of phthalates in extracts from paper and paperboard Specifies a method for the determination of phthalates in water, solvent and modified polyphenylene oxide (MPPO) extracts of P&B materials and articles intended for food contact using gas chromatography coupled to mass spectrometry (GC-MS). |
| EN 12498:2005 | P&B intended to come into contact with foodstuffs - Determination of cadmium and lead in an aqueous extract |
| EN 14719:2005 | Determination of the Diisopropyl naphthalene (DIPN) content by solvent extraction |
| EN 12497:2005 (CEN/TC 172) | Determination of mercury in an aqueous extract One in a series of Standards for the determination of heavy metals in an aqueous extract of paper/paperboard intended for contact with food. |
| CEN/TS 14234:2002 (CEN/TC 194) | Materials And Articles In Contact With Foodstuffs - Polymeric Coatings On P&B - Guide To The Selection Of Conditions And Test Methods For Overall Migration Provides test methods for 'alternative tests' and 'substitute tests' performed with volatile test media, iso-octane and a volume fraction of 95 % aqueous ethanol, for the determination of overall migration from polymeric coatings on P&B intended to come into contact with fatty foodstuffs. |

ISO/TC 6 Paper, board and pulps; CEN/TC 172 Pulp, paper and board

In addition the Amtliche Sammlung von Untersuchungsverfahren nach §64 LFGB reports analytical methods for the determination of PCBs (BVL B 80.56-1, 1991-05), diisopropyl naphthalene (DIPN) (BVL B 80.56-8, 2008-10 – copy of DIN EN 14719:2005-10), antimicrobial constituents (BVL B 80.56-5, 2008-10 – copy of DIN EN 1104:2005-09), and 1,3-dichloro-2-propanol and 3-monochloro-1,2-propanediol (BVL B 80.56-2, 2002-09 and BVL B 80.56-2 Berichtigung, 2004-06) in P&B or in extracts of P&B as well as the colour fastness of P&B samples (BVL B 80.56-3, 2008-10 – copy of DIN EN 646:2006-07, BVL B 80.56-4, 2008-10 – copy of DIN EN 648:2006-12). Some of these methods are copies of EN-standards. Beyond the EU, the Korean Standards Association adapted an ISO standard for paper (KS M ISO 15318:2007). Swiss Standards adapted several CEN standards (SN EN 647:1994, SN EN 1541:2001, SN EN 14338:2004, SN EN 12497:2005, SN EN 12498:2005, SN EN 1104:2005, SN EN 646:2006, SN EN 648:2008, SN EN 1230-1:2010 and SN EN 1230-2:2010).

Substances in common in three or more MSs.

List: Colour coding: blue: qualitative restrictions; light orange: restriction but low fit between limits, dark orange: common restrictions and better fit.

| Substance name, CAS Number | Legislation | Restrictions and comments |
|--|--|---|
| 1-bromo-3-chloro-5,5-dimethylhydantoin 16079-88-2 | CZ 38/2001 A. 12 | not more than 0.04 %, relative to the dry fibre; hypochlorite and hypobromite shall not be detectable in the extract of the finished products. As slimicide |
| | CoE P.S. paper and board | to be fixed, as additive |
| | SK 1799/2003 A. 8 | not more than 0.04 %. As slimicide |
| 1,2-Benzisothiazolin-3-one 2634-33-5 | DE Recomm. 36 | No more than 10 µg/dm ² of this substance must be detectable in the extract of the finished product. As slimicide and preservative |
| | FR Lettre-circulaire du 4 janvier 1982 | Admis dans la préparation : 1,2 benzisothiazoline-3-one, 2,2'-dithiobisbenzamide et chlorbenzisothiazolone = 9,5 % ; propylène glycol = 45 % ; soude caustique = 2,6 % ; eau q.s. = 100 %. Comme agent bactéricide à 56 grammes de 1,2 benzoisothiazoline-3-one par tonne de papier sec, comme agent de préservation dans les adhésifs et autres compositions aqueuses pour les revêtement du papier du papier à la dose de 0,03 gramme de 1,2 benzisothiazoline-3-one par 100 grammes de composition aqueuse |
| | NL II 1.2.2 c, NL II 1.2.2 k | SML = 30 mg/kg. As slimicide, exclusively for use in process water or as other additive or as preservative |
| | IT D.M. 21/3/73 | Not detectable with the test in Annex IV DM21/3/73, Sect.3 point 6. As technological adjuvant |
| | CZ 38/2001 A. 12 | not more than 0.15 mg.dm ⁻² ; in the extract of the finished products this substance shall not be detectable at the method detection limit: 5 µg.dm ⁻² . As slimicide, also used for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers |
| | CoE P.S. paper and | SML = 0.5 mg/kg. Only to be used in aqueous polymer dispersions and emulsions and at |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|---|---|--|
| | board | concentrations which do not result in an anti-microbial effect at the surface of the polymer or on the food itself. As additive |
| | HR NN 125/2009 | this substance must not be detectable in the extract below detection limit: 5µg/dm ² |
| | SK 1799/2003 A. 8 | not more than 0.15 mg.dm ⁻² . As slimicide |
| 1,2-Dibromo-2,4-dicyanobutane 35691-65-7 | DE Recomm. 36 | max. 0.005 %, based on dry fibres weight. This substance must not be detectable in extract of the finished product (detection limit of method of analysis: 0.6 µg/dm ²) |
| | CZ 38/2001 A. 12 | not more than 0.005 % relative to the dry fibre; in the extract this substance shall not be detectable at the method detection limit: 0.6 µg.dm ⁻² . As slimicide |
| | CoE P.S. paper and board | to be fixed, as additive |
| | HR NN 125/2009 | this substance must not be detectable in the extract below detection limit: 0.6 µg/dm ² |
| | SK 1799/2003 A. 8 | not more than 0.005 %. As slimicide |
| 1,2-Propanediol 57-55-6 | FR Lettre-Circulaire du 28 octobre 1980 | Admis dans la préparation : 1,2 benzisothiazoline-3-one, 2,2'-dithiobisbenzamide et chlorbenzisothiazolone = 9,5 % ; propylène glycol = 45 % ; soude caustique = 2,6 % ; eau q.s. = 100 %. Préparation : 18 % de 2-bromo-2-nitropropane-1,3diol + 12 % de bromure de sodium + 25 % de propylène glycol + 45 % d'eau |
| | NL II 1.2.2 j | as moisture control agent |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | CoE P.S. paper and board | as additive |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| 1,4-bis(bromoacetoxy)butane 20679-58-7 | CZ 38/2001 A. 12 | in the extract of finished products there may be a maximum of 0.01 mg of bromine.dm ⁻² . As slimicide |
| | DE Recomm. 36 | Extract of the finished products must contain no more than 0.01 mg bromine per dm ² . As slimicide |
| | HR NN 125/2009 | the content of bromine in the extract of the finished product may not exceed 0.01 mg/dm ² |
| | SK 1799/2003 A. 8 | in the extract of finished products there may be a maximum of 0.01 mg of bromine.dm ⁻² . As slimicide |
| 2-(Thiocyanomethylthio)benzothiazole 21564-17-0 | DE Recomm. 36 | max. 0.00045 %, based on dry fibres weight. As slimicide |
| | FR A of 7/05/1996 of CSHPF | 0,5 g/kg of material |
| | CoE P.S. paper and board | to be fixed, as additive |
| 2-Amino-2-methylpropanol 124-68-5 | DE Recomm. 36 | no more than 0.25 mg/dm ² must be detectable in extract of the finished product. Dispersion and flotation agent |
| | HR NN 125/2009 | no more than 0.25 mg/dm ² must be detectable in extract of the finished product |
| | CoE P.S. paper and board | to be fixed, as additive |
| 2-Aminoethanol 141-43-5 | DE Recomm. 36 | max. 0.1 %, based on the dry fibres weight No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002. BfR 36: wet-strength agent BfR 36/1: paper-refining agent BfR 36/2: wet-strengt agent |
| | NL II 1.2.2 r | as other additive |
| | CoE P.S. paper and board | SML = 0.05 mg/kg. As additive |
| 2-Bromo-2-nitro-1,3-propanediol 52-51-7 | DE Recomm. 36 | max. 0.003 %, based on dry fibres weight. This substance must not be detectable in extract of the finished product |
| | FR A of 7/05/1996 of CSHPF | |
| | CoE P.S. paper and board | to be fixed, as additive |
| | CZ 38/2001 A. 12 | not more than 0.003 % relative to the dry fibre; this substance shall not be detectable in the extract of the finished products. As slimicide |
| | HR NN 125/2009 | This substance must not be detectable in extract of the finished products |
| SK 1799/2003 A. 8 | not more than 0.003 %. As slimicide | |
| 2-Bromo-2-nitrostyrene 7166-19-0 | DE Recomm. 36 | max. 0.045 %, based on dry fibres weight. This substance must not be detectable in the extract of the finished product (detection limit: 0.06 mg/kg paper). Experiments have shown that following cold extraction with n-heptane, the conversion products, benzaldehyde and bromonitromethane are not detectable in the finished product (detection limits for benzaldehyde and bromonitromethane = 0.04 and 2.0 mg/kg, respectively). |
| | CoE P.S. paper and board | to be fixed, as additive |
| | HR NN 125/2009 | this substance must not be detectable in the extract below detection limit: 0.06 mg/kg |
| 2-Bromo-4'-hydroxyacetophenone 2491-38-5 | NL II 1.2.2 k | max 0.006% in coating. As preservative |
| | IT D.M. 21/3/73 | Not detectable with the test in Annex IV DM21/3/73, Sect.3 point 6. As technological adjuvant |
| | CoE P.S. paper and board | to be fixed, as additive |
| 2-Mercaptobenzothiazole, sodium salt 2492-26-4 149-30-4 | NL II 1.2.2 c, NL II 1.2.2 r | max 0.05% in EP; SML = ND. as slimicide, exclusively for use in process water or as other additive |
| | HR NN 125/2009 | This substance must not be detectable in extract of the finished products |
| | CoE P.S. paper and board | to be fixed, as additive |
| | DE Recomm. 36 | Neither substance, nor their conversion products (mainly methylthiourea, N,N'-dimethylthiourea and dithiocarbamates) must be detectable in extract of the finished |

| Substance name, CAS Number | Legislation | Restrictions and comments |
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| | | product. As slimicide |
| 2-Methyl-4-isothiazolin-3-one 2682-20-4 | DE Recomm. 36 | No more than 1 µg/dm ² of this substance must be detectable in the extract of the finished product. As slimicide and preservative |
| | NL II 1.2.2 c | SML = 0.01 mg/kg. As slimicide, exclusively for use in process water |
| | CoE P.S. paper and board | SML = 0.5 mg/kg. Only to be used in aqueous polymer dispersions and emulsions and at concentrations which do not result in an anti-microbial effect at the surface of the polymer or on the food itself. As additive |
| | IT D.M. 21/3/73 am IT D.M. 7/08/87 and IT D.M. 24/02/95 | The migrateable residue in the paper and board must not exceed 0.1 ppm. As technological adjuvant |
| 2-Oxo-2(4-hydroxyphenyl)-acethydroxamic acid chloride | DE Recomm. 36 | This substance must not be detectable in extract of the finished products |
| | CZ 38/2001 A. 12 | this substance shall not be detectable in the extract of the finished products. As slimicide |
| | HR NN 125/2009 | This substance must not be detectable in extract of the finished products |
| | SK 1799/2003 A. 8 | neither the substance nor its degradation products shall be detectable in the extract of the final material or finished product. As slimicide |
| 2-Phenylphenol, sodium salt 132-27-4 | DE Recomm. 36 | max 0.01 % for o-Phenyl phenol and its sodium and potassium salts. As preservatives |
| | NL II 1.2.2 k | SML = 0.1 mg/kg. As preservative |
| | CoE P.S. paper and board | to be fixed, as additive |
| 2,2-Dibromo-2-cyanoacetamide 10222-01-2 | DE Recomm. 36 | max. 0.0045 %, based on dry fibres weight |
| | CoE P.S. paper and board | to be fixed |
| | CZ 38/2001 A. 12 | not more than 0.0045 %, relative to the dry fibre; this substance shall not be detectable in the extract of the finished products. As slimicide |
| | HR NN 125/2009 | This substance must not be detectable in extract of the finished products |
| | SK 1799/2003 A. 8 | not more than 0.0045 %. As slimicide |
| 3,5-Dimethyl-1,3,5,2h-tetrahydrothiadiazine-2-thione 533-74-4 | NL II 1.2.2 c, NL II 1.2.2 k | SML = 0.3 mg/kg. As slimicide, exclusively for use in process water or as other additive or as preservative |
| | DE Recomm. 36 | This substance must not be detectable in extract of the finished products. As slimicide |
| | BE Arr. 11/5/92 A.4, III | extraction 0. As bactericide |
| | CoE P.S. paper and board | to be fixed, as additive |
| | CZ 38/2001 A. 12 | this processing aid shall not be detectable in the finished products. As slimicide |
| | HR NN 125/2009 | This substance must not be detectable in extract of the finished products |
| | SK 1799/2003 A. 8 | neither the substance nor its degradation products shall be detectable in the extract of the final material or finished product. As slimicide |
| | 4,4'-bis[[4-[bis(2-Hydroxyethyl)amino]-6-(m-sulphoanilino)-s-triazine-2-yl]amino]-2,2'-stilbenedisulphonic acid 47910-88-3 | NL II 1.2.2 p |
| CZ 38/2001 A. 12 | | The sodium salts are also allowed. Not more than 0.3 % of sulphonated derivatives of stilbene may be used. As dye and optical whitener |
| SK 1799/2003 A. 8 | | The sodium salts are also allowed. An aggregate quantity of not more than 0.1 % of dyes and optical brighteners may be used. As dye and optical whitener |
| 4,4'-bis[[4-[bis(2-Hydroxyethyl)amino]-6-(o-sulphoanilino)-s-triazine-2-yl]amino]-2,2'-stilbenedisulphonic acid NO CAS | NL II 1.2.2 p | The ammonium-, potassium-, sodium-, calcium- and magnesium salts of this acid are also allowed. SML (total of all types of stilbenedisulphonic acids) = 6 mg/kg . As optical whitener |
| | CZ 38/2001 A. 12 | The sodium salts are also allowed. Not more than 0.3 % of sulphonated derivatives of stilbene may be used. As dye and optical whitener |
| | SK 1799/2003 A. 8 | The sodium salts are also allowed. An aggregate quantity of not more than 0.1 % of dyes and optical brighteners may be used. As dye and optical whitener |
| 4,4'-Bis[[4-[(2-cyanoethyl) (2-hydroxypropyl)amino]-6-(2,5-disulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, hexasodium salt 76508-02-6 | FR Avis du CSHPF du 13/10/98 | |
| | IT D.M. 21/3/73 am D 267 30/05/01 | max amount 0.3% p/p , for individual components or all together. As optical whitening |
| | CoE P.S. paper and board | to be fixed, as additive |
| 4,4'-Bis[[4-[bis(2-hydroxyethyl)amino]-6-(2,5-disulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, hexasodium salt 68971-49-3 | FR Avis du CSHPF du 13/10/98 | |
| | IT D.M. 21/3/73 am D 267 30/05/01 | max amount 0.3% p/p , for individual components or all together. As optical whitening |
| | CoE P.S. paper and board | to be fixed, as additive |
| 4,4'-Bis[[4-[bis(2-hydroxyethyl)amino]-6-(p-sulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, tetrasodium salt 16470-24-9 | FR Avis du CSHPF du 13/10/98 | |
| | CoE P.S. paper and board | to be fixed, as additive |
| | IT D.M. 21/3/73 am D 267 30/05/01 | max amount 0.3% p/p , for individual components or all together. As optical whitening |
| 4,4'-Bis[[4-anilino-6-[(2-carbamoyl)ethyl]-2- | FR Avis du CSHPF du 13/10/98 | A |
| | IT D.M. 21/3/73 am D | max amount 0.3% p/p , for individual components or all together. As optical whitening |

| Substance name, CAS Number | Legislation | Restrictions and comments |
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| hydroxyethyl)amino]-s-triazin-2-yl]amino]-2,2'-stilbenedisulphonic acid, disodium salt 27344-06-5 | 267 30/05/01 | |
| | CoE P.S. paper and board | to be fixed, as additive |
| 4,4'-Bis[[4-diethylamino-6-(2,5-disulphoanilino)-s-triazin-2-yl]amino]-2,2'-stilbene-disulphonic acid 41098-56-0 | FR Avis du CSHPF du 13/10/98 | Hexasodium salt is also allowed |
| | IT D.M. 21/3/73 am D 267 30/05/01 | max amount 0.3% p/p, for individual components or all together. As optical whitening |
| | NL II 1.2.2 p | The ammonium-, potassium-, sodium-, calcium- and magnesium salts of this acid are also allowed. SML (total of all types of stilbenedisulphonic acids) = 6 mg/kg. As optical whitener |
| | CoE P.S. paper and board | Hexasodium salt is also allowed. To be fixed, as additive |
| | CZ 38/2001 A. 12 | The sodium salts are also allowed. Not more than 0.3 % of sulphonated derivatives of stilbene may be used. As dye and optical whitener |
| | SK 1799/2003 A. 8 | The sodium salts are also allowed. An aggregate quantity of not more than 0.1 % of dyes and optical brighteners may be used. As dye and optical whitener |
| 4,5-Dichloro-1,2-dithiol-3-one 1192-52-5 | DE Recomm. 36 | max. 0.004 %, based on dry fibres weight. Extract of finished products must not contain more than 2.0 mg of this substance per kg dry fibres |
| | CoE P.S. paper and board | to be fixed, as additive |
| | CZ 38/2001 A. 12 | not more than 0.004 % relative to the dry fibre; in the extract this processing aid shall not be detectable in an amount greater than 2.0 mg.kg ⁻¹ relative to the dry fibre. As slimicide |
| | HR NN 125/2009 | the content in the extract of the finished product may not contain more than 2.0 mg/kg in relation to dry fibres |
| | SK 1799/2003 A. 8 | not more than 0.004 %. As slimicide |
| Adduct of 70 % benzyl alcohol and 30 % formaldehyde | DE Recomm. 36 | Extract of the finished products must contain no more than 1.0 mg formaldehyde/dm ² . As preservative, CAS of benzyl alcohol: 100-51-6 |
| | CZ 38/2001 A. 12 | may be used in amounts necessary to ensure that raw materials, processing aids and paper treatment agents are protected from spoilage. Packaging, by the addition of those, shall not have a preservative effect on the foods that are in contact with it. As preservative |
| | SK 1799/2003 A. 8 | may be used in quantities necessary to ensure that the raw material, additives and processing agents for the paper are protected from deterioration. Packaging material with the addition of these substances shall not have a preservation effect on the food in contact with it. As preservative |
| Alginates | DE Recomm. 36 | The general and specific purity requirements after Annex 2, List A, Part II of the Regulation on Food Additives (Zusatzstoff-Verkehrsverordnung) apply. The general and specific purity requirements after Annex 2, List A, Part II of the Regulation on Food Additives (Zusatzstoff-Verkehrsverordnung) apply |
| | CZ 38/2001 A. 12 | 1 kg of these substances shall not contain more than: 3 mg arsenic, 10 mg lead, 25 mg zinc, 50 mg copper and zinc on aggregate, 2 mg mercury, 2 mg cadmium and 10 polychlorinated biphenyls (of which 5 mg of PCB 60); the sum of these impurities shall not exceed 50 mg.kg ⁻¹ . As agents for surface treatment and painting |
| | SK 1799/2003 A. 8 | (slimy substances of seaweed). An aggregate quantity of not more than 0.1 % of agents to adjust the viscosity of pigmented mixtures may be used. As agents for surface treatment and painting and as agent to adjust the viscosity of pigmented mixtures |
| Aluminium oxide 1344-28-1 | CZ 38/2001 A. 12 | shall comply with the filler purity requirements referred to in Section 7 of the Implementing Decree. For the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers, as fillers |
| | CoE P.S. paper and board | as additive |
| | DE Recomm. 36 | as auxiliary agent |
| Aluminium sulphate 10043-01-3 | BE Arr. 11/5/92 A.4, III | as fixer or participant |
| | CZ 38/2001 A. 12 | as filler and processing aid, also as neutraliser and precipitation agent for cooking bags, for paper for hot filtration and filtering layers used in hot filtration and for the manufacture of paper for use as filtering layers in cold filtration (filtering layers means products weighing 500 mg.m ⁻² or more) |
| | CoE P.S. towels and napkins | as retention aid |
| | DE Recomm. 36 | 36: precipitating, fixing and parchmentisation agent 36/1: special raw material and production aid for cook-in packages 36/2: precipitating, fixing and parchmentisation agent |
| | SK 1799/2003 A. 8 | as fillers and precipitating and fixing agent |
| Ammonia 7664-41-7 | NL II 1.2.2 e, NL II 2.2.2 a | as dispersion, flotation or antifoam agent, or as basic additive |
| | CZ 38/2001 A. 12 | as precipitant, fixing and parchment agent; also for cooking bags |
| | CoE P.S. paper and board | as additive |
| | DE Recomm. 36 | 36: precipitating, fixing and parchmentisation agent 36/1: neutralising and precipitating agent for cook-in packages 36/2: precipitating, fixing and parchmentisation agent |
| | SK 1799/2003 A. 8 | as precipitating and fixing agent |
| Ammonium bis-(N-ethyl-2-perfluoroalkylsulfonamide ethyl) phosphates not containing more than 15 % ammonium mono-(N-ethyl-2-perfluoroalkylsulfonamide ethyl) phosphates | BE Arr. 11/5/92 A.4, III | maximum usable dose, on the surface, of 8.3 mg/dm ² Fluorine dose: maximum content of 4.4 mg F/dm ² of paper. As processing aid |
| | CZ 38/2001 A. 12 | the content of the C ₈ alkyl groups of the two compounds, relative to the total content of alkyl groups, shall amount to more than 95 %, the content of fluorine in these compounds shall not be less than 50 % or greater than 55 %; paper, cardboard and paperboard treated with the this impregnating agent shall not come into contact with food containing alcohol; for paper, cardboard and paperboard coming into contact with non-alcoholic food at temperatures lower than 66 °C, it may be used in a maximum amount of 8.3 mg.dm ⁻² |

| Substance name, CAS Number | Legislation | Restrictions and comments |
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| NO CAS | | (equivalent to 4.4 mg fluorine.dm ⁻²); for paper, cardboard and paperboard coming into contact with non-alcoholic food at temperatures higher than 66 °C, it may be used in a maximum amount of 4.3 mg.dm ⁻² (equivalent to 2.2 mg fluorine.dm ⁻²). As agent for surface treatment and painting |
| | HR NN 125/2009 | Where the temperature at which it comes into contact with food is up to 66 °C, it must not release more than 8.3 mg/dm ² of this compound (i.e. 4.4 mg/dm ² of fluorine), and where the temperature is higher than 66 °C, it must not release more than 4.3 mg/dm ² of this compound (i.e. 2.2 mg/dm ² of fluorine) |
| Ammonium salt of a copolymer of an anhydride of maleic acid, an isopropyl polyester of maleic acid and diisobutylene | CZ 38/2001 A. 12 | maximum 0.5 % by weight of dry paper, cardboard and paperboard. As processing aid |
| | SK 1799/2003 A. 8 | total maximum 0.5 %. As sizing agent |
| Ammonium salt of a copolymer of styrene (approx. 60 %), acrylic acid (approx. 23 %) and maleic acid (approx. 17 %) | DE Recomm. 36 | max. 0.5 %, based on weight of the dry paper. As sizing agent |
| | DE Recomm. 36 | max. 0.5 %, based on the dry fibres weight. As sizing agent |
| | CZ 38/2001 A. 12 | maximum 0.5 % by weight of dry paper, cardboard and paperboard. As processing aid |
| | SK 1799/2003 A. 8 | maximum 0.5 %. As sizing agent |
| Anionic, water-soluble polyurethanes, made from glycerol monostearate, toluylene diisocyanate, dimethylol propionic acid and N-methyl diethanol amine (mean mol. wt. 10 000) | DE Recomm. 36 | (mean mol. wt. 10 000) max. 0.15 %, based on the fibres weight. In producing the aforementioned polyurethanes, in each case a maximum of 0.03 % dibutyl tin diacetate, based on the sizing agent, may be used; 1 dm ² of sized paper must not contain more than 0.3 µg dibutyl tin diacetate. Primary aromatic amines must not be detectable in extract of the finished product. As preservative for the aforementioned polyurethanes, max. 0.5 % formaldehyde, based on the sizing agent, may be used. Obey BfR footnotes concerning epichlorohydrine and primary aromatic amines. As sizing agent |
| | CZ 38/2001 A. 12 | not more than 0.15 % relative to the dry fibre; Not more than 0.03 % of stannic dibutyl diacetate, relative to the sizing agent, shall be used to manufacture the above polyurethanes; 1 dm ² of sized paper shall not contain more than 0.3 mg of stannous dibutyl diacetate. As processing aid |
| | SK 1799/2003 A. 8 | not more than 0.15 %; a maximum of 0.03 % dibutyl tin acetate, relative to the sizing agent, may be used in the manufacture of such polyurethanes; 1 dm ² of paper treated with sizing agent shall not contain more than 0.3 mg dibutyl tin acetate. As sizing agent |
| Anthraquinone 84-65-1 | DE Recomm. 36 | max. 0.15 %, based on the finished paper. 1 kg of dry paper must not contain more than 30 mg anthraquinone. Most of the anthraquinone is washed out during manufacture |
| | CZ 38/2001 A. 12 | no more than 0.15 %, relative to the finished paper The residual content of anthraquinone shall not be higher than 30 mg.kg ⁻¹ of dry paper. As an accelerator for separating lignin and cellulose from wood |
| | CoE P.S. paper and board | to be fixed, as additive |
| Arabic gum 9000-01-5 | CZ 38/2001 A. 12 | as processing aid |
| | CoE P.S. paper and board | as additive |
| | SK 1799/2003 A. 8 | as sizing agent |
| Barium sulphate 7727-43-7 | IT D.M. 21/3/73 | 0.1 N HCl Soluble barium :max 0.01%. As additive filler |
| | DE Recomm. 36 | free of soluble barium compounds. As filler |
| | CZ 38/2001 A. 12 | free of soluble barium salts, purity according to the 1997 Czech Pharmacopoeia. As filler |
| | SK 1799/2003 A. 8 | purity according to the Slovak Pharmacopoeia. As fillers |
| Beeswax 8012-89-3 | NL II 1.2.2 i | as paraffin or waxe |
| | CoE P.S. paper and board | as additive |
| | SK 1799/2003 A. 8 | as agents for surface treatment and painting |
| Bentonite 1302-78-9 | CZ 38/2001 A. 12 | as fillers |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | as retention aid |
| | SK 1799/2003 A. 8 | as fillers |
| Benzoic acid 65-85-0 | CoE P.S. paper and board | as additive |
| | DE Recomm. 36 | as preservative |
| | HR NN 125/2009 | not more than 1 g per 1 m ² of paper |
| Benzoic acid and its sodium, potassium and calcium salts | IT D.M. 21/3/73 | Not detectable in the test in Annex IV DM 21/3/73 sect.3, point 6. As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | CZ 38/2001 A. 12 | may be used in amounts necessary to ensure that raw materials, processing aids and paper treatment agents are protected from spoilage. Packaging, by the addition of those, shall not have a preservative effect on the foods that are in contact with it. As preservative |
| | NL II 1.2.2 k | as preservative |
| | SK 1799/2003 A. 8 | may be used in quantities necessary to ensure that the raw material, additives and processing agents for the paper are protected from deterioration. Packaging material with the addition of these substances shall not have a preservation effect on the food in contact with it. As preservative |
| Bromohydroxyacetophenone | CZ 38/2001 A. 12 | this processing aid shall not be detectable in the extract of the finished products. As slimicide |
| | HR NN 125/2009 | This substance must not be detectable in extract of the finished products |
| | SK 1799/2003 A. 8 | neither the substance nor its degradation products shall be detectable in the extract of the final material or finished product. As slimicide |
| Calcium carbonate 72608-12-9 | IT D.M. 21/3/73 | As additive filler |
| | BE Arr. 11/5/92 A.4, III | As fillers |
| | CZ 38/2001 A. 12 | very finely ground, free of BaE ₂ +; |

| Substance name, CAS Number | Legislation | Restrictions and comments |
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| | | shall comply with the filler purity requirements referred to in Section 7 of the Implementing Decree. As fillers, also used for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers |
| | SK 1799/2003 A. 8 | very finely ground, free of divalent barium. As fillers |
| Calcium chloride 10043-52-4 | IT D.M. 21/3/73 | As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | NL II 1.2.2 j | as moisture control agent |
| | BE Arr. 11/5/92 A.4, III | Where several softeners are used simultaneously, their total quantity must not exceed 7 %. As softener |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| Calcium sulphate 99400-01-8 | IT D.M. 21/3/73 | As additive filler |
| | BE Arr. 11/5/92 A.4, III | As fillers |
| | DE Recomm. 36 | 36: filler 36/1: auxiliary agent 36/2: filler |
| | CZ 38/2001 A. 12 | shall comply with the filler purity requirements referred to in Section 7 of the Implementing Decree. For the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers, as fillers |
| | CZ 38/2001 A. 12 | (free of BaE2+). As fillers |
| | SK 1799/2003 A. 8 | free of divalent barium. As fillers |
| Calcium sulphoaluminate (white satin) 12004-14-7 | IT D.M. 21/3/73 | As additive filler |
| | CoE P.S. paper and board | as additive |
| | DE Recomm. 36 | as filler |
| Carboxymethyl cellulose 9000-11-7 | NL II 1.2.2 h | as size- and fibre-binding agents |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | Typical range of dosage mg/dm ² : 0.03 to 5; 0 - 4* (as pick-up glue); 0 to 0.03* (as tail sea glue). As dry strength and laminating glue *Typical ranges of dosage were calculated for both "tail seal glue" and "pick-up glue", from on-machine glue consumption versus kitchen roll production. Although "pick-up glue" is present only on the core and "tail seal glue" only at the end of the roll, it is calculated as an average for the total surface of the paper contained in the roll. |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 0.1 % of agents to adjust the viscosity of pigmented mixtures may be used. As agent for surface treatment and painting, as agent to adjust the viscosity of pigmented mixtures as binder of pigmented mixtures and as agent to increase water retention in coating compositions |
| Carboxymethylcellulose, sodium salt [or sodium carboxymethylcellulose] 9004-32-4 | BE Arr. 11/5/92 A.4, III | (technically pure quality). As binder |
| | DE Recomm. 36 | BfR 36: technically pure. The Sodium glycolate content may not exceed 12 %. BfR 36/1: purity at least 98 % BfR 36/2: technically pure. The Sodium glycolate content may not exceed 12 %. BfR 36: Sizing agent and Surface refining and coating agent BfR 36/1: For tea bags BfR 36/2: Sizing and fibre binding agent and Surface refining agents for the food-contact surface |
| | CZ 38/2001 A. 12 | (pure), 1 kg of these substances shall not contain more than: 3 mg arsenic, 10 mg lead, 25 mg zinc, 50 mg copper and zinc on aggregate, 2 mg mercury, 2 mg cadmium and 5 g sodium glycolate; the sum of these impurities shall not exceed 50 mg.kg ⁻¹ . As agents for surface treatment and painting and agents for surface finishing and laminating for teabags |
| | SK 1799/2003 A. 8 | technically pure; sodium glycolate impurities shall be removed in the manufacture of paper, paperboard and cardboard. As sizing agent |
| | CZ 38/2001 A. 12 | as processing aid. Sodium glycolate impurities shall be completely removed in the manufacture of paper, cardboard and paperboard |
| Casein and vegetable protein | CZ 38/2001 A. 12 | 1 kg of these substances shall not contain more than: 3 mg arsenic, 10 mg lead, 2 mg mercury, 2 mg cadmium and chlorinated biphenyls; the sum of these impurities shall not exceed 50 mg.kg ⁻¹ . As agent for surface treatment and painting |
| | DE Recomm. 36 | as surface refining and coating agent |
| | SK 1799/2003 A. 8 | maximum limit of 6.0 % glyoxal (by weight of protein), only for paper materials not coming into direct contact with food. As agent for surface treatment and painting |
| Cationic water-soluble polyurethane crosslinked with epichlorohydrin, prepared from glycerol monostearate, toluene diisocyanate and N-methyl-diethanolamine (average molecular weight of 10 000) | CZ 38/2001 A. 12 | not more than 0.6 % relative to the dry fibre; the ethyleneimine and epichlorohydrin shall not be detectable at a method sensitivity of 100 ppb; Not more than 0.03 % of stannic dibutyl diacetate, relative to the sizing agent, shall be used to manufacture the above polyurethanes; 1 dm ² of sized paper shall not contain more than 0.3 mg of stannous dibutyl diacetate. As processing aid |
| | DE Recomm. 36 | (mean mol. wt. 100 000) max. 0.6 %, based on the fibres weight. In producing the aforementioned polyurethanes, in each case a maximum of 0.03 % dibutyl tin diacetate, based on the sizing agent, may be used; 1 dm ² of sized paper must not contain more than 0.3 µg dibutyl tin diacetate. Primary aromatic amines must not be detectable in extract of the finished product. As preservative for the aforementioned polyurethanes, max. 0.5 % formaldehyde, based on the sizing agent, may be used. Obey BfR footnotes concerning epichlorohydrine and primary aromatic amines. As sizing agent |
| | SK 1799/2003 A. 8 | not more than 0.6 %; ethyleneimine and epichlorohydrin shall not be detectable at a DL of 100 mg.kg ⁻¹ ; a maximum of 0.03 % dibutyl tin acetate, relative to the sizing agent, may be used in the manufacture of such polyurethanes; 1 dm ² of paper treated with sizing agent shall not contain more than 0.3 mg dibutyl tin acetate. As sizing agent |
| Cationic water-soluble polyurethanes made from glycerol monostearate, toluene diisocyanate and N-methyl-diethanolamine (average molecular | CZ 38/2001 A. 12 | not more than 0.15 % relative to the dry fibre; Not more than 0.03 % of stannic dibutyl diacetate, relative to the sizing agent, shall be used to manufacture the above polyurethanes; 1 dm ² of sized paper shall not contain more than 0.3 mg of stannous dibutyl diacetate. As processing aid |
| | DE Recomm. 36 | (mean mol. wt. 10 000) max. 0.15 %, based on the fibres weight. In producing the aforementioned polyurethanes, in each case a maximum of 0.03 % dibutyl tin diacetate, based on the sizing agent, may be used; 1 dm ² of sized paper must not contain more than |

| Substance name, CAS Number | Legislation | Restrictions and comments |
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| weight of 10 000) | | 0.3 µg dibutyl tin diacetate. Primary aromatic amines must not be detectable in extract of the finished product. As preservative for the aforementioned polyurethanes, max. 0.5 % formaldehyde, based on the sizing agent, may be used. Obey BfR footnotes concerning epichlorohydrine and primary aromatic amines. As sizing agent |
| | SK 1799/2003 A. 8 | not more than 0.15 %; a maximum of 0.03 % dibutyl tin acetate, relative to the sizing agent, may be used in the manufacture of such polyurethanes; 1 dm ² of paper treated with sizing agent shall not contain more than 0.3 mg dibutyl tin acetate. As sizing agent |
| Cellulose ethers [or cellulose ethers (technically pure qualities)] | IT D.M. 21/3/73 | 0,5 % max. It must be free from monomers. The treated papers and boards must comply with the requirements of Title II, Point I DM 21/03/73. As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | DE Recomm. 36 | as sizing agent |
| | BE Arr. 11/5/92 A.4, III | maximum usable dose, on the surface, of 4 g/m ² . As binder |
| Chlorine dioxide 10049-04-4 | DE Recomm. 36 | no restriction. BfR 36: Slimicide BfR 36/1: Slimicide BfR 36/2: Slimicide BfR 36/3: Slimicide |
| | NL II 1.2.2 d | as bleaching agents |
| | CZ 38/2001 A. 12 | for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers, as slimicides |
| | CoE P.S. paper and board | to be fixed, as additive |
| | CoE P.S. towels and napkins | as broke treatment |
| Cyanodithiocarbamic acid, disodium salt [or disodium cyanodithioimidocarbamate] 138-93-2 | DE Recomm. 36 | Neither substance must not be detectable in extract of the finished products. As slimicide |
| | HR NN 125/2009 | This substance must not be detectable in extract of the finished products |
| | CoE P.S. paper and board | to be fixed, as additive |
| Dextrin 9004-53-9 | NL II 1.2.2 h | as size- and fibre-binding agents |
| | CZ 38/2001 A. 12 | as processing aid |
| | CoE P.S. paper and board | In compliance with the FCC specifications. As additive |
| | CoE P.S. towels and napkins | Typical range of dosage mg/dm ² : 0 to 0.5. As laminating glue |
| | SK 1799/2003 A. 8 | as sizing agent |
| Di-alkyl (C ₁₀ -C ₁₈) of diketene | CZ 38/2001 A. 12 | not more than 0.5 %. As processing aid |
| | DE Recomm. 36 | max. 0.5%. As size- and fibre-binding agents |
| | SK 1799/2003 A. 8 | a maximum of 0.5 %. As sizing agent |
| Didecyl dimethyl ammonium chloride 7173-51-5 | DE Recomm. 36 | max. 0.05 %, based on the dry fibres weight. Not in 2002/72 slimicide |
| | CZ 38/2001 A. 12 | not more than 0.05 % relative to the dry fibre. As slimicide |
| | CoE P.S. paper and board | to be fixed, as additive |
| | DE Recomm. 36 | max. 0.05 %, based on the dry fibres weight. As slimicide |
| | SK 1799/2003 A. 8 | not more than 0.05 %. As slimicide |
| Dipropylene glycol [or 1,1'-oxydipropan-2-ol] Dipropylene glycol, free from dethyleneglycol 25265-71-8 110-98-5 | CoE P.S. paper and board | as additive |
| | NL II 1.2.2 r | SML = 30 (total of 1,1'-Oxydipropan-2-ol, bis(2-hydroxyethyl) ether and ethanediol). As other additive |
| | IT D.M. 21/3/73 | If used as vehicles for preservatives, must not be detected with the test in Annex IV DM21/3/73, Sect.3. As technological adjuvant |
| Dispersion of paraffin containing silicones, as well as silicones and paraffins complying with hygiene requirements for food contact | CZ 38/2001 A. 12 | not more than 0.5 % by dry weight of dispersion. As drainage accelerator |
| | SK 1799/2003 A. 8 | not more than 0.5 %. As drainage accelerator |
| | DE Recomm. 36 | provided that the silicones and paraffins comply with amended Recommendations XV and XXV, Part I, max. 0.5 % (based on dispersion dry substance). As dewatering accelerator |
| Ethyl hydroxyethyl cellulose 9004-58-4 | NL II 1.2.2 h | as size- and fibre-binding agents |
| | CZ 38/2001 A. 12 | as processing aid |
| | CoE P.S. paper and board | as additive |
| | SK 1799/2003 A. 8 | as sizing agent |
| Ethylcellulose 9004-57-3 | NL II 1.2.2 n | as macromoleculair compound |
| | CZ 38/2001 A. 12 | 1 kg of these substances shall not contain more than: 3 mg arsenic, 10 mg lead, 25 mg zinc, 50 mg copper and zinc on aggregate, 2 mg mercury and 2 mg cadmium; the sum of these impurities shall not exceed 50 mg.kg ⁻¹ . As agents for surface treatment and painting |
| | CoE P.S. paper and board | as additive |
| | SK 1799/2003 A. 8 | as agents for surface treatment and painting |
| Formaldehyde 50-00-0 | DE Recomm. 36 | As preservative for the aforementioned polyurethanes, max. 0.5 % formaldehyde, based on the sizing agent, may be used. Assessed only as a preservative for the polyurethanes mentioned in BfR recommendation 36 |
| | NL II 1.2.2 k | SML = 15 mg/kg (total of formaldehyde, glyoxal and hexamethylenetetramine). As preservative |
| | CoE P.S. paper and board | SML(T) = 15 mg/kg (SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 17260, 54880, 59280). As additive |
| | HR NN 125/2009 | not more than 1 mg/dm ² in the extract |
| | CoE P.S. towels and napkins | as protection agent used during production process or storage of products |
| Formic acid 64-18-6 | CZ 38/2001 A. 12 | may be used in amounts necessary to ensure that raw materials, processing aids and paper treatment agents are protected from spoilage. Packaging, by the addition of those, |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|---|-------------------------------|--|
| | | shall not have a preservative effect on the foods that are in contact with it. As preservative |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | as yankee coating component |
| | DE Recomm. 36 | |
| | SK 1799/2003 A. 8 | may be used in quantities necessary to ensure that the raw material, additives and processing agents for the paper are protected from deterioration. Packaging material with the addition of these substances shall not have a preservation effect on the food in contact with it. As preservative |
| Fructose polysaccharide (levan)-hydrolase | DE Recomm. 36 | 12.5 mg dry substance per kg paper. No more than one unit of levanase activity must be detectable |
| | CZ 38/2001 A. 12 | 12.5 mg of dry matter per kilogram of paper; more than 1 unit of levanase activity shall not be detectable. As slimicide, also used for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers |
| | SK 1799/2003 A. 8 | 12.5 mg of dry matter per kilogram of paper. As slimicide |
| Gluconic acid (= E574) 526-95-4 | DE Recomm. 36 | no restriction. As precipitating, fixing and parchmentsation agents |
| | CZ 38/2001 A. 12 | as precipitant, fixing and parchment agent |
| Glucose [or Glucose en massé] 50-99-7 | CoE P.S. paper and board | as additive |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| | NL II 1.2.2 j | as moisture control agent |
| Glucose syrup 8029-43-4 | CoE P.S. paper and board | In compliance with the FCC specifications. As additive |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| Glutaraldehyde 111-30-8 | DE Recomm. 36 | max. 2.5 %, based on dry fibres weight. No more than 2 mg glutaraldehyde must be detectable in 1 kg of finished product. As slimicide |
| | FR Avis du CSHPF du 15/12/95 | maximum dose of 250 mg/l of water. As bactericide |
| | NL II 1.2.2 c | SML = ND. As slimicide, exclusively for use in process water |
| | IT D.M. 21/3/73 am DM 15/7/93 | not detectable with the test in Annex IV DM21/3/73, Sect.3 point6. As technological adjuvant |
| | CZ 38/2001 A. 12 | not more than 2.5 %, relative to the dry fibre; not more than 2 mg of glutaraldehyde shall be detected in 1 kg of finished product. As slimicide |
| | CoE P.S. paper and board | to be fixed, as additive |
| | CoE P.S. towels and napkins | as protection agent used during production process or storage of products |
| | HR NN 125/2009 | the content in the finished product may not exceed 2 mg/kg |
| | SK 1799/2003 A. 8 | not more than 2.5 %. As slimicide |
| Glycerine [or glycerol] 56-81-5 | BE Arr. 11/5/92 A.4, III | Where several softeners are used simultaneously, their total quantity must not exceed 7 %. As softener |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | IT D.M. 21/3/73 | To treat paper and board maximum amount 0.5% w/w. As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | NL II 1.2.2 j | as moisture control agent |
| | CoE P.S. paper and board | |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| | | |
| Glyoxal 107-22-2 | NL II 1.2.2 r | Specification: For waterproofing starches in coatings, not to exceed 1% calculated in relation to the starch content of the coating and exclusively for paper and paperboard not intended for contact with alcohol-containing foods and beverages; SML = 15 mg/kg (total of formaldehyde, glyoxal and hexamethylenetetramine). As other additive |
| | BE Arr. 11/5/92 A.4, III | maximum extraction of 1.0 mg/dm ² of paper |
| | CZ 38/2001 A. 12 | in the extract of the finished products, the detectable amount shall not be more than 1.5 mg of glyoxal per dm ² . As agent for improving wet strength |
| | CoE P.S. paper and board | to be fixed, as additive |
| | DE Recomm. 36 | Extract of the finished product must not contain more than 1.5 mg glyoxal per dm ² . As wet-strength agent |
| | SK 1799/2003 A. 8 | as agent for improving wet strength |
| Hydrogen peroxide 7722-84-1 | NL II 1.2.2 d | SML = ND. As bleaching agents |
| | CZ 38/2001 A. 12 | not more than 0.1 % relative to the dry fibre; in aqueous extract from the finished products, there shall be no positive reaction to chlorides, peroxides or sulphides. As slimicide, also used for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers |
| | CoE P.S. paper and board | In compliance with the FCC specifications. As additive |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|--|-----------------------------|--|
| | CoE P.S. towels and napkins | as protection agent used during production process or storage of products |
| | DE Recomm. 36 | max. 0.1 %, based on dry fibres weight. As slimicide |
| | SK 1799/2003 A. 8 | not more than 0.1 %. As slimicide |
| Hydroxyethyl cellulose 9004-62-0 | NL II 1.2.2 h | as size- and fibre-binding agents |
| | CoE P.S. paper and board | as additive |
| | CZ 38/2001 A. 12 | 1 kg of these substances shall not contain more than: 3 mg arsenic, 10 mg lead, 25 mg zinc, 50 mg copper and zinc on aggregate, 2 mg mercury and 2 mg cadmium; the sum of these impurities shall not exceed 50 mg.kg-1. As processing aid and agent for surface treatment and painting, also for teabags |
| | DE Recomm. 36 | 36: surface refining and coating agent 36/1: surface refining and coating agent for tea bags |
| | SK 1799/2003 A. 8 | as sizing agent and agent for surface treatment and painting |
| Kaolin 1332-58-7 | CZ 38/2001 A. 12 | as fillers |
| | CoE P.S. paper and board | as additive |
| | SK 1799/2003 A. 8 | as fillers |
| Lignosulphonic acid 8062-15-5 | CoE P.S. paper and board | SML = 0.24 mg/kg. As additive |
| | DE Recomm. 36 | as dewatering accelerator |
| | CZ 38/2001 A. 12 | as drainage accelerator, dispersant and subsidy fund, for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers |
| Ligninsulphonic acids, sodium, potassium, calcium and magnesium salts NO CAS | IT D.M. 21/3/73 | As technological adjuvant |
| | DE Recomm. 36 | in total, max. 1.0 %. As dewatering accelerator; dispersion and flotation agent, CAS-No of different salts: 1. 8062-15-5; 2. 8061-52-7; 3. 8061-54-9; 4. 8061-51-6; 5. 19222-41-4 |
| | CZ 38/2001 A. 12 | in total not more than 1 % |
| | SK 1799/2003 A. 8 | not more than 1 %. as drainage accelerator |
| Magnesium carbonate 23389-33-5 | BE Arr. 11/5/92 A.4, III | as drainage accelerator; as dispersing and flotation agent, as fillers |
| | CZ 38/2001 A. 12 | shall comply with the filler purity requirements referred to in Section 7 of the Implementing Decree. As fillers, also used for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers |
| | IT D.M. 21/3/73 | As additive filler |
| | SK 1799/2003 A. 8 | as fillers |
| Magnesium chloride 7786-30-3 | NL II 1.2.2 j | as moisture control agent |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| Magnesium silicate (talc) 1343-88-0 | CZ 38/2001 A. 12 | as fillers |
| | CoE P.S. towels and napkins | as antipitch |
| | SK 1799/2003 A. 8 | as fillers |
| Melamine-formaldehyde resins 9003-08-1 | DE Recomm. 36 | Extract of the finished product must not contain more than 1.0 mg formaldehyde per dm ² . 36/1 and 36/3: max. 3.0%. 36: wet-strength agent 36/1: paper-refining agent 36/2: wet-strength agent 36/3: paper-refining agent |
| | BE Arr. 11/5/92 A.4, III | maximum extraction of formaldehyde of 1.0 mg/dm ² of paper |
| | CZ 38/2001 A. 12 | as agent for improving wet strength, also for the manufacture of paper for use as filtering layers in cold filtration (filtering layers means products weighing 500 mg.m ⁻² or more) |
| | SK 1799/2003 A. 8 | as agent for improving wet strength |
| Methylcellulose 9004-67-5 | NL II 1.2.2 h | as size- and fibre-binding agents |
| | CZ 38/2001 A. 12 | 1 kg of these substances shall not contain more than: 3 mg arsenic, 10 mg lead, 25 mg zinc, 50 mg copper and zinc on aggregate, 2 mg mercury and 2 mg cadmium; the sum of these impurities shall not exceed 50 mg.kg-1. As processing aid and agent for surface treatment and painting, also for teabags |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | Typical range of dosage mg/dm ² : 0 - 4* (as pick-up glue), 0 to 0.03* (as tail seal glue). *Typical ranges of dosage were calculated for both "tail seal glue" and "pick-up glue", from on-machine glue consumption versus kitchen roll production. Although "pick-up glue" is present only on the core and "tail seal glue" only at the end of the roll, it is calculated as an average for the total surface of the paper contained in the roll. |
| | DE Recomm. 36 | as surface refining and coating agent for tea bags |
| | SK 1799/2003 A. 8 | as sizing agent and agent for surface treatment and painting |
| Methylenebisthiocyanate 6317-18-6 | DE Recomm. 36 | This substance must not be detectable in extract of the finished products. As slimicide |
| | CZ 38/2001 A. 12 | this substance shall not be detectable in the extract of the finished products. As slimicide |
| | CoE P.S. paper and board | to be fixed, as additive |
| | DE Recomm. 36 | this substance must not be detectable in extract of the finished product. 36: preservative 36/2: slimicide |
| | HR NN 125/2009 | this substance must not be detectable in the extract |
| | SK 1799/2003 A. 8 | neither the substance nor its degradation products shall be detectable in the extract of the final material or finished product. As slimicide |
| Mixture of 5-chloro-2-methyl-4-isothiazoline-3-one (approx. 3 parts) and 2-methyl-4-isothiazoline-3-one (approx. 1 part) | DE Recomm. 36 | No more than 0.5 µg/dm ² of the mentioned isothiazolinones in total must be detectable in the extract of the finished product. As slimicide |
| | CZ 38/2001 A. 12 | a total of not more than 0.0004 % by weight of dry fibre |
| | DE Recomm. 36 | No more than 0.5 µg/dm ² of the mentioned isothiazolinones in total must be detectable in the extract of the finished product. As slimicide and as preservative |
| | SK 1799/2003 A. 8 | a total of not more than 0.0004 %. As slimicide |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|---|-----------------------------------|---|
| | HR NN 125/2009 | the extract of the finished product must contain not more than 1.0 mg/dm ² of formaldehyde and 0.005 mg/dm ² isothiazolinone |
| Mixture of N,N'-dihydroxymethyleneurea (1), 1,6-dihydroxy-2,5-dioxahexene (2), 5-chloro-2-methyl-4-isothiazolin-3-one (3), and 2-methyl-4-isothiazolin-3-one (4) | CZ 38/2001 A. 12 | (1) not more than 0.0125 %, (2) not more than 0.029 %, (3) not more than 0.00045 %, (4) not more than 0.00015 %. The foregoing percentage restrictions are always based on the weight of dry fibre. As slimicide |
| | HR NN 125/2009 | the extract of the finished product must contain not more than 1.0 mg/dm ² of formaldehyde and 0.005 mg/dm ² isothiazolinone |
| | SK 1799/2003 A. 8 | (1) not more than 0.0125 %, (2) not more than 0.029 %, (3) not more than 0.00045 %, (4) not more than 0.00015 %. As slimicide |
| Mixture of Phenyl-(2-chloro-2-cyanovinyl)sulfone (approx. 80 %), phenyl-(1,2-dichloro-2-cyanovinyl)sulfone (approx. 10 %) and 2-phenylsulfonylpropionitrile (approx. 10%) | DE Recomm. 36 | in total, max. 0.001 %, based on dry fibres weight. These substances and the degradation product, phenylsulfonyl acetonitrile, must not be detectable in the extract of the finished product. As slimicide |
| | CZ 38/2001 A. 12 | a total of not more than 0.001 % by weight of dry fibre; these substances and their degradation product phenylsulphonyl-acetonitrile shall not be detectable in the extract of the finished products. As slimicide |
| | SK 1799/2003 A. 8 | a total of not more than 0.001 %. As slimicide |
| Mixture of Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine (1), linear, high-molecular polyethylene oxide (2) and a condensation product of b-naphtholsulfonic acid, phenol and formaldehyde as sodium salt (3) | DE Recomm. 36 | (1) max. 0.05 % (2) max. 0.015 % (3) max. 0.06 % No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case |
| | CZ 38/2001 A. 12 | (1) not more than 0.05 %, (2) not more than 0.015 %, (3) maximum 0.06 %. As retention agent |
| | SK 1799/2003 A. 8 | (1) not more than 0.05 %, (2) not more than 0.015 %, (3) maximum 0.06 %; The content of free epichlorohydrin in those condensation products shall be a maximum of 1.0 mg.kg ⁻¹ . As retention agent |
| | CZ 38/2001 A. 12 | (1) not more than 0.05 %, (2) not more than 0.015 %. Not more than 0.1 %. As retention agent |
| Mixture of Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine (1), linear, high-molecular polyethylene oxide (2) and a condensation product of xylene sulfonic acid, dihydroxydiphenylsulfone and form aldehyde (sodium and ammonium salt) (3) | DE Recomm. 36 | (1) max. 0.05 % (2) max. 0.015 % (3) max. 0.1 % No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case |
| | SK 1799/2003 A. 8 | (1) not more than 0.05 %, (2) not more than 0.015 %. not more than 0.1 %; The content of free epichlorohydrin in those condensation products shall be a maximum of 1.0 mg.kg ⁻¹ . As retention agent |
| | CZ 38/2001 A. 12 | (1) not more than 0.05 %, (2) not more than 0.015 %. Not more than 0.1 %. As retention agent |
| N-(2-p-chlorobenzoyl)ethyl)hexaminium chloride | DE Recomm. 36 | Extract of the finished products must contain no more than 1.0 mg formaldehyde per dm ² . The breakdown product, 2-(p-chlorobenzoyl)-ethylamine must not be detectable in methanol extract. As slimicide |
| | CZ 38/2001 A. 12 | the cleavage product of 2-(p-chloro-benzoyl)-ethylamine shall not be detectable in methanolic extract. As slimicide |
| | HR NN 125/2009 | the methanol extract may not contain 2-(p-chlorobenzene)-ethylamine |
| | SK 1799/2003 A. 8 | neither the substance nor its degradation products shall be detectable in the extract of the final material or finished product. As slimicide |
| N,N'-Ethylenebisstearamide 110-30-5 | DE Recomm. 36 | no restriction. BfR 36: Defoamer BfR 36/1:Defoamer BfR 36/2: Defoamer BfR 36/3: Defoamer |
| | NL II 1.2.2 e | as dispersion, flotation or antifoam agent |
| | CoE P.S. paper and board | as additive |
| N,N'-Ethylidenebis[(3-sulpho-4,1-phenylene)imino(6-[(4-sulphophenyl)amino]-s-triazin-4,2-diy)]bis[N-(carboxymethyl)glycine], octasodium salt 174305-36-3 | FR Avis du CSHPF du 13/10/98 | |
| | IT D.M. 21/3/73 am D 267 30/05/01 | max amount 0.3% p/p , for individual components or all together. As optical whitening |
| Natural fibres and synthetic fibres based on cellulose, | CoE P.S. paper and board | to be fixed, as additive |
| | CZ 38/2001 A. 12 | |
| | DE Recomm. 36 | as fibrous materials |
| | SK 1799/2003 A. 8 | as fibrous raw material |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|---|------------------------------|--|
| unbleached or bleached | | |
| N-Hydroxymethyl-N-methylthiocarbamic acid, potassium salt 51026-28-9 | DE Recomm. 36 | Neither substance, nor their conversion products (mainly methylthiourea, N,N'-dimethylthiourea and dithiocarbamates) must be detectable in extract of the finished product. As slimicide |
| | HR NN 125/2009 | this substance must not be detectable in the extract |
| | CoE P.S. paper and board | to be fixed, as additive |
| Organopolysiloxanes, with methyl and/or phenyl groups NO CAS | IT D.M. 21/3/73 | As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | BE Arr. 11/5/92 A.4, III | the maximum usable dose is set at 0.05 %. Minimum viscosity at 20 °C: 180 centistokes. As antifoaming product |
| | CZ 38/2001 A. 12 | viscosity at 20 °C of at least 97.3 mPa.s.; no more than 0.1 % shall be added. As defoaming agent |
| | DE Recomm. 36 | according to Section I of Recommendation XV. Kinematic viscosity of the silicone oils, determined according to DIN 51 562 at 20 °C, min. 100 mm ² s ⁻¹ . As defoamer |
| | SK 1799/2003 A. 8 | viscosity at 20 °C of at least 97.3 mPa.s.; no more than 0.1 % shall be added. As defoaming agent |
| Paraffin oil [or Paraffin, liquid (refined mineral oil)] 8012-95-1 | DE Recomm. 36 | max. 0.1 % (for purity requirements see 155th Communication). As defoamer |
| | CoE P.S. towels and napkins | as yankee coating component |
| | NL II 1.2.2 e, NL II 1.2.2 i | specifications: colour < Standard Saybolt 30; virtually no odour; UV extinction of hexane extract <0,10/cm at 260-350 nm. As dispersion, flotation or antifoam agent; as paraffin or waxe |
| Peroxyacetic acid 79-21-0 | DE Recomm. 36 | max. 0.1 %, based on the dry fibres weight |
| | CZ 38/2001 A. 12 | not more than 0.1 % relative to the dry fibre; in aqueous extract from the finished products, there shall be no positive reaction to chlorides, peroxides or sulphides. As slimicide |
| | CoE P.S. paper and board | to be fixed, as additive |
| | CoE P.S. towels and napkins | as broke treatment |
| | SK 1799/2003 A. 8 | not more than 0.1 %. As slimicide |
| Phosphoric acid, tributyl ester [or tributyl phosphate] 126-73-8 | NL II 1.2.2 e | excl. for protective coatings, max 0.5% in EP. As dispersion, flotation or antifoam agent |
| | CoE P.S. paper and board | to be fixed, as additive |
| | BE Arr. 11/5/92 A.4, III | the maximum usable dose is set at 0.05 %. As antifoaming product |
| | CZ 38/2001 A. 12 | no more than 0.1 % shall be added. As defoaming agent |
| | SK 1799/2003 A. 8 | not more than 0.1 %. As defoaming agent |
| | NL II 1.2.2 e | excl. for protective coatings, max 0.5% in EP. As dispersion, flotation or antifoam agent |
| | CZ 38/2001 A. 12 | no more than 0.1 % shall be added. As defoaming agent |
| Phosphoric acid, triisobutyl ester [or triisobutyl phosphate] 126-71-6 | CoE P.S. paper and board | to be fixed, as additive |
| | DE Recomm. 36 | as defoamer |
| | SK 1799/2003 A. 8 | not more than 0.1 %. As defoaming agent |
| | IT D.M. 21/3/73 | Containing not more than 0.2% acrylamide monomer; maximum use level:0.3%. As technological adjuvant |
| | CZ 38/2001 A. 12 | if it contains no more than 0.1 % monomeric acrylamide; not more than 0.015 %. For the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers, as special-treating agents |
| Polyacrylamide 9003-05-8 | DE Recomm. 36 | provided it contains no more than 0.1 % monomeric acrylamide, max. 0.015 %. As paper-refining agent |
| | CoE P.S. towels and napkins | as retention aid |
| | NL II 1.2.2 b | Specification: For the manufacture of (co)polymers, use shall be made exclusively of the following additives: ammonium peroxydisulphate; tert.butylhydroxy peroxide; ethylenediaminetetraacetic acid, sodium salt; potassium metabisulphite; potassium peroxydisulphate. Containing a maximum of 0.2% of free monomer; exclusively in paperboard intended for contact with dry foods, max 0.1% in EP, SML (acrylamide) = 0.1 mg/kg, SML (dimethylaminoethyl methacrylamide) = 0.1 mg/kg, SML (peroxide) = ND. As precipitant, fixative, retentive or dehydrating agent |
| | CZ 38/2001 A. 12 | unless they contain more than 0.1 % monomeric acrylamide, not more than 0.1 %. As retention agent |
| Polyacrylamide and/or copolymers of acrylamide with dimethylaminoethylmet hacrylate | SK 1799/2003 A. 8 | unless they contain more than 0.1 % monomeric acrylamide, not more than 0.1 %. As retention agent |
| | BE Arr. 11/5/92 A.4, III | |
| | CZ 38/2001 A. 12 | as retention agent and agent for improving wet strength, also for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers and for the manufacture of paper for use as filtering layers in cold filtration |
| | DE Recomm. 36 | (This substance is a cross-linked, cationic polyalkylene amine which is restricted together with the other cationic polyalkylene amines in BfR 36.); Cross-linked, cationic polyalkylene amine, in total with the other cross-linked, cationic polyalkylene amines mentioned in the respective section of BfR 36: max. 4.0 %; BfR 36 - obey respective restrictions (e.g. footnotes concerning primaric aromatic amines and ethyleneimine). No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002 |
| Polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia | SK 1799/2003 A. 8 | cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|--|-------------------|--|
| | | 4.0 % |
| Polyamide-epichlorohydrin resin made from adipic acid, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine | CZ 38/2001 A. 12 | not more than 0.2 %, not more than 0.1 % for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers and for the manufacture of paper for use as filtering layers in cold filtration. As retention agent, also for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers and for the manufacture of paper for use as filtering layers in cold filtration |
| | DE Recomm. 36 | No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002. 36: max. 0.2%; 36/1: max. 0.1%; 36/3: max. 0.1%. 36: retention agent 36/1: paper-refining agent 36/3: paper-refining agent |
| | SK 1799/2003 A. 8 | not more than 0.2 %; cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| Polyamide-epichlorohydrin resin, produced from epichlorohydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine | DE Recomm. 36 | (This substance is a cross-linked, cationic polyalkylene amine which is restricted together with the other cationic polyalkylene amines in BfR 36.); Cross-linked, cationic polyalkylene amine, in total with the other cross-linked, cationic polyalkylene amines mentioned in the respective section of BfR 36: max. 4.0 %; BfR 36 - obey respective restrictions (e.g. footnotes concerning primaric aromatic amines and ethyleneimine). No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002 |
| | CZ 38/2001 A. 12 | as retention agent and agent for improving wet strength, also for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers and for the manufacture of paper for use as filtering layers in cold filtration |
| | SK 1799/2003 A. 8 | cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| | | |
| Polyamide-epichlorohydrin resin made from epichlorohydrin, diethylenetriamine, adipic acid and ethyleneimine | CZ 38/2001 A. 12 | not more than 0.5 %, not more than 0.3% for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers and for the manufacture of paper for use as filtering layers in cold filtration. As retention agent, also for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers and for the manufacture of paper for use as filtering layers in cold filtration |
| | DE Recomm. 36 | No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002. 36: max. 0.5%; 36/1: max. 0.3%; 36/2: max. 0.5%; 36/3: max. 0.3%. 36: retention agent 36/1: paper-refining agent 36/2: retention agent 36/3: paper-refining agent |
| | SK 1799/2003 A. 8 | not more than 0.5 %; cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. as retention agent and agent for improving wet strength |
| | | |
| Polyamide-epichlorohydrin resin, produced from epichlorohydrin, diethylenetriamine, adipic acid, ethyleneimine and polyethyleneglycol | DE Recomm. 36 | in total (with the other substances mentioned in the respective section of Recomm. 36), max. 4.0 %, obey respective footnotes. As retention agent; wet-strength agent |
| | CZ 38/2001 A. 12 | not more than 0.2 %. As retention agent and agent for improving wet strength |
| | SK 1799/2003 A. 8 | not more than 0.2 %; cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| Polyamide-epichlorohydrin resin made from polyepichlorohydrin, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine | CZ 38/2001 A. 12 | not more than 0.2 %. As retention agent |
| | DE Recomm. 36 | No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002. max. 0.2%. As retention agent |
| | SK 1799/2003 A. 8 | not more than 0.2 %; cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| Polyamide-polyamine-dichloroethane resin made from adipic acid, diethylenetriamine and 1,2-dichloroethane | CZ 38/2001 A. 12 | not more than 0.2 %. As retention agent |
| | Recomm. 36 | max. 0.2%. As retention agent |
| | SK 1799/2003 A. 8 | not more than 0.2 %; a maximum total of 7.0 % of surface protection agents may be used. As retention agent and agent for improving wet strength |
| Polyamide-polyamine-dichloroethane resin, produced from dichloroethane and an amide of adipic acid, caprolactam and diethylenetriamine | DE Recomm. 36 | in total (with the other substances mentioned in the respective section of Recomm. 36), max. 4.0 %, BfR 36 - obey respective restrictions. As retention agent (substance mentioned 2 times with different molecular weight) |
| | CZ 38/2001 A. 12 | as retention agent |
| | SK 1799/2003 A. 8 | cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| Polyamide-polyamine-epichlorohydrin resin, produced from epichlorohydrin, adipic | DE Recomm. 36 | in total (with the other substances mentioned in the respective section of Recomm. 36), max. 4.0 %, BfR 36 - obey respective restrictions |
| | CZ 38/2001 A. 12 | as retention agent and agent for improving wet strength, also for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers and for the |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|---|--|--|
| acid dimethyl ester and diethylenetriamine | | manufacture of paper for use as filtering layers in cold filtration |
| | SK 1799/2003 A. 8 | cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| Polyamide-polyamine-epichlorohydrin resin, produced from epichlorohydrin, adipic acid dimethyl ester, glutaric acid dimethyl ester and diethylenetriamine | DE Recomm. 36 | max. 2.0 % in total (with the other substances mentioned in the respective section of Recomm. 36), max. 4.0 % BfR 36 - obey respective restrictions. No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002 |
| | CZ 38/2001 A. 12 | not more than 2.0 %. As retention agent |
| | SK 1799/2003 A. 8 | not more than 2.0 %; cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| Polyamideamine-polyetheramine epichlorohydrin resin made from diethylenetriamine, caprolactam, adipic acid, polyethylene glycol and epichlorohydrin | CZ 38/2001 A. 12 | not more than 0.2 %. As retention agent |
| | DE Recomm. 36 | No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002. max. 0.2%. As retention agent |
| | SK 1799/2003 A. 8 | not more than 0.2 %; cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| Polyamine-dichloroethane resin made from bis-(3-aminopropyl)-methylamine and 1,2-dichloroethane | CZ 38/2001 A. 12 | not more than 0.2 %. As retention agent |
| | DE Recomm. 36 | max. 0.2%. As retention agent |
| | SK 1799/2003 A. 8 | not more than 0.2 %; cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| | BE Arr. 11/5/92 A.4, III | |
| | CZ 38/2001 A. 12 | Of the agents increasing wet strength an aggregate of no more than 4 % may be used, relative to the dry fibre of the finished product. As retention agent and agent for improving wet strength, also for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers and for the manufacture of paper for use as filtering layers in cold filtration |
| Polyamine-epichlorohydrin resin based on epichlorohydrin and diaminopropylmethylamine | DE Recomm. 36 | (This substance is a cross-linked, cationic polyalkylene amine which is restricted together with the other cationic polyalkylene amines in BfR 36.); in total with the other cross-linked, cationic polyalkylene amines mentioned in the respective section of BfR 36: max. 4.0 %; BfR 36 - obey respective restrictions (e.g. concerning primary aromatic amines and ethyleneimine). As retention agent, wet-strength agent. No ethyleneimine must be detectable in the resin (detection limit 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in water extract of the finished product (detection limit 2 µg/l). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case. For compliance with the requirement in respect to chloropropanols, a transitional period has been granted until the 31.03.2002 |
| | SK 1799/2003 A. 8 | cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 %. As retention agent and agent for improving wet strength |
| | | |
| Polyethyleneglycol 25322-68-3 | FR Lettre-Circulaire du 28 octobre 1980 | <u>Préparation</u> : 15 % de chlorure de l'acide parahydroxy-2-oxophényl-acétydroxynique + 85 % de polyéthylène glycol + 0,5 % de HCl (impureté). |
| | NL II 1.2.2 j | Molecular weight shall be higher than 200. As moisture control agent |
| | IT D.M. 21/3/73 | Purity requirements in Annex IV DM 21/3/73 Sect 4 point 2. As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | Typical range of dosage mg/dm ² : 0 to 1; < 7% in the paper monoethylene glycol in PEG < 0.2 %. As laminating glue |
| | CoE P.S. towels and napkins | Typical range of dosage mg/dm ² : 0 - 4* (as pick-up glue), 0 to 0.03* (as tail seal glue); PEG < 7% in the paper with monoethylene glycol in PEG < 0.2 %. *Typical ranges of dosage were calculated for both "tail seal glue" and "pick-up glue", from on-machine glue consumption versus kitchen roll production. Although "pick-up glue" is present only on the core and "tail seal glue" only at the end of the roll, it is calculated as an average for the total surface of the paper contained in the roll. |
| | CZ 38/2001 A. 12 | molecular weight of 200; a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| SK 1799/2003 A. 8 | molecular weight greater than 200; an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent | |
| Polyethylene glycols containing monoethylene glycol NO CAS | CZ 38/2001 A. 12 | not more than 0.2 %; a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | DE Recomm. 36 | no more than 0.2 % monoethyleneglycol. In total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | not more than 0.2 % on aggregate; an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| Polyethyleneimine 99932-76-0 | IT D.M. 21/3/73 | 0.5% max . The final products must not release ethyleneimine. As auxiliary substance b) insoluble in water and/or solvent |
| | BE Arr. 11/5/92 A.4, III | maximum usable dose: 0.4 % in relation to the finished product. As retention product |
| | CZ 38/2001 A. 12 | maximum 0.5 %. As retention agent and drainage accelerator; as dispersing and flotation agent; as binder and agent to increase wet strength for the manufacture of paper for use as filtering layers in cold filtration (filtering layers means products weighing 500 mg.m ⁻² or more) |
| | CoE P.S. towels and | as dispersion agent and surfactant and retention aid |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|--|--------------------------------|---|
| | napkins | |
| | Recomm. 36 | max. 0.5% (max. 0.05% as paper-refining agent). 36: retention agent, dewatering accelerator and dispersion and flotation agent 36/1: binding and wet-strength agent for filter layers for cold filtration and paper-refining agent 36/2: dewatering accelerator, dispersion and flotation agent and retention agent |
| | SK 1799/2003 A. 8 | maximum 0.5 %. As retention agent and drainage accelerator; as dispersing and flotation agent |
| Polyvinyl alcohol 9002-89-5 | IT D.M. 21/3/73 am D 26 /04/93 | Not detectable in the test in Annex IV DM 21/3/73 sect.3, point 6. As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | NL II 1.2.2 n | viscosity of 4% solution of starting substance in water at 20°C is at least 5 mPas. As macromoleculair compound |
| | BE Arr. 11/5/92 A.4, III | viscosity of a 4 % aqueous solution at 20 °C at least 20 cP; maximum usable dose, on the surface, of 4 g/m ² . As sundry product |
| | CZ 38/2001 A. 12 | the viscosity of its 4 % aqueous solution at 20 °C is at least 5 cP. As agent for surface treatment and painting |
| | CoE P.S. paper and board | Polyvinyl alcohol Weight average molecular weight should not be less than 2500 Da. As additive |
| | CoE P.S. towels and napkins | Typical range of dosage mg/dm ² : 0 to 0.5; 0 - 4* (as pick-up glue), 0 to 0.03* (as tail seal glue). as laminating glue; *Typical ranges of dosage were calculated for both "tail seal glue" and "pick-up glue", from on-machine glue consumption versus kitchen roll production. Although "pick-up glue" is present only on the core and "tail seal glue" only at the end of the roll, it is calculated as an average for the total surface of the paper contained in the roll. Also as yankee coating component |
| | DE Recomm. 36 | viscosity of 4 % aqueous solution at 20 °C, min. 5 cP. As surface refining and coating agent |
| | SK 1799/2003 A. 8 | the viscosity of its 4 % aqueous solution at 20 °C is at least 5 cP. As agent for surface treatment and painting |
| Polyvinylpyrrolidone 9003-39-8 | IT D.M. 21/3/73 | As technological adjuvant |
| | NL II 1.2.2 e | viscosity of the 5% solution of starting substance in water of 20°C shall not exceed 34 cP. As dispersion, flotation or antifoam agent |
| | BE Arr. 11/5/92 A.4, III | molecular weight of at least 11 000; maximum usable dose is set at 0.1 %. In addition, where several of ispersion and flotation products are used simultaneously, their total usable dose must not exceed 0.3 %. As dispersion and flotation products and dewatering accelerators |
| | CZ 38/2001 A. 12 | molecular weight of not more than 11 000, viscosity of 5 % aqueous solution at 20 °C, at least 34 mPa.s. 5. As dispersion and flotation agent, also for the manufacture of paper for use as filtering layers in cold filtration (filtering layers means products weighing 500 mg.m ⁻² or more) |
| | CoE P.S. paper and board | Polyvinylpyrrolidone The substance shall meet the purity criteria established in Commission Directive 96/77/EC. As additive |
| | DE Recomm. 36 | molecular weight minimum 11000. As dispersion and flotation agent |
| | SK 1799/2003 A. 8 | molecular weight of not more than 11 000, viscosity of 5 % aqueous solution at 20 °C, at least 34 mPa.s. ⁻¹ . As dispersing and flotation agent |
| Reaction product of polyacrylamide with formaldehyde and dimethylamine NO CAS | DE Recomm. 36 | max. 0.06 %, based on weight of the dry paper. Extract of the finished products must not contain more than 1.0 mg formaldehyde per dm ² . Dimethylamine must not be detectable in the aqueous extract (detection limit: 0.002 mg/dm ²). Residual monomeric acrylamide, based on the reaction product of polyacrylamide with formaldehyde and dimethylamine, must not exceed 0.1% |
| | CZ 38/2001 A. 12 | not more than 0.06 %, by weight of dry paper, cardboard or paperboard; the dimethylamine shall not be detectable in aqueous extraction at a method sensitivity of 0.002 mg.dm ⁻² . As retention agent |
| | SK 1799/2003 A. 8 | not more than 0.06 %. As retention agent |
| Sebacic acid, dibutyl ester [or dibutyl sebacate] 109-43-3 | NL II 1.2.2 o | as plasticizer |
| | CoE P.S. paper and board | as additive |
| Silicon dioxide [or Silicon oxide] 7631-86-9 | SK 1799/2003 A. 8 | an aggregate quantity of not more than 5.0 % of plasticizers may be used. As plasticizer |
| | CZ 38/2001 A. 12 | shall comply with the filler purity requirements referred to in Section 7 of the Implementing Decree. As fillers, also used for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | as drainage and retention aid |
| | SK 1799/2003 A. 8 | as fillers |
| Sodium aluminate 1302-42-7 | BE Arr. 11/5/92 A.4, III | as fillers |
| | NL II 1.2.2 b | as precipitant, fixative, retentive or dehydrating agent |
| | BE Arr. 11/5/92 A.4, III | as fixer or participant |
| | CZ 38/2001 A. 12 | as precipitant, fixing and parchment agent, also for cooking bags, for paper for hot filtration and filtering layers used in hot filtration and for the manufacture of paper for use as filtering layers in cold filtration (filtering layers means products weighing 500 mg.m ⁻² or more) |
| | CoE P.S. paper and board | as additive |
| | DE Recomm. 36 | 36: precipitating, fixing and parchmentsation agent 36/1: special raw material and production aid for cook-in packages 36/2: precipitating, fixing and parchmentsation agent |
| Sodium bicarbonate 144-55-8 | SK 1799/2003 A. 8 | as precipitating and fixing agent |
| | NL II 1.2.2 r | as other additive |
| | CZ 38/2001 A. 12 | as precipitant, fixing and parchment agent, also for cooking bags |
| | CoE P.S. towels and | as pH and charge control |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|--|--|--|
| | napkins | |
| | DE Recomm. 36 | 36: precipitating, fixing and parchmentsation agent 36/1: neutralising and precipitating agent for cook-in packages 36/2: precipitating, fixing and parchmentsation agent |
| | SK 1799/2003 A. 8 | as precipitating and fixing agent |
| Sodium bisulphite 7631-90-5 | BE Arr. 11/5/92 A.4, III | extraction 0. As bactericide |
| | DE Recomm. 36 | max. 0.1 %, based on dry fibres weight. As slimicide |
| | CoE P.S. paper and board | SML(T) = 10 mg/kg (SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF N° : 86960, 87120) (as SO2). As additive |
| Sodium carbonate 497-19-8 | NL II 1.2.2 a, NL II 2.2.2 a | as basic additive |
| | CZ 38/2001 A. 12 | as precipitant, fixing and parchment agent, also for cooking bags |
| | DE Recomm. 36 | 36: precipitating, fixing and parchmentsation agent 36/1: neutralising and precipitating agent for cook-in packages 36/2: precipitating, fixing and parchmentsation agent |
| | SK 1799/2003 A. 8 | as precipitating and fixing agent |
| Sodium chloride 7647-14-5 | IT D.M. 21/3/73 | As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | NL II 1.2.2 j | as moisture control agent |
| | NL II 1.2.2 r | as other additive |
| | BE Arr. 11/5/92 A.4, III | Where several softeners are used simultaneously, their total quantity must not exceed 7 %. As softener |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| | | |
| Sodium chlorite 7758-19-2 | BE Arr. 11/5/92 A.4, III | extraction 0. As bactericide |
| | CZ 38/2001 A. 12 | for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers, as slimicides |
| | DE Recomm. 36 | max. 0.1 %, based on dry fibres weight. As slimicide |
| Sodium dithionite [or Sodium hydrosulphite] 7775-14-6 | NL II 1.2.2 d, NL II 1.2.2 r | as bleaching agent or other additive |
| | CZ 38/2001 A. 12 | for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers, as slimicides |
| | CoE P.S. paper and board | to be fixed, as additive |
| | DE Recomm. 36 | as slimicide |
| | SK 1799/2003 A. 8 | only as an antioxidant for wax. As agents for surface finishing and laminating for teabags |
| | CZ 38/2001 A. 12 | not more than 0.1 % relative to the dry fibre; in aqueous extract from the finished products, there shall be no positive reaction to chlorides, peroxides or sulphides. As slimicide |
| | SK 1799/2003 A. 8 | not more than 0.1 %. As slimicide |
| Sodium hydroxide 1310-73-2 | DE Recomm. 36 | |
| | NL II 1.2.2 a | as basic additive |
| | FR Lettre-circulaire du 4 janvier 1982 | |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | as pH and charge control |
| Sodium hypochlorite 7681-52-9 | CZ 38/2001 A. 12 | not more than 0.1 % relative to the dry fibre; in aqueous extract from the finished products, there shall be no positive reaction to chlorides, peroxides or sulphides. As slimicide |
| | CoE P.S. towels and napkins | as protection agent used during production process or storage of products and as broke treatment |
| | SK 1799/2003 A. 8 | not more than 0.1 %. As slimicide |
| | CoE P.S. paper and board | to be fixed, as additive |
| Sodium nitrate only with urea | BE Arr. 11/5/92 A.4, III | maximum usable dose, on the surface, of 7 % of the finished product, with the mixture containing one part NaNO3 and two parts urea. Where several of these products are used simultaneously, their total quantity must not exceed 7 %. As softener |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| Sodium peroxide 1313-60-6 | NL II 1.2.2 d | SML = ND. As bleaching agents |
| | BE Arr. 11/5/92 A.4, III | extraction 0. As bactericide |
| | CZ 38/2001 A. 12 | not more than 0.1 % relative to the dry fibre; in aqueous extract from the finished products, there shall be no positive reaction to chlorides, peroxides or sulphides. As slimicide, also used for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers |
| | CoE P.S. paper and board | to be fixed, as additive |
| | DE Recomm. 36 | max. 0.1 %, based on dry fibres weight. As slimicide |
| | SK 1799/2003 A. 8 | not more than 0.1 %. As slimicide |
| Sodium salt of ethylenediamine tetraacetic acid, diethylene triamine pentaacetic acid and n- | CZ 38/2001 A. 12 | as precipitant, fixing and parchment agent |
| | DE Recomm. 36 | as precipitant, fixing and parchment agent |
| | SK 1799/2003 A. 8 | not more than 1.0 %. As precipitating and fixing agent |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|---|------------------------------|--|
| oxoethyl-ethylene-diamino-triacetic acid | | |
| Sorbic acid and its sodium, potassium and calcium salts | IT D.M. 21/3/73 | Not detectable in the test in Annex IV DM 21/3/73 sect.3, point 6. As auxiliary substance a) soluble or partially soluble in water and/or solvent |
| | NL II 1.2.2 k | as preservative |
| | CZ 38/2001 A. 12 | may be used in amounts necessary to ensure that raw materials, processing aids and paper treatment agents are protected from spoilage. Packaging, by the addition of those, shall not have a preservative effect on the foods that are in contact with it. As preservative |
| | SK 1799/2003 A. 8 | may be used in quantities necessary to ensure that the raw material, additives and processing agents for the paper are protected from deterioration. Packaging material with the addition of these substances shall not have a preservation effect on the food in contact with it. As preservative |
| Sorbic acid 110-44-1 | CZ 38/2001 A. 12 | This preservative may be used only in amounts necessary to ensure that raw materials and processing aids are protected from spoilage. Papers for cooking and hot filtration and the filtering layers shall in no way be applied to food as preservatives. As preservative |
| | DE Recomm. 36 | Sorbic acid must only be used in amounts necessary to protect the raw materials and processing aids from deterioration and decay. As preservative |
| | CoE P.S. paper and board | as additive |
| Sorbitol 50-70-4 | NL II 1.2.2 j | as moisture control agent |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | CoE P.S. paper and board | as additive |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. An aggregate quantity of not more than 5.0 % of plasticizers may be used. As hydrophobising agent, as plasticizer and as agent to increase water retention in coating compositions |
| | | |
| Sucrose 57-50-1 | NL II 1.2.2 j | as moisture control agent |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | CoE P.S. paper and board | as additive |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. As hydrophobising agent |
| Sulphonated castor oil 8002-33-3 | CZ 38/2001 A. 12 | as dispersing and flotation agent |
| | DE Recomm. 36 | as dispersion and flotation agent |
| | SK 1799/2003 A. 8 | 14 - turkey red oil (sulphoricinoleates), an aggregate quantity of not more than 5.0 % of plasticizers may be used. As dispersing and flotation agent and as plasticizer |
| Sulphuric acid 7664-93-9 | NL II 1.2.2 b, NL II 2.2.2 a | as precipitant, fixative, retentive or dehydrating agent |
| | CZ 38/2001 A. 12 | as precipitant, fixing and parchment agent; also for cooking bags |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | as pH and charge control |
| | DE Recomm. 36 | 36: precipitating, fixing and parchmentsation agent 36/1: parchmentsation agent for cook-in packages 36/2: precipitating, fixing and parchmentsation agent |
| | SK 1799/2003 A. 8 | as precipitating and fixing agent |
| Tannin 18483-17-5 | IT D.M. 21/3/73 | As technological adjuvant |
| | CZ 38/2001 A. 12 | as precipitant, fixing and parchment agent |
| | DE Recomm. 36 | as precipitant, fixing and parchment agent |
| | SK 1799/2003 A. 8 | as precipitating and fixing agent |
| Tetrakis(hydroxymethyl)phosphonium sulfate 55566-30-8 | DE Recomm. 36 | The extract of the finished products must contain no more than 0.15 ppm of this substance. As slimicide |
| | HR NN 125/2009 | the content in the extract of the finished product may not exceed 0.15 ppm |
| | CoE P.S. paper and board | to be fixed, as additive |
| Tetramethylthiuram disulphide 137-26-8 | NL II 1.2.2 c | Max 1 mg/kg of (di)thiocarbamates and thiuram disulphide in EP if not solely in contact with dry foods; SML=ND. As slimicide, exclusively for use in process water |
| | CoE P.S. paper and board | to be fixed, as additive |
| | BE Arr. 11/5/92 A.4, III | maximum usable dose, in the mass, of 0.1 % in relation to the finished product. Tetramethylthiuram cannot be detectable in the water extract. As bactericide |
| | CZ 38/2001 A. 12 | this processing aid shall not be detectable in the extract of the finished products. As slimicide |
| | DE Recomm. 36 | this substance must not be detectable in extract of the finished products. As slimicide |
| | HR NN 125/2009 | this substance must not be detectable in the extract |
| | SK 1799/2003 A. 8 | neither the substance nor its degradation products shall be detectable in the extract of the final material or finished product. As slimicide |
| Titanium dioxide 13463-67-7 | IT D.M. 21/3/73 | As additive filler |
| | CZ 38/2001 A. 12 | shall comply with the filler purity requirements referred to in Section 7 of the Implementing Decree. As fillers, for the manufacture of paper for use at boiling point, for hot filtration, and for use as filtering layers, as fillers |
| | BE Arr. 11/5/92 A.4, III | as fillers |
| | CoE P.S. paper and board | as additive |
| | DE Recomm. 36 | 36: filler 36/1: auxiliary agent 36/2: filler |
| | SK 1799/2003 A. 8 | as fillers |

| Substance name, CAS Number | Legislation | Restrictions and comments |
|---|-----------------------------|--|
| Triethylene glycol 112-27-6 | NL II 1.2.2 o | as plasticizer |
| | CoE P.S. paper and board | |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 5.0 % of plasticizers may be used. As plasticizer |
| Urea 57-13-6 | NL II 1.2.2 j | as moisture control agent |
| | BE Arr. 11/5/92 A.4, III | Where several softeners are used simultaneously, their total quantity must not exceed 7 %. As softener |
| | CZ 38/2001 A. 12 | a maximum total of 7.0 % of surface protection agents may be used. As surface protection agent |
| | CoE P.S. paper and board | as additive |
| | CoE P.S. towels and napkins | as surfactant component |
| | DE Recomm. 36 | in total max. 7% of humectants. As humectant |
| | SK 1799/2003 A. 8 | an aggregate quantity of not more than 7.00 % of hydrophobising agents may be used. An aggregate quantity of not more than 0.1 % of agents to adjust the viscosity of pigmented mixtures may be used. As hydrophobising agent and as agent to adjust the viscosity of pigmented mixtures |
| Urea-formaldehyde resins | BE Arr. 11/5/92 A.4, III | maximum extraction of formaldehyde of 1.0 mg/dm ² of paper |
| | CZ 38/2001 A. 12 | as agent for improving wet strength |
| | DE Recomm. 36 | Extract of the finished product must not contain more than 1.0 mg formaldehyde per dm ² . As wet-strength agents |
| | SK 1799/2003 A. 8 | not chemically modified with one or more of the following: 6-aminohexalactam; bis-(2-aminoethyl) amine; diaminoethane; dicyandiamide; sodium hydrosulphite; triethylenetetramine; tris(2-hydroxyethyl) amine. As agent for improving wet strength |
| Wax and paraffin dispersion NO CAS | CZ 38/2001 A. 12 | complying with hygiene requirements for food contact, up to a maximum of 2.0 % by weight of the dry paper, cardboard and paperboard. As processing aid |
| | DE Recomm. 36 | provided the waxes and paraffins comply with amended Recommendation XXV, Part I, in total max. 2.0 %. As sizing agent |
| | SK 1799/2003 A. 8 | in a total quantity of not more than 2.0 %. As sizing agent |
| Xanthan gum 11138-66-2 | DE Recomm. 36 | BfR 36: The general and specific purity requirements after Annex 2, List A, Part II of the Regulation on Food Additives (Zusatzstoff-Verkehrsverordnung) apply. BfR 36/2: Except for sodium chloride, these must comply with the general and special purity requirements of the Regulation on Food Additives (Zusatzstoffverkehrsverordnung). BfR 36: Sizing agent and Surface refining and coating agents BfR 36/1: For tea bags BfR 36/2: sizing and fibre binding agent |
| | IT D.M. 21/3/73 | If used as vehicles for preservatives, must not be detected with the test in Annex IV DM21/3/73, Sect.3. As technological adjuvant |
| | CZ 38/2001 A. 12 | as agents for surface treatment and painting, also for teabags |
| | CoE P.S. paper and board | as additive |
| Methyldithiocarbamic acid, potassium salt [or potassium methyldithiocarbamate] 137-41-7 | Recomm. 36 | Neither substance must not be detectable in extract of the finished products |
| | NL II 1.2.2 c | Max 1 mg/kg of (di)thiocarbamates and thiuram disulphide in EP if not solely in contact with dry foods; SML=ND |
| | CoE P.S. towels and napkins | |
| | CoE P.S. paper and board | |
| Polyamide-polyamine-epichlorohydrin resin, produced from epichlorohydrin, adipic acid dimethyl ester and diethylenetriamine | Recomm. 36 | in total (with the other substances mentioned in the respective section of Recomm. 36), max. 4.0 %, BfR 36 - obey respective restrictions |
| | CZ 38/2001 A. 12 | |
| | SK 1799/2003 A. 8 | cross-linked cationic polyalkyleneamines in a total aggregate quantity of not more than 4.0 % |

Annex 17. Frameworks or documents for rubbers and elastomers

Definitions

Variation in definition across MSs is shown below for elastomers, rubber, caoutchouc, latex

| MS | definitions |
|-----|---|
| CZ | "elastomers means the full spectrum of elastic polymers or polymers with rubbery behaviour, called 'unsystematic': rubber, synthetic rubbers or elastomers;" "caoutchouc means a polymer which can be converted to rubber by vulcanisation" "rubber means a vulcanised rubber mixture or caoutchouc;" "natural rubber means rubber obtained from the latex of rubber plants (e.g. Hevea brasiliensis). The essence is cis-1,4-polyisoprene, with a small amount of non-rubber impurities;" "synthetic rubber means rubber produced by polyreactions, especially polymerisation and copolymerisation;" |
| HR | Term "elastomer" is not clearly defined. It is sometimes broadly used, sometimes with reference to natural and synthetic rubber. Term "polymer material" is not clearly defined in NN125-2009 "Articles made of elastomers (natural and synthetic rubber) that are intended to come into direct contact with drinking water have five fields of application: A, B and C, as referred to in paragraph 1 of this article, as well as D1, large-surface gaskets and gutter filling masses (e.g. hydrant gaskets), and D2, regular gaskets and adhesives (e.g. bottle sealants)." (Article 37) "..Articles made of elastomers may be produced from rubber or latex, or from rubber dispersions..." (Article 66) "..The term latex originally meant a milky fluid for natural rubber extracted from Hevea Brasiliensis species, but nowadays usually stands for an aqueous colloid dispersion of natural or synthetic rubber." "Natural rubber-latex"(Article 67) |
| FR | Rubber is a natural or synthetic polymer with a high elastic stretch rate made up of carbonaceous macromolecules generally obtained by cure the rubber latex and dry natural origin and the rubber latex and dry synthetic origin, consisting of homo or copolymers of organic. Thermoplastic elastomers, which do not require cure, are included in rubbers. In addition other mentions are made for example, in France, (Arrêté du 9/11/1994) Article 2 (translation from DGT) " - Polymer shall mean: - natural latexes and dry rubbers; - synthetic latexes and dry rubbers consisting of organic homo- or copolymers; An indicative list of these polymers and the abbreviations that may be used for them are given in Table A in Annex I..." The FCM SEC (Food contacts materials specialised expert committee) in Anses Opinion (Opinion for publication Request No '2011-SA-0183') recommends that the concept of 'reversible elongation' should be included in the definition of rubber materials that will be given in the updated version of the Order. This concept forms a distinguishing criterion between rubber materials and plastic materials. |
| NL | rubber products are defined as elastomer-based products to which one or more additives have been added. The rubber products are obtained from mixtures of elastomers and additives as a result of crosslinking on a molecular scale, usually at elevated temperatures and with or without the application of pressure. Elastomers are defined as the macromolecular natural and synthetic materials which, after having been deformed under the action of a deforming force at temperatures from 18 °C to 29 °C, rapidly and vigorously return to their original shape after removal of the force ²¹⁵ . |
| DE | differentiates natural and synthetic rubber, thermoplastic elastomers. |
| COE | In the CoE Resolution ResAP (2004) 4 a definition of rubber and thermoplastic rubber is given. ISO 1382 2002 also produced technical definitions for rubber and thermoplastic rubber. Technical document No2 of Practical Guide for Users of Resolution RESAP (2004) 4 on Rubber products intended to come into contact with food stuff did not consider ISO definitions and contains glossary defining used terms. Some examples from Technical document 2 Glossary are given: <u>Rubber</u> : Family of materials showing property of high elasticity. In an unaged state, rubber can be substantially deformed under stress, but recovers nearly to its original stage when stress is removed. Rubber is usually made from a mixture of (solid and/or liquid) materials and can be subjected to curing process, which changes its nature. <u>Elastomer</u> : A macromolecular material which return rapidly to approximately its initial dimensions and shape after substantial deformation by weak stress and release of the stress. <u>Natural rubber</u> : obtained from natural rubber latex after removal of the water. <u>Natural rubber latex</u> : An amorphous polymer consisting essentially of cis 1,4-polyisoprene obtained from the sap (latex), in general, of the botanical source Hevea brasiliensis |

The **overview of measures or instructions at national level** for rubber / elastomer is presented.

| MS | Name measure | Positive list / Negative list | Restrictions / QM / Residual / OM / SML | Test conditions Other info |
|-----|--|--|---|---|
| COE | PS concerning rubber products intended to come into contact with foodstuff | positive list of monomers and starting agents, activators, accelerators, colorants and pigments, cross-linkers, emulsifiers, fillers, initiators, plasticisers, protective agents, retarders, vulcanising agents, degradation products that can be used in the production of rubber FCM (App. 1) | - reports some restrictions as QM, QMA, maximum allowed amounts (App. 1), - suggests an OML of 60 mg/kg food or food simulant (Ch. 3.2.3), and provides SMLs for allowed substances (App. 1) | - information on compliance testing for the different rubber categories - explains in detail how to determine the rubber category of a given product - Categorisation is based on the surface to volume ratio for food contact, the contact time and temperature and whether it is an article for repeated use (Ch.s 3, 4, 5, Tech. Doc. 2) - states that rubber FCM should be manufactured according to GMP (Ch. 3.2.1) |
| AT | BGBI Nr. 258/1960, last amended by | n/a | - sets limits for the amount of Zn in FCM made of natural rubber or synthetic rubber - sets a limit for the release of Sb (§7 in | describes test conditions to determine its release from FCM made of natural or synthetic |

215 Note: The elastomers characteristics are further specified as: a) the molecules of elastomers are built up of at least 500 structural moieties (monomers), they can be chlorinated and/or brominated, b) elastomers can be vulcanised to a state where they are practically insoluble in boiling benzene, in methyl ethyl ketone or in an azeotropic mixture of ethanol and toluene, although swelling of the elastomers may take place under the influence of these liquids c) elastomers in the vulcanised state and containing no other substances than those necessary for vulcanization, do not break when stretched to three times the initial dimension at a temperature between 18 °C and 29 °C and contract within one minute to less than one and a half times the initial dimension after having been stretched to twice the initial length and held in that state for one minute.

| M S | Name measure | Positive list / Negative list | Restrictions / QM / Residual / OM / SML | Test conditions Other info |
|-----|--|--|---|--|
| | BGBI I Nr. 13/2006 | | conjunction with §1) | rubber (§7) |
| H R | NN125-2009 | - lists the substances that can be used in the production of FCM made of rubbers (Članak 66-67-68-69-70-77) - bans the use of two substances in the manufacture of articles made of natural latex and elastomers (Članak 69) | - sets limits for the quantity of some substances in production of rubber FCM (Članak 66-67-68-69-70-77) - stipulates OMLs for different elastomers depending on the food contact application (Članak 65-69-77) - sets SMLs for the release of substances from rubber, latex or rubber dispersions depending on the food contact application (Članak 69-77) | describes the test conditions for overall migration testing (Članak 65-77) |
| C Z | Vyhlaška č. 38/2001 | - establishes a list of substances that can be used in the preparation of rubbers and elastomers, including silicone elastomers (Příloha 7) - reports some substances that cannot be used (Příloha 7) | - establishes limits for the presence of substances as well as migration limits (Příloha 7) for individual chemicals or groups of chemicals into specified food simulants - some chemicals or chemical groups restrictions are formulated as maximum content in the material | n/a |
| F R | Arrêté du 9/11/1994 | establishes positive lists of ingredients for rubber products, divided by category: starting monomers, additive, etc. (Annexes I, II) | fixes limits of specific migration for some of the authorised substances (Annexes I, II) | provides guidance on how to perform tests, based on the type of contact (Annex III) |
| F R | Arrêté 09/08/05 | positive list of monomers of plastic materials (> 18 monomers and starting substances and 188 additives); sometimes also in the positive lists for plastic, but different limits | limits for teats and soothers | n/a |
| F R | DGCCRF Note d'information n°2004-64 | n/a | specifies limits for overall and specific migration for rubbers (Ch. 4) | - specifies methods for migration (Ch. 5) - guidance on information that producers of rubbers products must provide and parameters that must be checked (Ch. 3.2 and 5 of rubber section) |
| F R | Lettre-circulaire du 5 juin 1985 | n/a | modifies the maximum content of some heavy metals in zinc oxide used for rubbers | n/a |
| F R | BOCCRF n° 24 du 31/12/1998 BOCCRF n° 7 du 17 avril 1993 | specific individual substances | limiting their amount in materials | n/a |
| D E | BfR Rec. XXI | - establishes lists of starting substances and additives that may be used in the manufacturing of natural and synthetic Rubber products - reports some substances that cannot be present in or as rubber ingredients | - fixes maximum amounts for some substances in the manufacture as well as limits for the concentration of Zn and Pb impurities in the finished article - provides OMLs for each of the product categories - sets SMLs for some substances and degradation products and impurities - special limits for e.g. N-nitrosamines from certain product categories | with respect to control criteria, it defines different product categories and provides test conditions (time, temperature, simulants) for overall migration tests for each of the product categories defines different product categories |
| D E | BfR Rec. LII | establishes lists for fillers and filler additives that may, among other applications, be used in the manufacture of different products including the manufacture of commodities based on natural and synthetic rubber and in the manufacture of silicones | sets limits for the maximum amount of some filler additives based on the filler as well as purity criteria for fillers regarding contamination with heavy metals, which could be applicable for rubbers as well | n/a |
| D E | BfR Rec. XXX | reports the raw materials used in the manufacture of conveyor belts made from gutta-percha and balata | n/a | n/a |
| IT | D.M. of 21/03/1973 | establishes a positive list for rubbers | sets limits for some of the substances used in the manufacture of rubbers. (Titolo II, Capo II, art. 15, 18, Allegato II, Sezione II and amendments) | -reports how to test compliance, including migration tests for several categories of substances (Titolo II, Capo II, art. 17, All. IV, and amendments - specifies details that have to be inserted in the declaration of compliance for rubber parts of conveyor belts (amendment D.M. 26/04/1993, Annex III, Section 1, Part B, point 4) |
| N L | Commodities Act (Packagings and Consumer Articles) | establishes a list of substances that can be used (intended as products based on elastomers to which any of the auxiliaries mentioned have been added) | - sets the limits for the substances that can be used (Ch. 0, 0.3.Ch. III, 4.1-4.2.2) - sets OMLs as well as SMLs for some of the substances of the positive list (Ch. 0, 0.3; Ch. III, 4.1-4.2.2) | n/a |
| R O | Order 869 of 17/07/2006 | n/a | - limits for release of metals - limits for dry extracts in distilled water, in 10% alcohol solution and in 3% acetic | - EN 1400-3, for Pb, Cd, As, Hg, Cr. (Annex, Art. 3) - requires a declaration of |

| M S | Name measure | Positive list / Negative list | Restrictions / QM / Residual / OM / SML | Test conditions Other info |
|-----|---------------------------|---|--|---|
| | | | acid. (Annex, Art. 3) | compliance, specifying the documents needed. (Annex, Art.4, 5, 6) |
| S K | Foodstuffs Code 1799/2003 | - reports allowed starting materials and additives that can be used in the manufacturing of paper FCM (§ 20, Príloha č. 8) - bans the use of inorganic and organic pigments, dyes and fillers for materials and articles made of rubber category I, meaning materials and articles for medical purposes, in particular baby pacifiers/dummies, and other products that children can put into their mouth or are likely to come into contact with baby food (§32) - states that peroxide radicals shall not be present in rubber FCM (Príloha č. 10 Časť B II) | sets maximum allowed amounts for allowed substances (Príloha č. 10) as well as limits of migration (Príloha č. 10 Časť C I, II, III) | n/a |
| E S | Real Decreto 847/2011 | establishes a list of substances that can be used in the preparation of polymeric rubbers (Art. 4, Anexo I) | - sets restrictions on content of substances in polymeric elastomers /rubbers (Anexo I) - reports OML (Art. 7, Anexo I) and SMLs for substances from polymeric rubbers /elastomers (Art. 7, 8, Anexo I) | - provides some limited information on the verification of compliance with migration limits (Art. 9) - states that failure to comply with law would imply sanctions based on the Real Decreto 1945/1983 provisions (Art. 12) |

Standards

Standards for rubbers and elastomers exist and are presented.

| standard code and source | standard title and contents |
|--------------------------------------|--|
| ISO 14285:2014 (ISO/TC 45/SC 4) | Rubber and plastics gloves for food services -- Limits for extractable substances Specifies limits for extractable chemical substances for single-use gloves made from natural rubber, synthetic rubber, or plastic materials that are intended for use in food preparation, food handling, and related application in food service industry. |
| EN 12868:1999 (CEN/TC 252) | Child use and care articles - Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soothers Specifies methods for the isolation, identification and determination of N-nitrosamines and N-nitrosatable substances released by artificial saliva from elastomer or rubber teats and soothers. |
| EN 12873-4:2006-06 (CEN/TC 164) | Influence of materials on water intended for human consumption - Influence due to migration Part 4: Test Method For Water Treatment Membranes (rubber?) |
| EN 15768:2015 (CEN/TC 164) | Influence of materials on water intended for human consumption. GC-MS identification of water leachable organic substances This standard describes the analytical procedures based upon gas chromatography and mass spectrometry (GC-MS) used to screen migration waters for organic substances derived from finished products such as pipes, protective coatings, membranes, etc. (unclear whether coatings/ rubbers) |
| ASTM F1313-90(2011) ASTM - F15.22 | Standard Specification for Volatile N-Nitrosamine Levels in Rubber Nipples on Pacifiers: this specification applies to the nitrosamine content of rubber used in the manufacture of nipples for infant pacifiers. This specification is intended for use in reducing the normal exposure to nitrosamines. |
| DIN 11861 (1976) | Drink- and dairy fittings; sealing rings made of elastomeric materials, requirements testing |
| DIN 5080 (1978) | Preserving Jars And Bottles For Domestic Purposes; Rubber Seal Rings |
| DIN 7750:1979-01 | Rubber sealing rings for lever stoppers of bottles |
| PN C-94150:1997 PKN (PL) TC 186 | Rubber Seals For Weck Type Jars |
| GB 4806.2-1994 SAC (CN) C53 | Hygienic standard for rubber nipple: this Chinese standard specifies the rubber nipple hygiene requirements and test methods. It applies to natural rubber, silicone rubber as the main raw material, with specific additives, processed into pacifier for infants, breast-feeding and drinking with the old and weak, not as a pacifier of other rubber materials. |
| GB/T 5009.64-2003 SAC (CN) | Method for analysis of hygienic standard of rubber sheet (ring) for food use: this standard specifies the rubber hose used for food hygiene inspection method. It applies to rubber as main raw material, with certain additives, specific formula, processing made of pure rubber hose and enhanced rubber hose (fabric). Food with a rubber hose for transportation or suction liquid seasoning of soy sauce, vinegar, wine and drinks, such as the caramel non oil liquid food. |
| GB/T 5009.79-2003 SAC (CN) | Hygienic analysis method of rubber hose for food use: this specification applies to the nitrosamine content of rubber (for nipples / infant pacifiers) Note: "GB 4806.2-2015 National Standard for Food Safety—Nipples applies from 22 September 2016 superseding GB 4806.2-1994 Hygienic Standard for Rubber Nipple." |
| GB/T 5009.152-2003 SAC (CN) | Determination of residual acrylonitrile monomer in styrene – acrylonitrile copolymers and rubber – modified acrylonitrile – butadiene – styrene resins and their products used for food packaging This standard specifies: headspace gas chromatography (HS-GC) determination of acrylonitrile styrene copolymer (AS) and acrylonitrile butadiene-styrene copolymer (ABS) residual acrylonitrile methods. It applies to: acrylonitrile styrene and acrylonitrile butadiene styrene resins and their products in the residual acrylonitrile monomer Determination, also applies to rubber modified Acrylonitrile butadiene styrene resin and product residual acrylonitrile monomer determination. |
| GB/T 5009.65-2003 SAC (CN) | Method for analysis of hygienic standard of rubber sealing ring for pressure cooker for food use No comprehensible translation to english |
| KS M 6762:2014 KSA (KR) | Rubber band for packaging |
| ASTM D4316-95(2010) | Standard Specification for Elastomeric Water Bottles: it covers requirements for molded, non-fabric reinforced, elastomeric water bottles with closure and screw stopper, generally used with hot or cold water in personal hygiene and |

| standard code and source | standard title and contents |
|--------------------------|--|
| ASTM international (USA) | health care. Bottles to be used shall be manufactured from an elastomeric compound that has the following physical properties determined: tensile strength, ultimate elongation, resistance to heating at a certain temperature and resistance to water also at a certain degree. Aside from that, the stopper of the bottles shall also be manufactured from a noncorrosive metal or polymeric material. The bottle and stopper shall not be toxic, sensitizing, locally irritating, or otherwise harmful under normal conditions of use. The construction shall consist of an integral body and closure designed for use with hot or cold water. |

ISO/TC 45/SC 4 Products (other than hoses); F15.22 on Toy Safety; CEN/TC 252 - Child use and care articles; TC 186 ?

Substances in common for three or more MSs.

List: Colour coding: blue: qualitative restrictions; light orange: restriction but low fit between limits, dark orange: common restrictions and better fit.

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|---|---|
| 1-Butene CAS 106-98-9 FCM 222 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | CoE ResAP (2004) (CoE cites DE, IT) | monomer and starting agent |
| 1-Octadecanol [or octadecyl alcohol] CAS 112-92-5 PM 68225 | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | ES Real Decreto 847/2011 | |
| 1,1-Bis(2-methyl-4-hydroxy-5-tertbutylphenyl)butane [or 6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol] [or 4,4'-butylidene-bis(3-methyl-6-tert-butylphenol)] CAS 85-60-9 | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidégradants) Catégories A, B, C, D |
| | CoE ResAP (2004) (CoE cites FR, IT, USA) | Additives, Polymerization aids and vulcanizing agents |
| 1,2-Benzisothiazolin-3-one CAS 2634-33-5 PM 37520 | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| | CZ 38/2001 | Elastomer, antidegradants Overall maximum limit of 1.0 % |
| | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Agents de protection contre la fermentation LMS = 1,2 mg/kg Qmax = 0,02 % |
| | DE Recomm. 21 | Anti-fouling agent max 0.02% in total max 0.4% together with Sodium benzoate, Ammonium benzoate and 1,2-Benzisothiazolin-3-one (the maximum amount given is based on the latex) for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| 1,2-Propanediol CAS 57-55-6 FCM 109 | ES Real Decreto 847/2011 | SML = 0.5 mg/kg. Only for use in aqueous dispersions and polymer emulsions at concentrations that do not result in an antimicrobial effect on the polymer surface or food |
| | CoE ResAP (2004) (CoE cites DE, FR, USA) | Additives, Polymerization aids and vulcanizing agents SML=1.2 mg/kg |
| 1,2-Propanediol CAS 57-55-6 FCM 109 | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser EP=cat. 3 |
| | DE Recomm. 21 | If 1,2-propanediol and dipropylene glycol are used as pasting agents for Sodium benzoate, Ammonium benzoate, Potassium sorbate and 1,2-Benzisothiazolin-3-one as antifouling agents, dispersion films must not contain more than 0.15 mg/dm ² of the two substances, in total |
| | CoE ResAP (2004) (CoE cites IT) | Monomer and starting agent |
| | CoE ResAP (2004) (CoE cites DE, NL, USA) | Additives, Polymerisation aids and vulcanizing agents |
| 1,3,5-Trimethyl-2,4,6-tris-(3',5'-di-tert-Butyl-4'-hydroxybenzyl)-benzene CAS 1709-70-2 FCM 428 | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidégradants) Catégories A, B, C, D. T T: Qmax . 0,3% |
| | CZ 38/2001 | Elastomer, antidegradants Part A, only as part of the basic elastomer |
| | SK 1799/2003 A. 10 | Antidegradant Part A This substance may be used only as part of the base elastomer |
| | NL III 4.2.2e | Processing aids and additives: as protective agent |
| | DE Recomm. 21 | Additive max 0.3% for category 1, 2, 3 and 4 and special category as stabiliser for copolymers of butadiene, or isoprene and styrene in the form of sequential polymers |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL; USA, UK) | Additives, Polymerization aids and vulcanizing agents |
| 1,3-Bis(tertbutylperoxyisopropyl) benzene | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de vulcanisation |
| | NL III 4.2.2a | Processing aids and additives: as cross linking agent |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|--|--|
| CAS 2212-81-9 | | EP=cat. 3 |
| | CoE ResAP (2004) (CoE cites FR, USA, AU) | Additives, Polymerization aids and vulcanizing agents |
| Divinyl benzene CAS 1321-74-0 FCM 405 | IT D.M. 21/3/73 | Elastomer, other monomers. The restrictions are under revision |
| | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=0.05 |
| | CoE ResAP (2004) (coE cites DE, FR, IT, NL) | Monomer and starting agent |
| | FR Arrêté du 9/11/1994 (FR) in the ESCO list it was listed as 1,3-Divinyl benzene, but Arrêté du 9/11/1994 lists it as Divinyl benzene (meta- and para-, but it cites the CAS number of the undetermined form 1321-74-0) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. LMS = ND (LD = 0,05 mg/kg) for divinylbenzene |
| 1,4-Hexadiene CAS 592-45-0 | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Monomer and starting agent |
| 2(1-Methylcyclohexyl)-4,6-dimethylphenol [or 2- α -methylcyclohexyl-4,6-dimethylphenol] CAS 77-61-2 | DE Recomm. 21 | yes, before SCF Guidelines, BfR XXI category 3 and 4 max. 1.0 % BfR XXI category 3 and 4 - see respective restrictions |
| | CoE ResAP (2004) (CoE cites DE, AU) | Additives, Polymerization aids and vulcanizing agents |
| | HR NN 125/2009 | Additive max 1% |
| 2-Benzothiazyl disulfide [or Dibenzothiazyl disulphide] [or di-thio-bis(2-benzothiazole)] [or 2,2-di benzothiazolyl disulphide] CAS 120-78-5 PM 46400? | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for benzothiazyl disulphide |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories B, C, D |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| | CZ 38/2001 | Elastomer, accelerators Part A, SML=ND Sulphur compounds in the extract from the finished product shall not be detectable |
| | SK 1799/2003 A. 10 | Accelerator Part A The substance shall not be present in the autoclave leach from rubber articles |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=3; max 3% in EP |
| | DE Recomm. 21 | Secondary accelerator max 0.05% in total with 2-Mercaptobenzothiazole for category 1, 2, 3 and 4 max 1% for category 3 |
| | HR NN 125/2009 | not more than 1.0% (may only be added to the following Category 3 articles: teat rubbers, tubes and gaskets for machines in dairy industry, membranes, fittings and pump stators) |
| 2-Chloro-1,3-butadiene (or chloroprene) CAS 126-99-8 | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. Qm = 1 mg/kg. LMS = ND (LD = 0,02 mg/kg) |
| | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| | CoE ResAP (2004) (CoE cites DE,FR, IT,NL,USA) | Monomer and starting agent |
| | CoE ResAP (2004) | Monomer and starting agent |
| 2-Mercaptobenzothiazole CAS 149-30-4 PM 65768 | NL III 4.2.2b | Processing aids and additives: as accelerator max 0.05% in EP |
| | SK 1799/2003 A. 10 | Accelerator Part B total level of not more than 0.05 % by weight |
| | HR NN 125/2009 | for Articles made of Category 1, 2 or 3 elastomers only technically unavoidable quantities of 2-mercaptobenzothiazole may migrate into the |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|---|
| | | simulant |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs |
| | CoE ResAP (2004) (CoE cites DE, FR, NL, USA) | Additives, Polymerization aids and vulcanizing agents SML=8mg/kg rubber (24h extraction) |
| | DE Recomm. 21 | Secondary accelerator max 0.05% in total with Dibenzothiazyl disulfide for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) For special category: the content in 2-Mercaptobenzothiazole in commodities must be reduced as far as technically achievable, so that it is detectable in the extract of the finished articles only in technically unavoidable amounts. The Scientific Committee on Food of the EC has expressed an opinion in this respect (SCF/CS/PM/GEN/M83 of 13.11.2000). Concerning the analysis, please note DIN EN 1400-3. |
| | IT D.M. 21/3/73 In ESCO list it was added as "2-Mercaptobenzothiazole and/or zinc salts", but in D.M. 21/3/73 it is "2-Mercaptobenzothiazole and zinc salt" | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for mercaptobenzothiazole |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D, T T : Qmax=1% |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=3; max 3% in EP |
| | SK 1799/2003 A. 10 | Accelerator Part B total level of not more than 0.05 % by weight |
| 2-Mercaptobenzothiazole, zinc salt [or zinc 2-mercaptobenzothiazole] CAS 155-04-4 | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| | DE Recomm. 21 | max 1% for category 3 and 4 |
| | IT D.M. 21/3/73 In ESCO list it was added as "2-Mercaptobenzothiazole and/or zinc salts", but in D.M. 21/3/73 it is "2-Mercaptobenzothiazole and zinc salt" | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for mercaptobenzothiazole |
| | | |
| 2-Mercaptothiazoline CAS 96-53-7 | CoE ResAP (2004) (CoE cites FR, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| | NL III 4.2.2b | Processing aids and additives: as accelerator max 3% in EP |
| | FR Arrêté du 9/11/1994 (FR) (Arrêté du 9/11/1994 listed it wrongly as "2-Mercaptoimidazoline") | Additifs : Accélérateurs Catégorie D |
| 2-Methyl-1,3-butadiene [or isoprene] CAS 78-79-5 FCM 144 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| 2,2'-Methylenebis-(4-Ethyl-6-tert-Butylphenol) CAS 88-24-4 FCM 163 | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. Qm = 1 mg/kg |
| | IT D.M. 21/3/73 | Elastomers, dienic monomer The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | monomer and starting agent |
| 2,2'-Methylenebis-(4-methyl-6-tert-Butylphenol) CAS 119-47-1 FCM 285 | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents SML(T)=1.5mg/kg (with CAS 119-47-1) |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D, T T : Qmax = 0,4 % |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents SML(T)=1.5mg/kg (with CAS 88-24-4) |
| | CZ 38/2001 | Elastomer, antidegradants |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|---|
| | | Overall maximum limit of 1.0 %. |
| | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D, T T : Qmax = 0,4 % |
| | NL III 4.2.2e | Processing aids and additives: as protective agent SML=1.5 |
| | DE Recomm. 21 | yes, before SCF Guidelines, BfR XXI special category; max. 0.4 % - see respective restrictions; also as anti-aging agent for category 1, 2, 3 and 4 (max 1% in total together with all anti-aging agents) |
| 2,2'-Methylene-bis(4-methyl-6-cyclohexylphenol) [or bis(2-hydroxy-3-cyclohexyl-5-methylphenyl)methane] CAS 4066-02-8 FCM 472 | CZ 38/2001 | Elastomer, antidegradants Overall maximum limit of 1.0 %. |
| | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| | CoE ResAP (2004) (CoE cites DE, FR, NL, AU) | Additives, Polymerization aids and vulcanizing agents SML(T)=3mg/kg (with CAS 77-62-3) |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D |
| | DE Recomm. 21 | Anti-aging agent in total max 1% together with other anti-aging agents for category 1, 2, 3 and 4 |
| | NL III 4.2.2e | Processing aids and additives: as protective agent SML=0.05 |
| 2,2'-Methylene-bis(4-methyl-6-nonylphenol) CAS 7786-17-6 | CZ 38/2001 | Elastomer, antidegradants Overall maximum limit of 1.0 %. |
| | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories B, C, D |
| | CoE ResAP (2004) (CoE cites DE, FR, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| 2,2'-Methylene-bis(4-methyl-6-tert-octylphenol) CAS 14020-52-1 | CZ 38/2001 | Elastomer, antidegradants Overall maximum limit of 1.0 %. |
| | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| | CoE ResAP (2004) (CoE cites NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| 2,2'-Methylene-bis[4-methyl-6-(1-methylcyclohexyl)phenol] [or 2,2'-Methylene bis[4-methyl-6-(α -methylcyclohexyl)-phenol]] CAS 77-62-3 FCM 137 | CZ 38/2001 | Elastomer, antidegradants Overall maximum limit of 1.0 %. |
| | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| | CoE ResAP (2004) (CoE cites DE, FR, NL) | Additives, Polymerization aids and vulcanizing agents SML(T)=3mg/kg (with CAS 4066-02-8) |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D |
| | DE Recomm. 21 | Anti-aging agent in total max 1% together with other anti-aging agents for category 1, 2, 3 and 4 |
| | NL III 4.2.2e In NL III 4.2.2e it is (wrongly?) listed as "bis [2-hydroxy-3-(2-methyl cyclohexyl)-5-methyl phenyl]methane", that corresponds to "2,2'-Methylene-bis[4-methyl-6-(2-methylcyclohexyl)phenol]" | as protective agent SML=6 |
| 2,3-Dichloro-1,3-butadiene [or 2,3-Dichlorobutadiene] CAS 1653-19-6 | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|---|---|
| | | modification ou la suppression de cette liste est à l'étude actuellement. Qm = 2 mg/kg |
| | IT D.M. 21/3/73 | Elastomers, dienic monomer The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites DE, FR, IT) | monomer and starting agent |
| 2,4-Bis (octylthio-methyl),-6-methylphenol [or 2,4-Bis(octylthiomethyl)-6-methylphenol] CAS 110553-27-0 FCM 756 | IT D.M. 21/3/73 | Additive, The restrictions are under revision Limite di migrazione specifica 6 ppm (da D.M. 3.6.94). |
| | CoE ResAP (2004) (CoE cites DE, IT, USA, NL, AU) | Additives, Polymerization aids and vulcanizing agents SML=6 mg/kg |
| | CZ 38/2001 | Elastomer, antidegradants Part A, only as part of the basic elastomer,max.0.3% Only as a component of a basic elastomer |
| | SK 1799/2003 A. 10 | Antidegradant Part A not more than 0.3 % by weight. This substance may be used only as part of the base elastomer |
| | FR Avis BOCCRF 31/12/1998 (FR) | Antioxidant Minimum purity of 94 %. Emulsion styrene-butadiene, at the concentration of 0.5 %; acrylonitrile-butadiene, at the concentration of 0.25 % Emulsion styrene-butadiene rubber containing this antioxidant may not be used in contact with fatty food |
| | NL III 4.2.2e | as protective agent SML=6 |
| | DE Recomm. 21 | When this antioxidant is used, contact with fatty foodstuffs is only permitted for commodities made from acrylonitrile-butadiene rubber. yes, after SCF Guidelines max. 0.5 % BfR XXI category 1, 2, 3, 4 and special category - see respective restrictions |
| 2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine [or 4-[[[4,6-bis(octylthio)-1,3,5-triazin-2-yl]amino]-2,6-bis(1,1-dimethylethyl)-Phenol] [or 2,4-Bis(octylthio)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine] [or 2,4-Bis-n-octylthio-6(4'-hydroxy-3',5'-ditert-butyl-anilino)-1,3,5-triazine] CAS 991-84-4 FCM 384 | DE Recomm. 21 | yes, after SCF Guidelines, BfR XXI category 1, 2, 3 and 4 and special category max. 0.2 % (Suitable for contact with fatty foodstuffs; no more than 0.5 % of this antioxidant may be used in commodities which do not come into contact with fatty foodstuffs.), |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D, T Qmax = 0,5 % |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision Maximum use level :0.5%. Not for foods for which migration test with simulant D is required (da D.M. 4.4.85 e da D.M. 26.4.93). |
| | NL III 4.2.2e | Processing aids and additives: as protective agent |
| | CoE ResAP (2004) (CoE cites DE,FR,IT,NL,UK, USA) | Additives, Polymerization aids and vulcanizing agents SML=30mg/kg |
| 2,6-Di-tert-butyl-p-cresol (= BHT) [or 2,6-di-tert. butyl-4-methylphenol] CAS 128-37-0 FCM 315 | CZ 38/2001 | Elastomer, antidegradants Part A, only as part of the basic elastomer |
| | SK 1799/2003 A. 10 | Antidegradant Part A, part B Part A: this substance may be used only as part of the base elastomer Part B: this substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories B, C, D |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2e | Processing aids and additives: as protective agent |
| | DE Recomm. 21 | Anti-aging agent in total max 1% together with other anti-aging agents for category 1, 2, 3 and 4 and special category (for toy balloons); as prestabiliser in synthetic rubber |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, UK, USA) | Additives, Polymerization aids and vulcanizing agents SML=3 mg/kg |
| 4,4'-Thiobis(6-tert-butyl-3-methylphenol) [or 4,4'-Thio-bis(3-methyl-6-tert-butylphenol)] [or thiobis(2-methyl-4-hydroxy-5-tert.butyl-benzene)] CAS 96-69-5 FCM 178 | DE Recomm. 21 | before SCF Guidelines, BfR XXI category 1, 2, 3 and 4- see respective restrictions max. 0.25 % |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D |
| | NL III 4.2.2e | Processing aids and additives: as protective agent SML=0.3 |
| | CoE ResAP (2004) (CoE cites DE, FR, NL, USA) | Additives, Polymerization aids and vulcanizing agents SML=0.5mg/kg |
| 5-Ethylidenebicyclo[2.2.1 | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|---|---|
|]hept-2-ene CAS 16219-75-3 FCM 621 | | actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=0.05 |
| 5-Methylenebicyclo(2,2,1)hept-2-ene [or 5-methylene-2-norbornene] [or methylen norbornene] CAS 694-91-7 | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | monomer and starting agent |
| | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=0.05 |
| | CoE ResAP (2004) (CoE cites, IT, NL, USA) | monomer and starting agent |
| 5-vinyl-2-norbornene or 5-vinylbicyclo[2.2.1]hept-2-ene CAS 3048-64-4 | IT D.M. 21/3/73 | Elastomers, dienic monomer The restrictions are under revision |
| | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=0.05 |
| Acetic acid CAS 64-19-7 FCM 115 | CoE ResAP (2004) (CoE cites NL) | monomer and starting agent |
| | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Agents de coagulation |
| Acetic acid CAS 64-19-7 FCM 115 | DE Recomm. 21 | Neutralising agent for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE,FR,IT) | |
| Acetic acid, cyclohexylamine salt [or cyclohexylamine acetate] [or cyclohexyl aminoacetate] CAS 7346-79-4 | CoE ResAP (2004) (CoE cited DE) | Additives, Polymerization aids and vulcanizing agents |
| | HR NN 125/2009 | for rubber gloves only |
| | DE Recomm. 21 | only for rubber gloves The amount added must be limited so that migration is no more than 2 mg per dm ² (Testing is conducted in compliance with section 8 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 31 (MvP-Berichte; 2/78)) for category 3 and 4 |
| Acetic acid, vinyl ester [or vinyl acetate] CAS 108-05-4 FCM 231 | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés Qm=1 g/kg |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| Acrylamide CAS 79-06-1 FCM 145 | CoE ResAP (2004) (CoE cites DE, FR, It, NL) | monomer and starting agent SML=12 mg/kg (SCF status) |
| | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés LSM=12 mg/kg |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites FR, IT) | monomer and starting agent SML=n.d (DL=0.01mg/kg) |
| Acrylic acid CAS 79-10-7 FCM 147 | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés LMS=ND (LD=0,01 mg/kg) |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| Acrylic acid, glycidyl ester [or Acrylic acid, 2,3-epoxypropyl ester] [or 2,3-epoxypropyl acrylate] CAS 106-90-1 | CoE ResAP (2004) (CoE cites DE, FR, IT) | monomer and starting agent |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer EP=cat. 3 |
| Acrylic acid, ethyl ester [or ethyl acrylate] CAS 140-88-5 FCM 323 | CoE ResAP (2004) (CoE cites It, NL) | monomer and starting agent QM(T)=5 mg/kg in FP (expressed as epoxy m.w to 43) |
| | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer EP=cat. 3 |
| Acrylic acid, methyl ester [or methyl acrylate] CAS 96-33-3 FCM 176 | CoE ResAP (2004) (CoE cites DE,IT,NL) | monomer and starting agent |
| | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| Acrylic acid, n-butyl ester | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites DE, IT) | monomer and starting agent |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|---|--|
| [or n-butyl acrylate] [or butyl acrylate] CAS 141-32-2 FCM 325 | SK 1799/2003 A. 10 | Part B |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer EP=cat. 3 |
| | CoE ResAP (2004) | (CoE cites DE, IT, NL) monomer and starting agent |
| Acrylic acid, tert-butyl ester [or tert-butyl acrylate] CAS 1663-39-4 FCM 425 | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 CoE ResAP (2004) (CoE cites DE) | Part B monomer and starting agent |
| Acrylonitrile CAS 107-13-1 FCM 225 | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés Qm=1 mg/kg. LMS=ND (LD = 0,02 mg/kg.tolérance analytique comprise) |
| | IT D.M. 21/3/73 | Elastomer, other monomers The restrictions are under revision Acrylonitrile e suoi copolimeri: non devono cedere acrylonitrile monomero secondo il metodo di analisi riportato nell'Allegato IV del D.M. 21.3.73, sez.2, punto 7 |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=0.01 |
| | HR NN 125/2009 | for Articles made of Category 1, 2 or 3 elastomers the content of monomer acrylonitrile may not exceed 1.0 mg/kg, and it must not migrate into food in quantities exceeding the detection limit of a validated method of analysis |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | SML=n.d (DL=0.01 mg/kg) |
| Adipic acid, bis(2-ethylhexyl) ester [or bis(2-ethylhexyl) adipate] [or Di-2-ethylhexyladipate] CAS 103-23-1 FCM 207 | FR Arrêté du 9/11/1994 (FR) | Additifs : Plastifiants LMS = 18 mg/kg |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision Only for water, ice and ice products and for fresh and dry fruits and vegetables, for truffles.; in the case of caps, gaskets and similars, only for foods for which migration test with simulants A and B (excluding meat, milk and derivatives) and C |
| | HR NN 125/2009 | additive for category 3 elastomers and manufacture of articles from natural and synthetic rubber that come into direct contact with drinking water not more than 10.0%, for chloroprene rubber, nitrile rubber and ethylene propylene rubber exclusively |
| | DE Recomm. 21 | max 10% for category 3 and 4, but only for chloroprene rubber, nitrile rubber and ethylene-propylene rubber of the basic list of Recommendation 21 |
| | CoE ResAP (2004) (CoE cites DE,FR,IT) | Additives, Polymerization aids and vulcanizing agents SML=18mg/kg |
| Adipic acid, diisobutyl ester [or diisobutyl adipate] CAS 141-04-8 | FR Arrêté du 9/11/1994 (FR) | Additifs : Plastifiants LMS = 1,5 mg/kg |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites (FR, IT) | Additives, Polymerisation aids and vulcanizing agents |
| Adipic acid, diisooctyl ester [or diisooctyl adipate] CAS 1330-86-5 | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | CZ 38/2001 | Elastomer, processing additives Part A |
| | SK 1799/2003 A. 10 | Processing additive Part A |
| | CoE ResAP (2004) (CoE cites NL, USA) | Additives, Polymerisation aids and vulcanizing agents |
| Aluminium oxide CAS 1344-28-1 FCM 418 | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2g | Processing aids and additives: as filler |
| | CZ 38/2001 | filler |
| | SK 1799/2003 A. 10 | Filler Part A |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Charges Pour toutes les charges, il est spécifié que la teneur en éléments minéraux - déterminé après solubilisation dans l'acide chlorhydrique 0,1 M - ne doit pas dépasser les limites suivantes : plomb : 0,01 % ; arsenic : 0,01 % ; mercure : 0,005 % ; cadmium : 0 |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | |
| Aluminium silicate CAS 12141-46-7 | FR Arrêté du 9/11/1994 (FR) In Arrêté du 9/11/1994 it is wrongly listed with CAS 1309-48-4 | Additifs : Charges Pour toutes les charges, il est spécifié que la teneur en éléments minéraux - déterminé après solubilisation dans l'acide chlorhydrique 0,1 M - ne doit pas dépasser les limites suivantes : plomb : 0,01 % ; arsenic : 0,01 % ; mercure : 0,005 % ; cadmium : 0 |
| | CZ 38/2001 | Filler Part A |
| | SK 1799/2003 A. 10 | Filler Part A |
| Ammonium benzoate CAS 1863-63-4 | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Agents de protection contre la fermentation |
| | DE Recomm. 21 | Anti-fouling agent in total max 0.4% together with Sodium benzoate, Potassium sorbate and 1,2-Benzisothiazolin-3-one (the maximum amount given is based on the latex) for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|---|---|
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| Animal glue [or gelatin] [or gelatine] CAS 9000-70-8 FCM 547 | CoE ResAP (2004) (CoE cites FR, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Colloïdes protecteurs, épaississants |
| | DE Recomm. 21 | Protective colloids, thickeners and plasticiser for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE,FR) | Additives, Polymerization aids and vulcanizing agents |
| Azodicarbonamide CAS 123-77-3 | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents gonflants (La suppression de la liste de cette substance est à l'étude) |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2j | Processing aids and additives: as other subst. EP=cat. 3 |
| | CZ 38/2001 | Elastomer, processing additives Part B not more than 3.0 % |
| | SK 1799/2003 A. 10 | Processing additives Part B not more than 3.0 % by weight |
| | CoE ResAP (2004) (CoE cites DE,FR,IT,NL, USA, AU) | Additives, Polymerization aids and vulcanizing agents |
| | | |
| Benzoic acid CAS 65-85-0 FCM 116 | CZ 38/2001 | Elastomer, retarders Part A, max. 0.1%; overall maximum limit of 2.5 %. |
| | SK 1799/2003 A. 10 | Retardants Part A total level of not more than 1.0 % by weight |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Retardateurs |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2c | Processing aids and additives: as retarder |
| | DE Recomm. 21 | Vulcanisation retarder max 1.0% in total max 2.5% with phtalic anhydride and stearic acid for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, AU) | Additives, Polymerization aids and vulcanizing agents |
| Bis(2,4-dichlorobenzoyl) peroxide [or 2,4-Dichlorobenzoyl peroxide] CAS 133-14-2 | CZ 38/2001 | Elastomer, vulcanizing agents, cross-linking agents Part B, SML=ND; peroxide residues in a finished product made from silicone elastomer shall not be detectable |
| | SK 1799/2003 A. 10 | Vulcanising and cross-linking agent Part B Peroxide residues shall not be present in rubber materials and articles |
| | NL III 4.2.2a | Processing aids and additives: as cross linking agent SML=ND |
| | CoE ResAP (2004) (CoE cites DE,FR,NL,USA) | Additives, Polymerization aids and vulcanizing agents |
| Bis(3,5-dimethyl-2-hydroxyphenyl)isobutane [or 2,2'-isobutylidene-bis(4,6-dimethylphenol)] | CZ 38/2001 | Elastomer, antidegradants Part B, overall maximum limit of 1.0 % |
| | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| | CoE ResAP (2004) (CoE cites DE, AU, IT) | Additives, Polymerization aids and vulcanizing agents |
| Butadiene [or 1,3-butadiene] [or buta-1,3-diene] CAS 106-99-0 FCM 223 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés Qm=1 mg/kg. LMS=ND (LD = 0,02 mg/kg. tolérance analytique comprise) |
| | IT D.M. 21/3/73 | Elastomers, dienic monomer The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | monomer and starting agent QM=1mg/kg in FP or SML=n.d. (DL=0.02mg/kg) |
| Calcium carbonate CAS 471-34-1 | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2g | Processing aids and additives: as filler |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Charges Pour toutes les charges, il est spécifié que la teneur en éléments minéraux - déterminé après solubilisation dans l'acide chlorhydrique 0,1 M - ne doit pas dépasser les limites suivantes : plomb : 0,01 % ; arsenic : 0,01 % ; mercure : 0,005 % ; cadmium : 0 |
| | CZ 38/2001 | filler |
| | SK 1799/2003 A. 10 | filler Part A |
| Calcium oxide | FR Arrêté du | Additifs : Activateurs |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|---|---|
| CAS 1305-78-8 FCM 395 | 9/11/1994 (FR) | Les activateurs doivent être conformes aux critères de pureté relatifs à certains éléments minéraux applicables aux charges minérales destinées aux caoutchoucs |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2g | Processing aids and additives: as filler |
| | SK 1799/2003 A. 10 | Filler Part A |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents |
| Calcium stearate CAS 1592-23-0 | CZ 38/2001 | Elastomer, processing additives Part B |
| | SK 1799/2003 A. 10 | Processing additives Part B |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| Caprolactam disulphide CAS 23847-08-7 | HR NN 125/2009 | vulcanization accelerator max 1% of caprolactam disulfide, max 3% for sum of 6-10 from the list (Article 67). |
| | DE Recomm. 21 | vulcanization accelerator max 1.0%; max 3% in total with other accelerators (This dosage is necessary for the production of heat-resistant vulcanisates); in total max 3% of zinc content For the release of e-caprolactam, a limit of 100 mg/kg elastomer must not be exceeded. Commodities manufactured using caprolactam disulfide must be washed for one hour at 90 °C for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, AU) | Additives, Polymerization aids and vulcanizing agents |
| Carbon black CAS 1333-86-4 FCM 411 | DE Recomm. 21 | yes, before SCF Guidelines, BfR XXI category 1 - 4- see respective restrictions max. 30 %, The carbon blacks used must comply with the "Purity requirements for carbon blacks" laid down in Communication 82 of Bundesgesundheitsblatt, 15 (1972) 268. Acetylene black must comply with DAB purity requirements for medical grade carbon for category 3, only for rubbers teats, tubing for milking machines, seals for milk processing machines, membranes, plungers, mountings and the like and pump stators |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision Purity requirements in Annex IV D.M. 21.3.1973, Sect. 4, Point 3. (extract with toluene: it must not exceed 0.1 percent by weight) |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Charges Pour le noir de carbone, la teneur maximale (Qmax) est de 50 % en poids de l'article, ramenée à 30 % pour les articles au contact du lait ou des huiles. Le noir de carbone doit présenter un extrait toluénique inférieur ou égal à 0,15 %. L'extrait au cyclo |
| | CZ 38/2001 | Filler Part B not more than 10.0 % For selected applications where a small area of elastomer comes into contact with a large volume of food for a period not exceeding 10 minutes, at room temperature or lower (e.g. rubber components of milking apparatus, sealing for milk processing machines, sealing for the piping of a pump and valves for a drinking water distribution system, pump stators, conveyor belts, suction and pressure lines for filling and emptying containers). |
| | SK 1799/2003 A. 10 | Filler in vulcanised materials and articles Part B at a level of not more than 10.0 % by weight as per Annex 2 |
| | HR NN 125/2009 | Additive max 30% for category 2 elastomers (for articles remaining directly in contact with food between 10 minutes and 24 hours (e.g. tubes for conveying liquid food, bottle stoppers and caps, etc) |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA, UK) | Additives, Polymerisation aids and vulcanizing agents Max toluene extractable fraction=0.15% |
| | Casein CAS 9000-71-9 FCM 548 | FR Arrêté du 9/11/1994 (FR) |
| DE Recomm. 21 | | Protective colloids, thickeners and plasticiser for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| CoE ResAP (2004) (CoE cites DE, FR) | | Additives, Polymerization aids and vulcanizing agents |
| Cellulose [or Fibers of pure cellulose] CAS 9004-34-6 FCM 553 | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Colloïdes protecteurs, épaississants |
| | CoE ResAP (2004) (CoE cites DE, NL) | Additives, Polymerization aids and vulcanizing agents |
| | NL III 4.2.2g | Processing aids and additives: as filler EP=cat. 3 |
| Methylcellulose CAS 9004-67-5 FCM 561 | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Colloïdes protecteurs, épaississants |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Lubrifiants et agents de démoulage |
| | NL III 4.2.2h | Processing aids and additives: as emulsifier/stabiliser EP=cat. 3 |
| | DE Recomm. 21 | Slip agent and mould release agent, protective colloid, thickener and plasticiser for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|--|
| Hydroxyethylcellulose (same as 2-Hydroxyethyl ether cellulose) CAS 9004-62-0 FCM 558 | CoE ResAP (2004) (CoE cites DE; FR; NL; AU) | Additives, polymerisation aids and vulcanizing agents |
| | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Colloïdes protecteurs, épaississants |
| | NL III 4.2.2h | Processing aids and additives: as émulsifier/stabiliser EP=cat. 3 |
| | DE Recomm. 21 | Protective colloids, thickeners and plasticiser for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| Carboxymethylcellulose CAS 9000-11-7 FCM 542 | CoE ResAP (2004) (CoE cites DE,FR,NL) | Additives, polymerisation aids and vulcanizing agents |
| | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Colloïdes protecteurs, épaississants |
| | DE Recomm. 21 | Protective colloids, thickeners and plasticiser for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| Chlorinated rubber CAS 9006-03-5 PM 24220 | CoE ResAP (2004) (CoE cites DE, FR) | Additives, polymerisation aids and vulcanizing agents |
| | IT D.M. 21/3/73 | Elastomers, other macromolecules The restrictions are under revision |
| | HR NN 125/2009 | for articles in contact with drinking water may only contain di-(fenoxyethyl)formal softener in the amount not exceeding 25.0%, expressed in relation to finished film, provided that its presence may not be proven in drinking water |
| Chloroethylvinyl ether CAS 110-75-8 PM 14585 | CoE ResAP (2004) (CoE cites IT) | monomer and starting agent |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer EP=cat. 3 |
| Chlorotrifluoroethylene CAS 79-38-9 FCM 148 | CoE ResAP (2004) (CoE cites IT, NL) | monomer and starting agent |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer Only in combination with vinylidene fluoride; SML=0.05 |
| | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. Qm = 5 mg/kg |
| Citric acid CAS 77-92-9 FCM 139 | CoE ResAP (2004) | QMA=0.05 mg/6dm ² |
| | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Agents de coagulation |
| | DE Recomm. 21 | Neutralising agent for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| Cyclised rubber [or cyclo rubber] [or 1,3-Butadiene, 2-methyl-, homopolymer, of cis-1,4-configuration, cyclized] CAS 68441-13-4 | CoE ResAP (2004) (CoE cites DE, FR) | Additives, Polimerization aids and vulcanizing agents |
| | IT D.M. 21/3/73 | Elastomers, other macromolecules The restrictions are under revision |
| | HR NN 125/2009 | used in the manufacture of coloured films for drinking water containers may only contain di-(fenoxyethyl)formal softener in the amount not exceeding 25.0%, expressed in relation to finished film |
| Di-tert-butyl peroxide CAS 110-05-4 PM 47080 | CoE ResAP (2004) (CoE cites IT) | monomer and starting agent |
| | CZ 38/2001 | Elastomer, vulcanizing agents, cross-linking agents Part B, SML=ND Peroxide residues in a finished product made from silicone elastomer shall not be detectable |
| | SK 1799/2003 A. 10 | Vulcanising and cross-linking agent Part B Peroxide residues shall not be present in rubber materials and articles |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de vulcanisation |
| | NL III 4.2.2a | Processing aids and additives: as cross linking agent SML=ND |
| Dibenzoyl peroxide CAS 94-36-0 PM 46440 | CoE ResAP (2004) (CoE cites FR, NL, USA) | Additives, Polimerization aids and vulcanizing agents |
| | CZ 38/2001 | Elastomer, vulcanizing agents, cross-linking agents Part B, SML=ND Peroxide residues in a finished product made from silicone elastomer shall not be detectable |
| | SK 1799/2003 A. 10 | Vulcanising and cross-linking agent Part B Peroxide residues shall not be present in rubber materials and articles |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de vulcanisation |
| | NL III 4.2.2a | as cross linking agent SML=ND |
| Zn dibenzoyldithiocarbamate [or | CoE ResAP (2004) (CoE cites DE, FR, NL, USA) | Additives, Polimerization aids and vulcanizing agents |
| | HR NN 125/2009 | vulcanization accelerator max 0.5% (sum of all 1-5 from the positive list (Article67) should not exceed 1.2%) |
| | HR NN 125/2009 | for Articles made of Category 1, 2 or 3 elastomers. the same shall apply to Category 4 |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|--|--|
| Dibenzylthiocarbamic acid, zinc salt [or N,N-dibenzylthiocarbamate, zinc] CAS 14726-36-4 | | articles the content of free zincdibenzylthiocarbamate, expressed in relation to the share of elastomers, may not exceed 0.1 mg/kg; |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D, T |
| | CoE ResAP (2004) (CoE DE, FR, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| | CZ 38/2001 | Elastomer, accelerators Part A, The total content of zinc compounds in the vulcanized product must not exceed 2% (related to zinc) |
| | SK 1799/2003 A. 10 | Accelerator Part A The total level of zinc compounds in the vulcanised product shall not exceed 2 % by weight (expressed as zinc). |
| | DE Recomm. 21 | For the migration of zinc dibenzyl dithiocarbamate from Category 1 - 4 commodities a limit of 0.1 mg/kg elastomer is valid. yes, before SCF Guidelines; restriction for finished articles: For the migration of zinc dibenzyl dithiocarbamate from Category 1 -4 max. 0.5 % BfR XXI category 1, 2, 3 and 4 - see respective restrictions BfR XXI special category - see respective restrictions For the migration of zinc dibenzyl dithiocarbamate from Category 1 - 4 commodities a limit of 0.1 mg/kg elastomer is valid. |
| Dibutylamine CAS 111-92-2 | CZ 38/2001 | Elastomer, activators This substance or their residues must not be detectable in an extract from the finished product |
| | SK 1799/2003 A. 10 | Activator Part B The substance shall not be present in the autoclave leach from rubber articles |
| | NL III 4.2.2d | Processing aids and additives:as activator EP=cat. 3 |
| | DE Recomm. 21 | Surface hardener for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, NL) | Additives, Polymerization aids and vulcanizing agents |
| Dibutylthiocarbamic acid, sodium salt [or dibutylthiocarbamate of Na] [or sodium dibutylthiocarbamate] CAS 136-30-1 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégorie D |
| | NL III 4.2.2b | Processing aids and additives: as accelerator EP=cat. 3; max 3% in EP |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for dithiocarbamates |
| Dibutylthiocarbamic acid, zinc salt [or N,N-dibutylthiocarbamate, zinc] [or dibutylthiocarbamate of Zn] [or zinc dibutylthiocarbamate] CAS 136-23-2 PM 96160 | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D, T |
| | CZ 38/2001 | Elastomer, accelerators Part A, The total content of zinc compounds in the vulcanized product must not exceed 2% (related to zinc) |
| | SK 1799/2003 A. 10 | Accelerator Part A The total level of zinc compounds in the vulcanised product shall not exceed 2 % by weight (expressed as zinc). |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, polymerisation aids and vulcanizing agents |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for dithiocarbamates |
| Dicumyl peroxide CAS 80-43-3 | CZ 38/2001 | Elastomer, vulcanizing agents, cross-linking agents Part B, SML=ND Peroxide residues in a finished product made from silicone elastomer shall not be detectable |
| | SK 1799/2003 A. 10 | Vulcanising and cross-linking agent Part B Peroxide residues shall not be present in rubber materials and articles |
| | NL III 4.2.2a | Processing aids and additives: as cross linking agent SML=ND |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de vulcanisation |
| | CoE ResAP (2004) (CoE cites DE, FR, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Dicyclopentadiene [or tricyclo-(5,2,1)-dec-3,8-diene] CAS 77-73-6 PM 15730 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. |
| | IT D.M. 21/3/73 | Elastomers, dienic monomer The restrictions are under revision |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|--|---|
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=0.05 |
| | CoE ResAP (2004) (CoE cites DE, FR; IT,NL, USA) | Monomer and starting agent |
| Diethyldithiocarbamate of Zn [or Diethyldithiocarbamate, zinc salt] [or N,N-diethyldithiocarbamate, zinc] [or zinc diethyldithiocarbamate] CAS 14324-55-1 PM 96170 | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D, T |
| | CZ 38/2001 | Elastomer, accelerators Part A, The total content of zinc compounds in the vulcanized product must not exceed 2% (related to zinc) |
| | SK 1799/2003 A. 10 | Accelerator Part A The total level of zinc compounds in the vulcanised product shall not exceed 2 % by weight (expressed as zinc). |
| | CoE ResAP (2004) (CoE cites DE,FR,NL, IT, USA) | Additives, Polymerization aids and vulcanizing agents |
| Diethylene glycol [or bis(2-hydroxyethyl) ether] CAS 111-46-6 FCM 263 | NL III 4.2.2j | Processing aids and additives: as other subst. SML=30 (together with ethylene glycol) |
| | CoE ResAP (2004) (CoE cites NL) | Additives, Polymerization aids and vulcanizing agents SML(T)=30mg/kg with ethylene-glycol |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision The finished products must not release ethylene glycol |
| | CoE ResAP (2004) (CoE cites IT) | monomer and starting agent SML(T)=30mg/kg alone or with ethyleneglycol |
| Dimethyldiphenylthiuram disulphide [or sym-dimethyl diphenyl thiuram disulphide] CAS 53880-86-7 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D |
| | CZ 38/2001 | Elastomer, accelerators Part A, SML=ND Sulphur compounds in the extract from the finished product shall not be detectable |
| | SK 1799/2003 A. 10 | Accelerator Part A The substance shall not be present in the autoclave leach from rubber articles |
| | HR NN 125/2009 | vulcanization accelerator max 3% for sum of 6-10 from the list (Article 67) |
| | DE Recomm. 21 | vulcanization accelerator max 3% in total with other accelerators (This dosage is necessary for the production of heat-resistant vulcanisates); in total max 3% of zinc content for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE,FR,NL) | Additives, Polymerization aids and vulcanizing agents |
| Dimethyldithiocarbamic acid sodium salt [or Dimethyldithiocarbamate of Na] [or sodium dimethyldithiocarbamate] CAS 128-04-1 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D. |
| | NL III 4.2.2b | Processing aids and additives: as accelerator EP=cat. 3; max 3% in EP |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| | DE Recomm. 21 | Stabiliser and accelerator for natural latex in total max 1.2% with other accelerators for latexes and rubber dispersions The zinc content of Categories 1, 2 and 3 commodities must not exceed 3.0 % Here "alkyl" refers to methyl, ethyl, isopropyl, butyl and pentamethylene groups |
| Dimethyldithiocarbamic acid, copper salt [Dimethyldithiocarbamate of Cu] [or copper dimethyldithiocarbamate] CAS 137-29-1 | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2b | Processing aids and additives: as accelerator EP=cat. 3; max 3% in EP |
| | CoE ResAP (2004) (CoE cites FR,IT,NL,USA) | Additives, Polymerization aids and vulcanizing agents |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | FR Arrêté du 9/11/1994 (FR) In Arrêté du 9/11/1994 it is listed also with the CAS of "Potassium diethyldithiocarbamate" | Additifs : Accélérateurs Catégorie D |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D |
| Dimethyldithiocarbamic acid, zinc salt [or Dimethyldithiocarbamate of Zn] [or N,N-dimethyldithiocarbamate, zinc] [or zinc dimethyldithiocarbamate] | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| | CZ 38/2001 | Elastomer, accelerators Part A, The total content of zinc compounds in the vulcanized product must not exceed 2% (related to zinc) |
| | SK 1799/2003 A. 10 | Accelerator Part A The total level of zinc compounds in the vulcanised product shall not exceed 2 % by weight |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|---|---|
| CAS 137-30-4 PM 49425 | | (expressed as zinc). |
| | DE Recomm. 21 | Stabiliser for natural latex |
| | CoE ResAP (2004) (CoE cites DE,FR,IT NL, USA) | Additives, Polymerization aids and vulcanizing agents SML=1.2mg/kg |
| Dipentamethylenethiuram tetrasulphide [or di-N-pentamethylene thiuram tetrasulphide] CAS 120-54-7 | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D |
| | IT D.M. 21/3/73 | In D.M. 21/3/73 listed as "pentamethylenethiuram tetrasulphide", unlikely to be correct Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| | CZ 38/2001 | Elastomer, accelerators Part A, SML=ND Sulphur compounds in the extract from the finished product shall not be detectable |
| | SK 1799/2003 A. 10 | Accelerator Part A The substance shall not be present in the autoclave leach from rubber articles |
| | HR NN 125/2009 | vulcanization accelerator max 3% for sum of 6-10 from the list (Article 67) |
| | DE Recomm. 21 | Vulcanization accelerator max 3% in total with other accelerators (This dosage is necessary for the production of heat-resistant vulcanisates); in total max 3% of zinc content for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents | |
| Diphenylamine, styrenated CAS 68442-68-2 PM 51360 | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories C, D, contact gras exclu. Qmax = 1 % |
| | HR NN 125/2009 | anti-aging Elastomers that come into direct contact with food having fat or oil in its external phase must not contain styrenised diphenylamine as an anti-ageing agent |
| | DE Recomm. 21 | Anti-aging agent in total max 1% together with other anti-aging agents (Commodities manufactured using this antioxidant must not come into contact with fatty foodstuffs) for category 1, 2, 3 and 4 |
| | CoE ResAP (2004) (CoE cites DE, FR, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Diphenylguanidine [or 1,3- diphenylguanidine] [or N,N'- diphenylguanidine] CAS 102-06-7 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégorie D |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for primary aromatic amines |
| | NL III 4.2.2b | Processing aids and additives: as accelerator max 3% in EP, SML=0.05 |
| | CZ 38/2001 | Elastomer, accelerators Part B , max. 0.3% |
| | SK 1799/2003 A. 10 | Accelerator Part B not more than 0.3 % by weight |
| | HR NN 125/2009 | additive max 0.3 in category 3 articles |
| | DE Recomm. 21 | max 0.3% for category 3 and 4 |
| CoE ResAP (2004) (CoE cites DE,FR,IT,NL,USA) | | |
| Epichlorohydrin CAS 106-89-8 FCM 219 | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=ND |
| | CoE ResAP (2004) (CoE cites IT, UK) | Monomer and starting agent Qm=1mg/kg in fp |
| Erucamide CAS 112-84-5 FCM 271 | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de mise en œuvre Qmax = 0,2 % |
| | DE Recomm. 21 | Additive max 0.1% for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE,FR) | Additives, Polymerization aids and vulcanizing agents |
| | CoE ResAP (2004) (CoE cites UK) | Additives, Polymerization aids and vulcanizing agents |
| Ethylene [or ethene] CAS 74-85-1 FCM 125 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés |
| | IT D.M. 21/3/73 | Elastomer, olefyne The restrictions are under revision |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|---|--|
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Monomer and starting agent |
| Ethylene glycol [or ethandiol] CAS 107-21-1 FCM 227 | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision The finished products must not release ethylene glycol |
| | NL III 4.2.2j | Processing aids and additives: as other subst. SML=30 (together with diethylene glycol) |
| | CoE ResAP (2004) (CoE cites IT) | Monomer and starting agent SML=30mg/kg alone or with diethyleneglycol |
| | CoE ResAP (2004) (CoE cites NL) | Additives, Polymerization aids and vulcanizing agents SML=30mg/kg alone or with diethyleneglycol |
| Ethylphenyldithiocarbamic acid, zinc salt [or Ethylphenyldithiocarbamate of Zn and/or Zn N-dialkyldithiocarbamate] [or zinc ethylphenyldithiocarbamate] [or Zinc-N-ethylphenyldithiocarbamate] CAS 14634-93-6 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D, T. T : Qmax=0,4% |
| | CZ 38/2001 | Elastomer, accelerators Part A, The total content of zinc compounds in the vulcanized product must not exceed 2% (related to zinc) |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| | CoE ResAP (2004) (CoE cites DE, FR, NL, IT) | Additives, Polymerization aids and vulcanizing agents |
| | DE Recomm. 21 | Vulcanising accelerator max 0.4%, max 1.2% in total with other accelerants, in total max 3% of zinc content (According to available test results, it can be expected that, under the conditions of this Recommendation, no more than traces of zinc dithiocarbamates or their decomposition products, which are harmless to human health, transfer to foodstuffs) for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields). See also restrictions for N-Ethylaniline, CAS 103-69-5 |
| | HR NN 125/2009 | accelerant for vulcanisation sum max 0.4% (The total quantity of vulcanisation accelerator may not exceed 1.2% for accelerators under 1-5 (1. o-tolylbiguanide, not more than 1%; 2. Zn-N-dialkyl-dithiocarbamate ('alkyl' stands for methyl-, ethyl-, butyl- and pentamethylene groups) and/or 3. Zn-N-ethylphenyldithiocarbamate, not more than 0.4%; 4. tetramethylthiuram monosulfide; 5. Zn-dibenzylthiocarbamate, not more than 0.5%); |
| IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision | |
| Ethylphenyldithiocarbamate of Na [or Ethylphenyldithiocarbamic acid, sodium salt] [or sodium ethylphenyldithiocarbamate] CAS 13074-29-8 | IT D.M. 21/3/73 | |
| | DE Recomm. 21 in Recomm. 21 it is listed as "Sodium ethylphenyl dithiocarbamates" | Vulcanising aid max 0.4% in total max 1.2% together with sodium dialkyl dithiocarbamates, sodium alkyl xanthogenates and zinc alkyl xanthogenates for latexes and rubber dispersions |
| Factice CAS 12653-61-1 | CoE ResAP (2004) (CoE cites IT) | Additives, Polymerization aids and vulcanizing agents |
| | CZ 38/2001 | Elastomer, processing additives Part B Only natural or hydrogenated fats and oils of vegetable or animal origin, but not oxidised, may be used as a raw material for the production of factice |
| | SK 1799/2003 A. 10 | Processing additives Part B only natural fats and oils of vegetable or animal origin, or hydrogenated fats and oils of vegetable or animal origin, but not oxidised, may be used in the manufacture of factice |
| Formaldehyde CAS 50-00-0 FCM 98 | DE Recomm. 21 | Factice: unsaturated vegetable or animal oils reacted with sulfur, disulfur dichloride or hydrogen sulfide Processing aid max 20% In the production of factice, only natural and/or hydrogenated fats and oils of vegetable and/or animal origin, but no blown fats or oils, may be used as raw materials. Only aliphatic or cycloaliphatic secondary amines may be used as regulator in the production of factice. The regulators must be completely reacted (Testing for secondary aliphatic and cycloaliphatic amines is conducted in compliance with Section 2.5.2.2.5 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 20 (MvP-Berichte; 2/78)). Other factice additives and the amounts used must comply with this Recommendation for category 1, 2, 3 and 4 |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision For all the finished products for which in the production formaldehyde was used: the following is applicable: " limit test in Annex IV D.M. 21.3. 1973, sect.2 point 1: maximum release of formaldehyde: 0,5 mg/dm ² or 3 ppm with respect to the actua |
| Formaldehyde CAS 50-00-0 FCM 98 | FR Arrêté du 9/11/1994 (FR) | LMS = 3 mg/kg |
| | HR NN 125/2009 | for Articles made of Category 1, 2 or 3 elastomers in aqueous extracts may not exceed 3 µg/mL |
| | HR NN 125/2009 | for articles from category Special products baby feeding bottle components etc) must not release into the simulant more than 3 mg/kg of formaldehyde; |
| | CoE ResAP (2004) (CoE cites IT) | Additives, Polymerization aids and vulcanizing agents SML=15mg/kg |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|--|--|
| Formaldehyde-resorcinol, copolymer [or Resorcinol-formaldehyde resin] [or resorcinol-formaldehyde resins] CAS 24969-11-7 | FR Arrêté du 9/11/1994 (FR) | Additifs : Résines Rappel : LMS en formaldéhyde : 3 mg/kg. |
| | DE Recomm. 21 | Adhesion promoter max. 5.0 % 1 ml of aqueous extract obtained in accordance with the stipulated test procedure must contain no more than 3 µg formaldehyde (Testing is conducted according to section 2.7.1 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 21 (MvP-Berichte; 2/78) For category 1, 2, 3 and 4 |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, AU) | Additives, Polymerization aids and vulcanizing agents |
| Formaldehyde-xylene, copolymer [or xylene-formaldehyde resin] [or xylene-formaldehyde resins] CAS 9006-24-0 26139-75-3 | FR Arrêté du 9/11/1994 (FR) | Additifs : Résines Rappel : LMS en formaldéhyde : 3 mg/kg. |
| | NL III 4.2.2j | Processing aids and additives: as other subst. max 3% in EP |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents |
| | CZ 38/2001 | Elastomer, processing additives Part B Overall maximum limit of 5.0 % Formaldehyde content in the extract from the finished product transferring into food simulants, under leaching conditions laid down in Annex 4, and a ratio of 1 cm ² :1 ml, not more than 0.1 mg.dm ⁻² |
| | SK 1799/2003 A. 10 | Processing additives Part B not more than 5.0 % by weight |
| | DE Recomm. 21 | Processing aid in total max. 5%, together with liquid paraffins, palm kernel oil and lecithins, including any paraffin oils contained in factice for category 1, 2, 3 and 4 |
| Fumaric acid | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés Qm = 5 mg/kg |
| | CoE ResAP (2004) (CoE cites Fr, IT) | Monomer and starting agent |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| Glycerol CAS 56-81-5 FCM 103 | NL III 4.2.2d | Processing aids and additives: as activator EP=cat. 3 |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites IT) | Monomer and starting agent |
| | CoE ResAP (2004) (CoE cites NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Hexafluoropropylene [or hexafluoropropene] CAS 116-15-4 FCM 282 | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés LMS=ND (LD = 0,01 mg/kg) |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer specification: only in combination with vinylidene fluoride; molecular weight of the elastomer > 70,000; SML=0.05 |
| | CoE ResAP (2004) (CoE cites FR, IT; NL; USA) | Monomer and starting agent SML=0.01mg/kg |
| Hexamethylenediamine carbamate [or (6-Aminoheptyl)carbamic acid] CAS 143-06-6 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégorie D |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2a | Processing aids and additives: as cross linking agent EP=cat. 3, max 1.5% in EP; only in elastomers having vinylidene fluoride as a monomer |
| | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Hexamethylenetetramine CAS 100-97-0 FCM 196 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégorie D |
| | NL III 4.2.2b | Processing aids and additives: as accelerator EP=cat. 3; max 3% in EP |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for formaldehyde |
| | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents SML(T)=15mg/kg (expressed as formaldehyde) |
| Hydrocarbon waxes, paraffin and microcrystalline (hydrogenated) [or Food-grade paraffin waxes, including microcrystalline waxes] [or paraffin, | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de mise en œuvre 1. LMS = 0,3 mg/kg. 2. LMS = 3 mg/kg pour les cires hydrogénées |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | ES Real Decreto 847/2011 | Provisional list |
| | CoE ResAP (2004) (CoE cites FR, IT) | Additives, Polymerization aids and vulcanizing agents |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision Purity requirements in Annex IV D.M. 21.3.1973, Sect. 4, Point 1 |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|---|
| microcrystalline] [or paraffin] [or paraffin, solid] [or microcrystalline paraffin] [or microcrystalline petroleum wax] [or microcrystalline waxes] CAS 8002-74-2 63231-60-7 PM 71280 | CZ 38/2001 | Elastomer, processing additives Part B Paraffin approved by a body for the protection of public health |
| | SK 1799/2003 A. 10 | Processing additives Part B |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | CoE ResAP (2004) (CoE cites DE,IT, NL) | Additives, Polymerization aids and vulcanizing agents |
| | CZ 38/2001 | Elastomer, processing additives Part A Use of individual types for food contact approved by a body for the protection of public health |
| | SK 1799/2003 A. 10 | Processing additives Part A |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision Purity requirements in Annex IV D.M. 21.3.1973, Sect. 4, Point 1. |
| Hydrogen CAS 1333-74-0 | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CoE ResAP (2004) (CoE cites NL to be discussed) | monomer and starting agent |
| Hydroxymethanesulphonic acid, sodium salt [or sodium formaldehyde sulfoxylate] [or Sodium salt of hydroxymethanesulphonic acid] [or sodium hydroxymethanesulfinate] CAS 149-44-0 PM 61340 | NL III 4.2.2j | Processing aids and additives: as other subst. EP=cat. 3 |
| | ES Real Decreto 847/2011 | Provisional list |
| | CoE ResAP (2004) (CoE cites NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Isobutene [or 2-Methyl-1-propene] CAS 115-11-7 FCM 276 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés |
| | IT D.M. 21/3/73 | Elastomer, olefyne The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CoE ResAP (2004) (CoE cites DE, FR,IT,NL, USA) | Monomer and starting agent |
| Isopropanol [or 2-propanol] CAS 67-63-0 FCM 118 | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Antimousses |
| | DE Recomm. 21 | Defoaming agent for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR) | Additives, Polymerization aids and vulcanizing agents |
| Itaconic acid CAS 97-65-4 FCM 182 | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. |
| | CoE ResAP (2004) (CoE cites FR, IT) | Monomer and starting agent |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| Lecithin CAS 8002-43-5 FCM 528 | NL III 4.2.2h | Processing aids and additives: as emulsifier/stabiliser peroxide number of lecithin should not exceed 10 |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de mise en œuvre |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | CZ 38/2001 | Elastomer, processing additives Part A Maximum peroxide value of 10.0 |
| | SK 1799/2003 A. 10 | Processing additives Part A Peroxide number not more than 10.0 |
| | DE Recomm. 21 | Processing aid maximum peroxide value of 10 for category 1, 2, 3 and 4 |
| | CoE ResAP (2004) (CoE cites DE,FR,IT,NL) | Additives, Polymerization aids and vulcanizing agents |
| Linseed oil CAS 8001-26-1 PM 64160 (or 19532?) | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de mise en œuvre |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser EP=cat. 3 |
| | ES Real Decreto | |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|--|
| Magnesium carbonate CAS 546-93-0 | 847/2011 | |
| | CoE ResAP (2004) (CoE cites FR, NL) | Additives, Polymerization aids and vulcanizing agents |
| | CZ 38/2001 | Elastomer, activators, filler Part B (activator) A (filler) |
| | SK 1799/2003 A. 10 | Filler and activator Part A (filler) Part B (activator) |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2g NL III 4.2.2d | Processing aids and additives: as filler Processing aids and additives: as activator EP=cat. 3 |
| Magnesium oxide CAS 1309-48-4 FCM 397 | CZ 38/2001 | Elastomer, activators, fillers Part B (activator) A (filler) |
| | SK 1799/2003 A. 10 | Filler and activator Part A (filler) Part B (activator) |
| | FR Arrêté du 9/11/1994 (FR) In Arrêté du 9/11/1994 it is listed as "magnesium" but with the CAS of magnesium oxide | Additifs : Activateurs Les activateurs doivent être conformes aux critères de pureté relatifs à certains éléments minéraux applicables aux charges minérales destinées aux caoutchoucs |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2d | Processing aids and additives: as activator |
| | NL III 4.2.2g | Processing aids and additives: as filler |
| | CoE ResAP (2004) (CoE cites DE,FR,IT,NL,USA) | Polymerization aids and vulcanizing agents Additives, |
| | Magnesium silicate CAS 1343-88-0 | FR Arrêté du 9/11/1994 (FR) |
| CZ 38/2001 | | Filler Part A |
| SK 1799/2003 A. 10 | | Filler Part A |
| Maleic anhydride CAS 108-31-6 FCM 234 | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés LMS (T)= 30 mg/kg (exprimé en acide maléique) |
| | CoE ResAP (2004) (CoE cites DE, FR) | Monomer and starting agent SML(T)=30mg/kg (expressed as maleic acid) |
| | CoE ResAP (2004) (CoE cites DE, FR, UK) | Additives, Polymerization aids and vulcanizing agents |
| Melamine-resorcinol- formaldehyde resin [or Melamine- resorcinol- formaldehyde resins] | CZ 38/2001 | Elastomer, processing additives Part B Overall maximum limit of 5.0 % Formaldehyde content in the extract from the finished product transferring into food simulants, under leaching conditions laid down in Annex 4, and a ratio of 1 cm ² :1 ml, not more than 0.1 mg.dm ⁻² |
| | SK 1799/2003 A. 10 | Processing additives Part B not more than 5.0% by weight |
| | DE Recomm. 21 | Adhesion promoter max. 5.0 % 1 ml of aqueous extract obtained in accordance with the stipulated test procedure must contain no more than 3 µg formaldehyde (Testing is conducted according to section 2.7.1 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 21 (MvP-Berichte; 2/78) For category 1, 2, 3 and 4 |
| | | |
| Methacrylic acid CAS 79-41-4 FCM 150 | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés Qm = 5 mg/kg |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=3 |
| | CoE ResAP (2004) (CoE cites DE,FR, IT,NL,USA) | Monomer and starting agent |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| Methacrylic acid, diester with ethyleneglycol [or Methacrylic acid, ethylene ester] [or ethyleneglycol dimethacrylate] [or ethanediol dimethacrylate] CAS 97-90-5 FCM 185 | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=0.05 |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| | CoE ResAP (2004) (CoE cites IT, NL, USA) | Monomer and starting agent |
| | | |
| Methacrylic acid, | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|---|--|
| methyl ester [or methyl methacrylate] CAS 80-62-6 FCM 156 | CZ 38/2001 | Elastomer, monomers and starting substances Part B |
| | SK 1799/2003 A. 10 | Part B |
| | CoE ResAP (2004) (CoE cites DE, IT) | Monomer and starting agent |
| N,N'-Diphenylthiourea [or Thiocarbaniide] [or Diphenylthiourea] CAS 102-08-9 FCM 200 | NL III 4.2.2b In NL III 4.2.2b it is listed as "1,3-difeny-2-thioureum | Processing aids and additives: as accelerator EP=cat. 3 |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégorie D |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents SML=3mg/kg |
| N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine [or N-Phenyl-N'-(1,3-dimethylbutyl)-p-phenylenediamine] CAS 793-24-8 | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégorie D. Q _{max} = 1,5% |
| | HR NN 125/2009 | Additive not more than 1.5% for category 3 articles |
| | DE Recomm. 21 | max 1.5% (test under 3.4.4 of Recommendation 21) for category 3 and 4 |
| | CoE ResAP (2004) (CoE cites DE,FR) | Additives, Polymerization aids and vulcanizing agents |
| N-Cyclohexyl-2-benzothiazolesulphamide CAS 95-33-0 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories C, D |
| | NL III 4.2.2b | Processing aids and additives:as accelerator max 3% in EP, SML=0.05 |
| | CoE ResAP (2004) (CoE cites DE,FR;IT,NL) | Additives, Polymerization aids and vulcanizing agents |
| Natural rubber [or rubber, natural] CAS 9006-04-6 FCM 574 | DE Recomm. 21 | starting material light-coloured, non-smoked sorts (They must contain no p-nitrophenol, boric acid or sodium salt of pentachlorophenol; hydroxylamine must not be detectable in the finished product. Testing for these substances is conducted in accordance with sections 2.3.1, 3.7, 3.8 and 3.9 of the methods for "Testing commodities made of rubber", see. Part B II, XXI) for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | DE Recomm. 21 | starting material pre-cured. The amount of pre-cured rubber used is to be limited so that the total amount of substances permitted under 2.1.3.1.2 (additives, processing aids) of this basic list is not exceeded; if 2-mercaptobenzothiazole is use, its specific taste needs to be taken into account. for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | DE Recomm. 30 | Raw material in the form of pale crepes. The acetone extract from the natural rubber must not exceed 3.5 % |
| | IT D.M. 21/3/73 | Elastomers, other macromolecules The restrictions are under revision |
| | HR NN 125/2009 | starting substance for Special Category elastomers (light-coloured and pre-cross-linked types) Latex preserved with boric acid and pentachlorophenol sodium must not be used in the manufacture of Special Category elastomers. |
| | HR NN 125/2009 | for manufacture of articles from natural and synthetic rubber that come into direct contact with drinking water light-coloured natural rubber, cross-linked natural rubber, natural rubber polymerisates with esters of acrylic and methacrylic acid and C1-C4 monofunctional alcohols, butadiene and isoprene polymerisates |
| | CoE ResAP (2004) (CoE cites DE, IT, USA, AU/ to be discussed) | Monomer and starting agent |
| Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate CAS 2082-79-3 FCM 433 | DE Recomm. 21 | Commodities manufactured using this antioxidant must not come into contact with fatty foodstuffs. For ethylene-propylene rubber acc. to 2.1.3.1.1.7 of the basic list for Category 1 of Recomm. 21, max. 0.2 % as anti-aging agent max. 0.5 % BfR XXI category 1, 2, 3 and 4 - see respective restrictions |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2e in NL III 4.2.2e it is listed as "n-octadecyl-beta-(3,5-di-tert.butyl-4-hydroxyphenyl) propionate" | Processing aids and additives: as protective agent |
| | CZ 38/2001 | Elastomer, antidegradants Overall maximum limit of 1.0 %. |
| | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight |
| CoE ResAP (2004) | Additives, Polymerization aids and vulcanizing agents SML=6 mg/kg | |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|---|---|
| | (CoE cites DE, FR, IT, NL, USA; UK) | |
| Oleic acid, butyl ester [or butyl oleate] CAS 142-77-8 PM 69120 | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | ES Real Decreto 847/2011 | Provisional list |
| | CoE ResAP (2004) (CoE cites NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Oleic acid, dibutylamine salt [or dibutylammonium oleate] CAS 7620-75-9 | CZ 38/2001 | Elastomer, activators This substance or their residues must not be detectable in an extract from the finished product |
| | SK 1799/2003 A. 10 | Activator Part B The substance shall not be present in the autoclave leach from rubber articles |
| | NL III 4.2.2d | Processing aids and additives: as activator EP=cat. 3 |
| | CoE ResAP (2004) (CoE cites NL, USA) | |
| Organopolysiloxanes [or Silicone oils (organopolysiloxanes)] PM 69848 | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | DE Recomm. 21 | Slip agent and mould release agent and defoaming agent provided they comply with Section I of amended Recommendation XV ("Silicones") for category 1, 2, 3 and 4, for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR) | |
| o-Tolylbiguanide [or 1-(2-tolyl)-biguanide] CAS 93-69-6 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories B, C, D |
| | NL III 4.2.2b | Processing aids and additives: as accelerator max 3% in EP, SML=0.05 |
| | CZ 38/2001 | Elastomer, accelerators Part B, max. 1.0 % |
| | SK 1799/2003 A. 10 | Part B not more than 1.0 % by weight |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for secondary aromatic amines |
| | HR NN 125/2009 | vulcanization accelerator less than 1% |
| | DE Recomm. 21 | Vulcanising accelerator max 1.0% (max 1.2% in total with other accelerators - According to available test results, it can be expected that, under the conditions of this Recommendation, no more than traces of zinc dithiocarbamates or their decomposition products, which are harmless to human health, transfer to foodstuffs) for category 1, 2, 3 and 4 |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents |
| Palmitic acid CAS 57-10-3 FCM 105 | DE Recomm. 21 | yes, after SCF Guidelines, BfR XXI category 1, 2, 3 and 4 max. 1.5 %- see respective restrictions |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites IT, USA) | Additives, Polymerization aids and vulcanizing agents |
| Paraffin mineral oils [or paraffin, liquid (refined mineral oil)] [or liquid paraffins] [or refined mineral oil] CAS 8020-83-5 | IT D.M. 21/3/73 | Additive, The restrictions are under revision Purity requirements in Annex IV D.M. 21.3.1973, Sect. 4, Point 2 |
| | CZ 38/2001 | Elastomer, processing additives Part A 1997 Czech Pharmacopoeia, Volume 2 |
| | SK 1799/2003 A. 10 | Processing additives Part A purity as per the Slovak Pharmacopoeia |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | DE Recomm. 21 | Processing aid in total max. 5%, together with xylene-formaldehyde resins, palm kernel oil and lecithins, including any paraffin oils contained in factice The liquid paraffins used must comply with the purity requirements laid down in the Regulation on Food Additives (Zusatzstoffverkehrsverordnung). Testing for carcinogenic polycyclic hydrocarbons is conducted as prescribed in the 38th Communication on the testing of plastics (see Bundesgesundheitsblatt, 19 (1976) 231). Liquid paraffin, refined by hydrogenation, may also be used, provided it complies with the aforementioned purity requirements. for category 1, 2, 3 and 4, for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidégradants) Catégories A, B, C, D. Qmax = 1,4 % |
| p-Cresol-dicyclopentadiene - isobutylene, copolymer [or Butylated reaction products of p-cresol and dicyclopentadiene] [or Reaction product of 4-methylphenol with isobutylene and | DE Recomm. 21 | yes, after SCF Guidelines (Reaction product of 4-methylphenol with isobutylene and dicyclopentadiene) , BfR XXI category 1 and special category max. 1.4 % BfR XXI category 1 and special category - see respective restrictions |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|---|---|
| dicyclopentadiene] CAS 68610-51-5 FCM 732 | CoE ResAP (2004) (CoE DE, FR, IT, USA) | Additives, polymerisation aids and vulcanizing agents SML=0.05mg/kg |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision Not for foods for which migration test with simulant D is required. Specific migration limit: 30 ppm(da D.M. 3.6.94) |
| Pentachlorothiophenol, zinc salt [or zinc pentachlorothiophenolate] [or zinc salt of pentachlorothiophenol] CAS 117-97-5 PM 71520 | NL III 4.2.2j | Processing aids and additives: as other subst. EP=cat. 3; max 0.3% in EP |
| | CoE ResAP (2004) (CoE cites DE, NL) | Additives, Polymerization aids and vulcanizing agents |
| Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate] [or Tetrakis/methylene(3,5-di-tert-butyl-4-hydroxyhydrocinamat e)/-methane] [or tetrakis [methylene (3,5-di-tert.butyl-4-hydroxyphenyl) propionate]methane] [or pentaerythryl-tetrakis-3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate] [or pentaerythryl-tetrakis-3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate] CAS 6683-19-8 FCM 496 | DE Recomm. 21 | yes, after SCF Guidelines (German: Tetrakis-[methylen-(3,5-di-tert-butyl-4-hydroxyhydrocinamat)]methan) restricted use BfR XXI category 1, 2, 3 and 4 max. 0.25 % - see respective restrictions, BfR XXI special category max. 0.1 % - see respective restrictions e.g.: No contact with fat or foodstuffs in which fat forms the external phase). |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D, T. T: Qmax = 0,2% |
| Pentamethylenedithiocarbamic acid, piperidine salt [or piperidine pentamethylenedithiocarbamate] [or piperidinium pentamethylenedithiocarbamate] [or Pentamethylene-ammonium-N-pentamethylene-dithiocarbamate] CAS 98-77-1 PM 71710 | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2e | Processing aids and additives: as protective agent |
| Pentamethylenedithiocarbamic acid, piperidine salt [or piperidine pentamethylenedithiocarbamate] [or piperidinium pentamethylenedithiocarbamate] [or Pentamethylene-ammonium-N-pentamethylene-dithiocarbamate] CAS 98-77-1 PM 71710 | CZ 38/2001 | Elastomer, antidegradants Part A, only as part of the basic elastomer |
| | SK 1799/2003 A. 10 | Antidegradant Part A This substance may be used only as part of the base elastomer |
| Pentamethylenedithiocarbamic acid, piperidine salt [or piperidine pentamethylenedithiocarbamate] [or piperidinium pentamethylenedithiocarbamate] [or Pentamethylene-ammonium-N-pentamethylene-dithiocarbamate] CAS 98-77-1 PM 71710 | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| | DE Recomm. 21 | Surface hardener for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) Must not be detectable In the finished product (Testing is conducted in accordance with Section 2.5.2.2.6 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 21 (MvP-Berichte; 2/78)) |
| Pentamethylenedithiocarbamic acid, zinc salt [or Pentamethylenedithiocarbamate of Zn] [or zinc pentamethylenedithiocarbamate] CAS 13878-54-1 | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories B, C, D |
| | CZ 38/2001 | Elastomer, accelerators Part A, The total content of zinc compounds in the vulcanized product must not exceed 2% (related to zinc) |
| Phenols and/or cresol styrene and/or alpha-methyl-styrene and/or olefins (C3-C12), copolymers [or phenol and/or methylphenols, converted with styrene or α-methylstyrene and/or olefins of chain length C3-C12] [or reaction product of styrene and/or alpha methyl styrene and/or alkenes (C3-C12) with phenol and/or methyl phenol] [or styrene and/or | SK 1799/2003 A. 10 | Accelerator Part A The total level of zinc compounds in the vulcanised product shall not exceed 2 % by weight (expressed as zinc). |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| Phenols and/or cresol styrene and/or alpha-methyl-styrene and/or olefins (C3-C12), copolymers [or phenol and/or methylphenols, converted with styrene or α-methylstyrene and/or olefins of chain length C3-C12] [or reaction product of styrene and/or alpha methyl styrene and/or alkenes (C3-C12) with phenol and/or methyl phenol] [or styrene and/or | CoE ResAP (2004) (CoE cites FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| Phenols and/or cresol styrene and/or alpha-methyl-styrene and/or olefins (C3-C12), copolymers [or phenol and/or methylphenols, converted with styrene or α-methylstyrene and/or olefins of chain length C3-C12] [or reaction product of styrene and/or alpha methyl styrene and/or alkenes (C3-C12) with phenol and/or methyl phenol] [or styrene and/or | CoE ResAP (2004) (CoE cites DE, NL) | Additives, Polymerization aids and vulcanizing agents |
| | DE Recomm. 21 | Anti-aging agent max 1% in total, together with other anti-aging agents for category 1, 2, 3 and 4 |
| Phenols and/or cresol styrene and/or alpha-methyl-styrene and/or olefins (C3-C12), copolymers [or phenol and/or methylphenols, converted with styrene or α-methylstyrene and/or olefins of chain length C3-C12] [or reaction product of styrene and/or alpha methyl styrene and/or alkenes (C3-C12) with phenol and/or methyl phenol] [or styrene and/or | CZ 38/2001 | Elastomer, antidegradants Part B Overall maximum limit of 1.0 % |
| | NL III 4.2.2e | Processing aids and additives: as protective agent SML=0.05 |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|---|---|
| alfa-methylstyrene and/or -alkene(C3-C12)phenol and/or methylphenol reaction products] PM 72105 | | |
| Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester [or tris(2,4-di-tert-butylphenyl) phosphite] [or tris-(2,4-di-tert-butyl-phenyl)-diphosphite] CAS 31570-04-4 FCM 671 | DE Recomm. 21 | Commodities manufactured using this antioxidant must not come into contact with fatty foodstuffs. As pre-stabiliser in synthetic rubber or as stabiliser for copolymers of butadiene, or isoprene and styrene in the form of sequential polymers for the manuf max. 0.4 %, BfR XXI category 1, 2, 3 and 4 see footnote 22 and other respective restrictions BfR XXI special category - see respective restrictions |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidéggradants) Catégories A, B, C, D |
| | NL III 4.2.2e | Processing aids and additives: as protective agent |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, USA, NL) | Additives, Polymerization aids and vulcanizing agents |
| IT D.M. 21/3/73 | Additive For butadienic rubber, maximum amount 0.4% and not for foods for which migration test with simulants A,B,D is required (da D.M. 4.4.85e da D.M. 26.4.93). | |
| Phthalic acid, benzyl butyl ester [or benzyl butyl phthalate] CAS 85-68-7 FCM 159 | FR Arrêté du 9/11/1994 (FR) | Additifs : Plastifiants LMS = 6 mg/kg |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision maximum use level 5 %, cumulative for all phthalates and not for foods for which the test with simulant D is required. (DM 17/12/99) |
| | CoE ResAP (2004) (CoE cites FR, IT) | Additives, Polymerization aids and vulcanizing agents SML= 6 mg/kg |
| Phthalic acid, bis(2-ethylhexyl) ester [or bis(2-ethylhexyl) phthalate] [or di(2-ethyl hexyl) phthalate] CAS 117-81-7 FCM 283 | FR Arrêté du 9/11/1994 (FR) | Additifs : Plastifiants LMS = 1,5 mg/kg |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision maximum use level 5 %, cumulative for all phthalates and not for foods for which migration test with simulant D is required. (DM 17/12/99) |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser, SML will be updated SML=40 |
| | HR NN 125/2009 | softener for A-C fields of application not exceeding 10.0%; the total content of softener may not exceed 20.0%. Avoiding the use of di-(2- ethylhexyl) phthalate is recommended |
| | DE Recomm. 21 | max 10% for category 3 and 4 |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents SML=3 mg/kg |
| Phthalic acid, dibutyl ester [or dibutyl phthalate] CAS 84-74-2 FCM 157 | FR Arrêté du 9/11/1994 (FR) | Additifs : Plastifiants LMS = 3 mg/kg |
| | SK 1799/2003 A. 10 | Processing additives Part B |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision maximum use level 5 %, cumulative for all phthalates and not for foods for which the test with simulant D is required. (DM 17/12/99) |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser, SML will be updated SML=15 |
| | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents SML=3mg/kg |
| Phthalic acid, diethyl ester [or diethyl phthalate] CAS 84-66-2 PM 75120 | IT D.M. 21/3/73 | Additive, The restrictions are under revision maximum use level 5 %, cumulative for all phthalates and not for foods for which migration test with simulant D is required. (DM 17/12/99) |
| | ES Real Decreto 847/2011 | Provisional list |
| | CoE ResAP (2004) (CoE cites IT) | Additives, Polymerization aids and vulcanizing agents SML=12mg/kg |
| Phthalic acid, diisooctyl ester [or diisooctyl phthalate] CAS 27554-26-3 PM 75520 | IT D.M. 21/3/73 | Additive, The restrictions are under revision maximum use level 5 %, cumulative for all phthalates and not for foods for which migration test with simulant D is required. (DM 17/12/99) |
| | SK 1799/2003 A. 10 | Processing additives Part B |
| | CoE ResAP (2004) (CoE cites IT) | Additives, Polymerization aids and vulcanizing agents |
| Phthalic acid, di-n-octyl ester [or di-n-octyl phthalate] CAS 117-84-0 PM 75840 | NL III 4.2.2f | Processing aids and additives: as plasticiser, SML will be updated SML=6 |
| | SK 1799/2003 A. 10 | Processing additives Part B |
| | CoE ResAP (2004) (CoE cites NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Phthalic anhydride CAS 85-44-9 FCM 158 | CZ 38/2001 | Elastomer, retarders Part A, max. 0.5% Overall maximum limit of 2.5 %. |
| | SK 1799/2003 A. 10 | Retardants Part A not more than 0.5 % by weight |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|---|---|
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Retardateurs |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2c | Processing aids and additives: as retarder |
| | DE Recomm. 21 | Vulcanisation retarder max 0.5% in total max 2.5% with benzoic acid and stearic acid for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Monomer and starting agent |
| | CoE ResAP (2004) (DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Polybutene CAS 9003-29-6 PM 76520 | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de mise en œuvre |
| | CoE ResAP (2004) (CoE cites FR, NL, USA, UK) | Additives, Polymerization aids and vulcanizing agents |
| Polyethylene, chlorosulphonated CAS 68037-39-8 9008-08-6 (for Rubber, synthetic, chlorosulfonated polyethylene) | CoE ResAP (2004) (CoE cites DE, FR, IT, AU) | monomer and starting agent |
| | DE Recomm. 21 | starting material only for rubberised textiles and linings. Methanol extract from the chlorosulfonated polyethylene must not exceed 2.0 % (These requirements serve to ensure sufficiently high qualities of natural and synthetic rubber. Testing is conducted in accordance with Sections 2.1 and 2.2 of methods, see. Part 1. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, (MvP-Berichte; 2/78)) for category 1, 2, 3 and 4 |
| | IT D.M. 21/3/73 | Elastomers, other macromolecules The restrictions are under revision |
| Polyethylene wax [or Polyethylene] [or Polyethene] CAS 9002-88-4 FCM 549 | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de mise en œuvre |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser according to (EU) No 10/2011, molecular weight > 200 |
| | CZ 38/2001 | Elastomer, processing additives Part A Polyethylene complying with the hygiene requirements under Section 10 of the Implementing Decree |
| | SK 1799/2003 A. 10 | Processing additives Part A according to Annex 5 |
| | CoE ResAP (2004) (CoE cites FR) | Additives, Polymerization aids and vulcanizing agents |
| | CoE ResAP (2004) (CoE cites DE, NL, UK, USA) | Additives, Polymerization aids and vulcanizing agents |
| Polyethyleneglycol [or polyethylene oxide] [or polyoxyethylene] CAS 25322-68-3 FCM 638 | FR Arrêté du 9/11/1994 (FR) | Additifs : Lubrifiants et agents de démoulage |
| | NL III 4.2.2j | Processing aids and additives: as other subst. according to (EU) No 10/2011, molecular weight > 200 |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision The finished products must not release mono and diethylene glycol |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents |
| | DE Recomm. 21 | Polyethylene glycol may contain no more than 0.2 % monoethylene glycol. For method of determination see Communication 28 on the testing of plastics in Bundesgesundheitsbl. 16 (1973) 362 max. 2.0 % before SCF Guidelines BfR XXI category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) - see respective restrictions (especially footnote 26) |
| | CZ 38/2001 | Elastomer, processing additives Part A molecular weight higher than 4 000 (with a content of ethylene glycol and/or bis(2-hydroxyethyl) ether less than 0.3 %) |
| | SK 1799/2003 A. 10 | Processing additives Part A molecular weight greater than 4 000 with a level of ethylene glycol or bis-2-hydroxyethyl ether not more than 0.3 % by weight |
| Polypropyleneglycol [or polypropylene oxide] CAS 25322-69-4 FCM 639 | FR Arrêté du 9/11/1994 (FR) | Additifs : Lubrifiants et agents de démoulage |
| | NL III 4.2.2j | Processing aids and additives: as other subst. according to (EU) No 10/2011, molecular weight > 400 |
| | DE Recomm. 21 | Slip agent and mould release agent for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) | Additives, Polymerization aids and vulcanizing agents |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|---|--|
| | (CoE cites DE,FR, NL) | |
| Polyvinyl alcohol CAS 9002-89-5 PM 81280 | IT D.M. 21/3/73 | Elastomers, other macromolecules The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites IT) | Monomer and starting agent |
| | CoE ResAP (2004) (CoE cites DE, FR) | Additives, Polymerization aids and vulcanizing agents |
| | DE Recomm. 21 | Protective colloids, thickeners and plasticiser viscosity of 4 % aqueous solution at 20 °C min. 5 mPa · s for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | ES Real Decreto 847/2011 | Provisional list |
| Polyvinylpyrrolidone CAS 9003-39-8 FCM 552 | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Colloïdes protecteurs, épaississants |
| | IT D.M. 21/3/73 | Elastomers, other macromolecules The restrictions are under revision |
| | DE Recomm. 21 | Protective colloids, thickeners and plasticiser viscosity of 5 % aqueous solution at 20 °C 34-38 mPa · s for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites IT) | Monomer and starting agent |
| | CoE ResAP (2004) (CoE cites DE, FR) | Additives, Polymerization aids and vulcanizing agents |
| Potassium hydroxide CAS 1310-58-3 FCM 399 | FR Arrêté du 9/11/1994 (FR) In Arrêté du 9/11/1994 it is listed as "potassium", but with CAS 1310-58-3 | Additifs : Agents tampon ou de neutralisation |
| | DE Recomm. 21 | Neutralising agent for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR) | Additives, Polymerization aids and vulcanizing agents |
| Potassium sorbate [or sorbic acid, potassium salt] CAS 24634-61-5 590-00-1 | FR Arrêté du 9/11/1994 (FR) | Additifs (Latex) : Agents de protection contre la fermentation |
| | DE Recomm. 21 | Anti-fouling agent in total max 0.4% together with Sodium benzoate, Ammonium benzoate and 1,2-Benzisothiazolin-3-one (the maximum amount given is based on the latex) for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| Propylene [or propene] CAS 115-07-1 FCM 275 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés |
| | IT D.M. 21/3/73 | Elastomer, olefin The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CoE ResAP (2004) (CoE cites DE,FR,IT,NL,USA) | Monomer and starting agent |
| Rapeseed oil CAS 8002-13-9 PM 83580/1 | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | ES Real Decreto 847/2011 | |
| | CoE ResAP (2004) (CoE cites NL) | Additives, Polymerization aids and vulcanizing agents |
| Rosin [or Colophony] CAS 8050-09-7 FCM 535 | FR Arrêté du 9/11/1994 (FR) | Additifs : Résines |
| | D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser according to paper and board (NL) |
| | DE Recomm. 21 | Processing aid max 2% for category 1, 2, 3 and 4 |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Rosin, hydrogenated [or Colophony,hydrogenated] [or Ester of partially hydrogenated rosin] CAS 65997-06-0 FCM 717 | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | ES Real Decreto 847/2011 | |
| | CoE ResAP (2004) (CoE cites IT) | Additives, Polymerization aids and vulcanizing agents |
| Salicylic acid CAS 69-72-7 FCM 121 | CZ 38/2001 | Elastomer, retarders Part A, max. 0.1% Overall maximum limit of 2.5 % |
| | SK 1799/2003 A. 10 | Retardants Part A |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|--|
| | | total level of not more than 1.0 % by weight |
| | Arrêté du 9/11/1994 (FR) | Additifs : Retardateurs |
| | NL III 4.2.2c | Processing aids and additives: as retarder EP=cat. 3 |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Sebacic acid, bis(2-ethylhexyl) ester [or bis(2-ethylhexyl) sebacate] [or Di-2-ethylhexyl sebacate] CAS 122-62-3 PM 85120 | FR Arrêté du 9/11/1994 (FR) | Additifs : Plastifiants LMS (T) = 1,5 mg/kg |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites IT, FR) | Additives, Polymerization aids and vulcanizing agents |
| Sebacic acid, dibutyl ester [or dibutyl sebacate] CAS 109-43-3 FCM 242 | FR Arrêté du 9/11/1994 (FR) | Additifs : Plastifiants LMS (T) = 1,5 mg/kg |
| | D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | CZ 38/2001 | Elastomer, processing additives Part B |
| | SK 1799/2003 A. 10 | Processing additives Part B |
| | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Sebacic acid, di-n-octyl ester [or di-n-octyl sebacate] CAS 2432-87-3 PM 85520 | NL III 4.2.2f | Processing aids and additives: as plasticiser |
| | CZ 38/2001 | Elastomer, processing additives Part A |
| | SK 1799/2003 A. 10 | Processing additives Part A |
| | CoE ResAP (2004) (CoE cites NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Silicon dioxide [or Silica] [or oxides of silicon] [or silicon oxide] CAS 7631-86-9 112945-52-5 FCM 504 | NL III 4.2.2g | Processing aids and additives: as filler |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Charges Pour toutes les charges, il est spécifié que la teneur en éléments minéraux - déterminé après solubilisation dans l'acide chlorhydrique 0,1 M - ne doit pas dépasser les limites suivantes : plomb : 0,01 % ; arsenic : 0,01 % ; mercure : 0,005 % ; cadmium : 0 |
| | In Arrêté du 9/11/1994 it is listed as "Silica and silylated silica", thus a line with silylated silica has been added | |
| | CZ 38/2001 | Filler |
| | SK 1799/2003 A. 10 | Filler Part A |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA, UK) | Additives, Polymerization aids and vulcanizing agents |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| Sodium hydroxide [or soda] CAS 1310-73-2 FCM 400 | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents tampon ou de neutralisation |
| | DE Recomm. 21 | Neutralising agent for latexes and rubber dispersions and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR) | Additives, Polymerization aids and vulcanizing agents |
| Soybean oil, epoxidised CAS 8013-07-8 FCM 532 | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de mise en œuvre |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2f | Processing aids and additives: as plasticiser oxirane content of epoxidised oil between 6,4 en 8% |
| | CZ 38/2001 | Elastomer, processing additives Part B Maximum iodine value of 8.0 |
| | SK 1799/2003 A. 10 | Processing additives Part B iodine value of not more than 8.0 |
| | CoE ResAP (2004) (CoE cites FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents Oxirane <8%, iodine number <6 |
| Stearic acid CAS 57-11-4 FCM 106 | CZ 38/2001 | Elastomer, retarders Part A, max. 1.5% Overall maximum limit of 2.5 % |
| | SK 1799/2003 A. 10 | Retardants Part A not more than 1.5 % by weight |
| | IT D.M. 21/3/73 | Cross-linking accelerants |
| | DE Recomm. 21 | Vulcanisation retarder max 1.5% |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|--|
| | | in total max 2.5% with phthalic anhydride and benzoic acid for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, UK, AU, USA) | Additives, Polymerization aids and vulcanizing agents |
| Stearic acid, monoester with glycerol [or glycerol monostearate] [or glyceryl monostearate] CAS 31566-31-1 PM 57520 | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de mise en œuvre |
| | ES Real Decreto 847/2011 | |
| | CoE ResAP (2004) (CoE cites FR) | Additives, polymerisation aids and vulcanizing agents |
| Styrene CAS 100-42-5 FCM 193 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés |
| | IT D.M. 21/3/73 | Elastomer, other monomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer |
| | CoE ResAP (2004) (CoE cites DE,FR,IT,NL,UK, USA) | Monomer and starting agent |
| | CoE ResAP (2004) (CoE cites USA) | Additives, polymerization aids and vulcanizing agents |
| Sulphur CAS 7704-34-9 FCM 514 | CZ 38/2001 | Elastomer, vulcanizing agents, cross-linking agents Part A |
| | SK 1799/2003 A. 10 | Vulcanising agent Part A |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Agents de vulcanisation |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2a | Processing aids and additives: as cross linking agent |
| | DE Recomm. 21 | Vulcanising agent for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Barium sulfate (Ba So4) [or Sulphuric acid, barium salt] CAS 7727-43-7 PM 92000 | FR Arrêté du 9/11/1994 (FR) | Additifs : Charges Pour toutes les charges, il est spécifié que la teneur en éléments minéraux - déterminé après solubilisation dans l'acide chlorhydrique 0,1 M - ne doit pas dépasser les limites suivantes : plomb : 0,01 % ; arsenic : 0,01 % ; mercure : 0,005 % ; cadmium : 0 |
| | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2g | Processing aids and additives: as filler SML=1 (als Ba) |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL;USA) | Additives, polymerisation aids and vulcanizing agents |
| Tetrabutylthiuram monosulphide CAS 93-73-2 | CZ 38/2001 | Elastomer, accelerators Part A, SML=ND Sulphur compounds in the extract from the finished product shall not be detectable |
| | SK 1799/2003 A. 10 | Accelerator Part A The substance shall not be present in the autoclave leach from rubber articles |
| | NL III 4.2.2b | Processing aids and additives: as accelerator EP=cat. 3; max 3% in EP |
| | CoE ResAP (2004) (CoE cites NL, USA) | Additives, polymerisation aids and vulcanizing agents |
| Tetraethylthiuram disulphide CAS 97-77-8 PM 92400 | CZ 38/2001 | Part A, SML=ND Sulphur compounds in the extract from the finished product shall not be detectable |
| | SK 1799/2003 A. 10 | Accelerator Part A The substance shall not be present in the autoclave leach from rubber articles |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| | HR NN 125/2009 | vulcanization accelerator max 3% for sum of 6-10 from the list (Article 67) |
| | CoE ResAP (2004) (DE, FR, IT, NL, USA) | Additives, polymerisation aids and vulcanizing agents |
| | DE Recomm. 21 | Vulcanising accelerator and stabiliser for natural latex max 3% in total with other accelerators (This dosage is necessary for the production of heat-resistant vulcanisates); in total max 3% of zinc content for category 1, 2, 3 and 4 |
| IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision Limit test for thiourames | |
| Tetrafluoroethylene | FR Arrêté du | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|---|
| CAS 116-14-3 FCM 281 | 9/11/1994 (FR) | 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. LMS = ND (LD = 0,05 mg/kg) |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer only in combination with vinylidene fluoride and hexafluoropropylene; molecular weight of the elastomer > 100,000 SML=0.05 |
| | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | monomer and starting agent SML=0.05mg/kg |
| Tetramethylthiuram disulphide CAS 137-26-8 PM 92720 | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | CZ 38/2001 | P Elastomer, accelerators art A, SML=ND Sulphur compounds in the extract from the finished product shall not be detectable |
| | SK 1799/2003 A. 10 | Accelerator Part A The substance shall not be present in the autoclave leach from rubber articles |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| | HR NN 125/2009 | vulcanization accelerator max 3% for sum of 6-10 from the list (Article 67) |
| | DE Recomm. 21 | Vulcanising accelerator and stabiliser for natural latex in total max 3% with other accelerants (This dosage is necessary for the production of heat-resistant vulcanisates); in total max 3% of zinc content for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents | |
| Tetramethylthiuram monosulphide CAS 97-74-5 | CZ 38/2001 | Elastomer, accelerators Part A, SML=ND Sulphur compounds in the extract from the finished product shall not be detectable |
| | SK 1799/2003 A. 10 | Accelerator Part A The substance shall not be present in the autoclave leach from rubber articles |
| | NN 125/2009 | vulcanization accelerator sum of accelerators 1-5 in the ordinance should not exceed 1.2% |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Accélérateurs Catégories A, B, C, D |
| | NL III 4.2.2b | Processing aids and additives: as accelerator SML=1 (sum of all dithiocarbamates), max 3% in EP |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | DE Recomm. 21 | Vulcanising accelerator max 1.2% in total with other accelerants - max 3% in total of zinc content for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| CoE ResAP (2004) (CoE cites DE, FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents | |
| Thiodipropionic acid, didodecyl ester [or thiodipropionic acid dilauryl ester] [or didodecyl thiodipropionate] CAS 123-28-4 FCM 294 | DE Recomm. 21 | max. 0.25 %; layer not thicker than 20 µm, in some cases restricted use (see BfR XXI), There must be no contact with fat or with foodstuffs in which fat forms the external phase. BfR XXI category 1, 2, 3 and 4 and special category - see respective restrictions |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Antioxygènes (antidégradants) Catégories A, B, C, D, T. Qmax = 0,4 % |
| | IT D.M. 21/3/73 Not found in D.M. 21/3/73, where "Stearyl dithio propionate" is present instead | Additive, The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, UK) | Additives, polymerisation aids and vulcanizing agents SML(T)=5 mg/kg (with dioctadecyl ester) |
| Tin (II) chloride [or Stannous chloride] CAS 7772-99-8 PM 93415 | IT D.M. 21/3/73 | Additive, The restrictions are under revision Use level: 0,6 % (D.M. 3.6.94). |
| | NL III 4.2.2d | Processing aids and additives:as activator EP=cat. 3 |
| | CoE ResAP (2004) (CoE cites IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Titanium dioxide [or titanium oxide] [or oxides of titanium] CAS 1317-70-0 13463-67-7 FCM 610 | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2g | Processing aids and additives: as filler |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Charges Pour toutes les charges, il est spécifié que la teneur en éléments minéraux - déterminé après solubilisation dans l'acide chlorhydrique 0,1 M - ne doit pas dépasser les limites suivantes : plomb : 0,01 % ; arsenic : 0,01 % ; mercure : 0,005 % ; cadmium : 0 |
| | CZ 38/2001 | filler |
| | SK 1799/2003 A. 10 | Filler Part A |
| CoE ResAP (2004) | Additives, Polymerization aids and vulcanizing agents | |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|--|---|--|
| | (CoE cites FR, IT, NL, USA) | |
| Triethanolamine [or Tris(2-hydroxyethyl)amine] CAS 102-71-6 FCM 793 | FR Arrêté du 9/11/1994 (FR) | Additifs : Activateurs Les activateurs doivent être conformes aux critères de pureté relatifs à certains éléments minéraux applicables aux charges minérales destinées aux caoutchoucs |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2j | Processing aids and additives: as other subst. only to be used in mould release agents; SML=0.01 |
| | ES Real Decreto 847/2011 | SML = 0.05 mg / kg (including hydrochloric adduct) |
| | CoE ResAP (2004) (CoE cites FR, IT, NL, USA) | Additives, Polymerization aids and vulcanizing agents |
| Tri-n-butyl acetyl citrate [or acetyl tributyl citrate] CAS 77-90-7 FCM 138 | NL III 4.2.2f | Processing aids and additives: as plasticiser EP=cat. 3 |
| | CZ 38/2001 | Elastomer, processing additives Part B |
| | SK 1799/2003 A. 10 | Processing additives Part B |
| | CoE ResAP (2004) (CoE cites NL) | Additives, polymerisation aids and vulcanizing agents |
| Tris (mono-and / or dinonyl)-phenyl-phosphite [or Tris(mono- and dinonylphenyl) phosphite] | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | CZ 38/2001 | Elastomer, antidegradants Products made with elastomer produced from these compounds shall not be used for contact with fats and foods containing more than 5 % fat. Overall maximum limit of 1.0 %. Requirements regarding the purity of phosphite antioxidants: the content of unreacted nonylphenols (nonylphenol and dinonylphenol) shall not exceed 6.0 %. The content of free unsubstituted phenol shall not exceed 0.05 %. The content of tris(nonyl-phenyl) phosphate and bis(nonylphenyl) phosphite shall not exceed 1.0 %. As a means of preventing hydrolysis, a maximum of 1.0 % of tri-2-propanol amine may be added to tris(nonylphenyl) phosphite. This added substance shall not be detectable in the finished products. |
| | SK 1799/2003 A. 10 | Antidegradant Part B The substance shall not be used for rubber materials and articles intended for contact with food with more than 5.0 % by weight of fat; unless otherwise specified, it may be present in rubber materials articles at a total aggregate level of not more than 1.0 % by weight; it shall not contain more than: 6.0 % by weight of unreacted nonylphenols (nonylphenol and dinonyl); 0.05 % by weight of free unsubstituted phenol; an aggregate of not more than 1.0 % by weight of tris-(nonylphenol) phosphite and bis-(nonylphenol)-phosphite. To prevent hydrolysis, not more than 1.0 % by weight of 2-tri-phenylpropanolamine may be used for tris-(nonylphenol) phosphite. This substance shall be undetectable in rubber materials and articles |
| | NL III 4.2.2e | Processing aids and additives: as protective agent EP=cat. 3 tris(2-hydroxypropyl)amine content not to exceed 1% |
| Urea CAS 57-13-6 FCM 107 | IT D.M. 21/3/73 | Additive, The restrictions are under revision |
| | NL III 4.2.2j | Processing aids and additives: as other subst. |
| | CZ 38/2001 | Elastomer, processing additives Part B not more than 3.0 % |
| | SK 1799/2003 A. 10 | Processing additives Part B not more than 3.0 % by weight |
| | DE Recomm. 21 | Processing aid max 3% for category 1, 2, 3 and 4 |
| | CoE ResAP (2004) (CoE cites DE, IT, NL) | Additives, polymerisation aids and vulcanizing agents |
| Vinyl chloride CAS 75-01-4 FCM 127 | FR Arrêté du 9/11/1994 (FR) | Section A : monomères et substances de départ autorisés Qm=1 mg/kg. LMS=ND (LD = 0,01 mg/kg) |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | CoE ResAP (2004) (CoE cite DE,FR,IT) | monomer and starting agent Qm=1mg/kg in fp and SML=0.01 mg/kg |
| Vinylidene fluoride CAS 75-38-7 FCM 132 | FR Arrêté du 9/11/1994 (FR) | Section B : monomères et autres substances de départ qui peuvent être utilisées jusqu'au 31 décembre 1998. Ces substances ne peuvent donc plus être utilisées actuellement : la modification ou la suppression de cette liste est à l'étude actuellement. LMS = ND (LD = 0,05 mg/kg) |
| | IT D.M. 21/3/73 | Elastomer, monomers for special elastomers The restrictions are under revision |
| | NL III 4.2.1 | Monomers and other starting substances: as monomer SML=1 |
| | CoE ResAP (2004) (CoE cites, FR; IT; NL, USA) | monomer and starting agent SML=5mg/kg |
| Zinc carbonate CAS 3486-35-9 | CZ 38/2001 | Elastomer, activators, filler Part A, The total content of zinc compounds in the vulcanized product must not exceed 2% (related to zinc) |
| | SK 1799/2003 A. 10 | Activator and filler Part A |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Activateurs (1) (a) The migration of zinc into food or its simulants must not exceed 10 mg/kg. (b) With regard to the use of zinc salts or oxide in the manufacture of teats and soothers, the following specifications shall be observed: |

| Substance name, CAS Number, and FCM or PM Ref. number | Legislation | Restrictions and comments |
|---|--|--|
| | | Maximum contents: lead: 0.002 %; cadmium: 0.003 %; arsenic: 0.001 %; mercury: 0.001 %; selenium: 0.001 %; barium: 0.001 %. |
| | IT D.M. 21/3/73 In D.M. 21/3/73 it is listed as "zinc carbonates" | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | DE Recomm. 21 | Accelerator activator The zinc content of Categories 1, 2 and 3 commodities must not exceed 3.0 % for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | NL III 4.2.2g | Processing aids and additives: as filler |
| Zinc oxide CAS 1314-13-2 FCM 402 | CZ 38/2001 | Elastomer, activators Part A, The total content of zinc compounds in the vulcanized product must not exceed 2% (related to zinc) |
| | SK 1799/2003 A. 10 | Activator Part A |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Activateurs (1) (a) The migration of zinc into food or its simulants must not exceed 10 mg/kg. (b) With regard to the use of zinc salts or oxide in the manufacture of teats and soothers, the following specifications shall be observed: Maximum contents: lead: 0.002 %; cadmium: 0.003 %; arsenic: 0.001 %; mercury: 0.001 %; selenium: 0.001 %; barium: 0.001 %. |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| | NL III 4.2.2d | Processing aids and additives: as activator |
| | DE Recomm. 21 | Accelerator activator and stabiliser for natural latex The zinc content of Categories 1, 2 and 3 commodities must not exceed 3.0 % for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | CoE ResAP (2004) (CoE cites DE, FR, IT, NL) | Additives, Polymerization aids and vulcanizing agents Zinc oxide |
| Zinc stearate CAS 557-05-1 | FR Arrêté du 9/11/1994 (FR) | Additifs : Lubrifiants et agents de démoulage (1) (a) The migration of zinc into food or its simulants must not exceed 10 mg/kg. (b) With regard to the use of zinc salts or oxide in the manufacture of teats and soothers, the following specifications shall be observed: Maximum contents: lead: 0.002 %; cadmium: 0.003 %; arsenic: 0.001 %; mercury: 0.001 %; selenium: 0.001 %; barium: 0.001 %. |
| | DE Recomm. 21 | Accelerator activator and slip agent and mould release agent The zinc content of Categories 1, 2 and 3 commodities must not exceed 3.0 %. For special category zinc content must not exceed 1%. for category 1, 2, 3 and 4 and special category (for bottle teats, dummies (pacifiers), nipple cups, teething rings and gum shields) |
| | IT D.M. 21/3/73 | Elastomers, accelerants for vulcanization The restrictions are under revision |
| α -Methylstyrene CAS 98-83-9 FCM 187 | CZ 38/2001 | Elastomer, monomers and starting substances Part A |
| | SK 1799/2003 A. 10 | Part A |
| | IT D.M. 21/3/73 | Elastomer, other monomers The restrictions are under revision |
| | CoE ResAP (2004) (CoE cites DE, IT) | monomer and starting agent |
| α -Tocopherol CAS 59-02-9 10191-41-0 FCM 110 | NL III 4.2.2e | Processing aids and additives: as protective agent |
| | FR Arrêté du 9/11/1994 (FR) | Additifs : Retardateurs |
| | CoE ResAP (2004) (CoE cites FR, NL) | Additives, Polymerization aids and vulcanizing agents |

Annex 18. Framework and other documentation for silicones

The **overview of the measures** or instructions is presented below.

| M S | measure | Positive list of substances Negative list of banned substances | OM, SML/QM |
|-----|------------------------------------|--|---|
| CoE | PS silicones (2004) ²¹⁶ | <u>Positive list</u> : Ch.3.4, Tech. Doc. 1, List1 <u>Negative list</u> : Ch.3.4 Tech. Doc. 1, List 2 List 2 contains both starting substances (ca. 80) and polymerisation aids (ca. 80), as well as additives (ca. 190). | - OML (Chapter 3.5) (Tech. Doc. 1, List 1). - SMLs - maximum amount of propylene oxide in silicones |
| HR | NN125-2009 (Članak 61) | <u>Positive list</u> : : for: - silicone oils // - silicone resins // - silicone elastomers <u>Negative list</u> : if amine compounds used in production of silicone elastomer, then no cyclohexylamine, secondary butylamine, butanonoksim nor their products should be present in finished product. | - maximum amounts for substances authorised < 0.5% of volatile organic compounds < 0.5% extractable substances. |
| CZ | Vyhláška č. 38/2001 | <u>Positive list</u> : Příloha 7 -monomers, additives that can be used in the preparation of - rubbers and elastomers, including silicone elastomers - aspects both of FR and DE <u>Negative list</u> : yes | Yes SML QM: Yes + requirements of the final product. |
| FR | Arrêté du 25/11/1992 | <u>Positive list</u> : - Polymers and additives for articles in silicone (Art. 2, Annex I). - does not include monomers but contains an explanation on starting substances used - Subsequent measures for additional substances upon presenting an authorisation request as per Arrêté du 13/11/1986 (terms/obligations from Anses) <u>Negative list</u> : n/a | - OM < 0.5%) for volatile organic compounds (Art.6, Annex III), - limits for components used (Art. 2, Annex I) - SMLs for tins from organotin and a non-detectable presence of peroxides for caps, gaskets, stoppers or other closures (Art. 6c). - information on how to perform migration tests (Annex III), based on the EN standards for plastics (e.g. EN 1186 and EN 13130), as well as the French Pharmacopea (peroxides). - Avis from ANSES (2013) with favourable opinion for 3,7,11-triméthylododécyne-3-ol (TMDDO) in silicone (purity + SML) |
| DE | BfR Rec. XV and BfR Rec. LII | <u>Positive list</u> : - BfR Recommendation XV: for the manufacturing of silicone products. - BfR Recommendation LII: for fillers and filler additives that may also be used in silicones <u>Negative list</u> : n/a | <0.5% of volatile organic compounds < 0.5% extractable substances applying a given extraction procedure. BfR XV: It reports maximum amounts in which some substances may be used in the manufacture of silicone products or in which they may be present in the finished article. SML5 mg/kg for 2,4-dichloro benzoic acid formed as decomposition product of bis-(2,4-Dichlorobenzoyl) peroxide BfR II: - maximum amount of some filler additives based on the filler - purity criteria for fillers regarding contamination with heavy metals. |
| IT | D.M. 1973 (amdt) | - for the preparation of silicones (Allegato II) - mainly based on the Reg. 10/2011 | - SMLs, residual content and QM for some of substances used for the preparation of silicones |
| ES | RD 847/2011 | - for the preparation of <u>polymeric</u> silicones (Art. 4, Anexo I) | - OML (Art. 7, Anexo I) - restrictions on the content in polymeric silicones (Anexo I). - SMLs (Art. 7, 8, Anexo I) - basic information on verification of compliance with SMLs (Art. 9) - states that failure to comply with law would imply sanctions based on the Real Decreto 1945/1983 provisions (Art. 12). |
| CH | Ordinanza DFI del 23/11/2005 | - for production of silicone FCM (Section 8a, art. 26b, 26d, Annex 5). - mirrors that of the CoE. | - OML (Section 8a, art. 26b, 26d, Annex 5, Annex 1, Art. 7, 9, 16) - maximum amounts for substances (Sect. 8a, art. 26b, Annex 5). - SMLs (Sect. 8a, art. 26d, Annex 5). - compliance testing is conducted similarly to plastics. - A testing procedure for organic materials is adapted /transposed from the French approach. |

Substances in common in three of more MSs.

Colour coding: blue: qualitative restrictions; light orange: restriction but low fit between limits, dark orange: common restrictions and better fit.

| Substance name, CAS Number | Legislation | Restrictions and comments |
|---|--------------------------|---|
| Ammonium chloride 12125-02-9 | CH 23/11/2005 DFI | Additives |
| | CoE PS Silicones 2004 | Additives |
| | ES Real Decreto 847/2011 | |
| Diethylene monobutyl glycol ether 112-34-5 | CH 23/11/2005 DFI | Additives |
| | CoE PS Silicones 2004 | Additives SML(T) = 3 mg/kg |
| | ES Real Decreto 847/2011 | SML(T)= 3 mg/kg (group made up of 15780, 16993, 16996, 17002, 48030, 48050 and 53765) |

²¹⁶ Council of Europe. Public Health Committee. Committee of experts on materials coming into contact with food. Policy statement concerning silicones used for food contact applications. Version 1 - 10.06.2004

| Substance name, CAS Number | Legislation | Restrictions and comments |
|--|---------------------------------|--|
| Ethylcellulose 9004-57-3 | CH 23/11/2005 DFI | Additives 0.6 mg/kg |
| | CoE PS Silicones 2004 | Additives |
| | ES Real Decreto 847/2011 | |
| Ethylene glycol monobutyl ether 111-76-2 | CH 23/11/2005 DFI | Additives 3 mg/kg; w. Diethyleneglycol monobutyl ether |
| | CoE PS Silicones 2004 | Additives SML= 3 mg/kg |
| | ES Real Decreto 847/2011 | SML(T)= 3 mg/kg (group made up of 15780, 16993, 16996, 17002, 48030, 48050 and 53765) |
| Formic acid 64-18-6 | CH 23/11/2005 DFI | Additives |
| | CoE PS Silicones 2004 | Additives |
| | ES Real Decreto 847/2011 | |
| Glyceryl monostearate 31566-31-1 | ES Real Decreto 847/2011 | |
| | CH 23/11/2005 DFI | Additives |
| | CoE PS Silicones 2004 | Additives |
| Methyl ethyl ketone 78-93-3 | CH 23/11/2005 DFI | Additives 5 mg/kg |
| | CoE PS Silicones 2004 | Additives SML= 5 mg/kg |
| | ES Real Decreto 847/2011 | SML = 5 mg/kg |
| Methyl isobutyl ketone 108-10-1 | CH 23/11/2005 DFI | Additives 5 mg/kg |
| | CoE PS Silicones 2004 | Additives SML= 5 mg/kg |
| | ES Real Decreto 847/2011 | SML = 5 mg/kg |
| Polyglycerol monostearate 37349-34-1 | CH 23/11/2005 DFI | Additives |
| | CoE PS Silicones 2004 | Additives |
| | ES Real Decreto 847/2011 | |
| Polyvinyl alcohol 9002-89-5 | DE Rec. 15 | Additive to resins for coat. Paper (viscosity of 4 % aqueous solution at 20 °C min. 5 cP) |
| | CH 23/11/2005 DFI | Additive to resins for coat. Paper |
| | ES Real Decreto 847/2011 | |
| Silicone elastomers | ES Real Decreto 847/2011 | |
| | DE Rec. 15 | Silicone elastomers starting materials |
| | HR NN125-2009 | Silicone elastomers starting materials |
| Silicone oils | ES Real Decreto 847/2011 | |
| | DE Rec. 15 | Starting material |
| | HR 3092 to Art. 7 Rules | Starting material |
| Tetrahydrofuran 109-99-9 | CH 23/11/2005 DFI | Additives 0.6 mg/kg |
| | CoE PS Silicones 2004 | Additives SML=0,6 mg/kg |
| | ES Real Decreto 847/2011 | SML = 0.6 mg/kg |
| Toluene 108-88-3 | ES Real Decreto 847/2011 | SML = 1.2 mg/kg |
| | CH 23/11/2005 DFI | Additives |
| | CoE PS Silicones 2004 | Additives SML=1,2 mg/kg |
| Volatile Compounds Organic | FR Arrêté du 25/11/1992 (FR) | Qmax = 0.5 % |
| | HR NN 125/2009 | Silicone elastomers max 0.5 % |
| | DE Rec. 15 | Silicone elastomers max 0.5 % |
| Xylene 1330-20-7 | CH 23/11/2005 DFI | Additives |
| | CoE PS Silicones 2004 | Additives SML=1,2 mg/kg |
| | ES Real Decreto 847/2011 | SML(T)= 1.2 mg/kg, with 95945 |

Further look of substances in which lesser convergence are found.

A summary reports the substances present in the national sources of three or more MSs with little convergence across the 3 countries that commonly regulate the 22 that have restrictions.

Substances in common by 3MSs or more where there is little convergence:

| Substance | DE Rec 15 | CH 23/11/2 005 DFI | CoE PS Silicones 2004 | FR Arrêté du 25/11/1992 |
|---------------------------------------|---|--|--|--|
| Acetic acid 64-19-7 | Finished products: 1) Silicone oils: max 0.01 % 2) Silicone elastomers: 0.1%. As condensation agent | Additives | Starting substances | n/a |
| Hydrochloric acid 7647-01-0 | Finished products: 1) Silicone oils: max 0.01 % 2) Silicone elastomers: 0.1%. Condensation agent | Additives | Additives | n/a |
| Phosphoric acid 7664-38-2 | Finished products: 1) Silicone oils: max 0.01 % 2) Silicone elastomers: 0.1%. Condensation agent | Additives | Additives | n/a |
| Potassium hydroxide 1310-58-3 | Finished products: 1) Silicone oils: max 0.01 % 2) Silicone elastomers: 0.1%. Condensation agent | Additives | Additives | n/a |
| Sodium hydroxide 1310-73-2 | Finished products: 1) Silicone oils: max 0.01 % 2) Silicone elastomers: 0.1%. Condensation agent | Additives | Additives | n/a |
| Sulphuric acid 7664-93-9 | Finished products: 1) Silicone oils: max 0.01 % 2) Silicone elastomers: 0.1%. Condensation agent | Additives | Additives | n/a |
| Sorbic acid 110-44-1 | Additives only in silicon oils (preservative): max. 0.1 %; | Additives | Additives | n/a |
| Formaldehyde 50-00-0 | Additives only in silicon oils (preservative): - max. 0.1 %; - < 3 µg FA/ml extract also for HR (Croatia) | 15 mg/kg with Hexamethylenetetramine. Additives | SML= 15 mg/kg. Additives | n/a? |
| Cellulose 9004-34-6 | n/a | Additives | SML= ND (DL=0,01 mg/kg). Additives | Additifs : Charges |
| Hydroxyethyl cellulose 9004-62-0 | max 2% in resin. Additive to resins for coat. Paper | Additives | Additives | n/a |
| Di-n-octyltin dilaurate 3648-18-8 | For silicone elastomers, with other hardeners or catalysts and their conversion products of section: max. 1.5 % based on finished products. | 0.006 mg/kg (for all derivatives). Polymerisation auxil. | SML(T)=0.02 mg/kg (as Sn) Polymerisation aids | Total des organoétains < 1,5 % par rapport au matériau ou objet fini LMS = 0,1 mg/kg (Sn). Additifs : Durcisseurs-catalyseurs |
| Di-n-octyltin dimaleate 15571-60-5 | For silicone resins/ elastomers, with other hardeners or catalysts and their conversion products (in section of Rec. 15: II2b/ III2c): max. 1.5 % based on finished products. | Polymerisation auxil. | SML(T)=0.02 mg/kg (as Sn) Polymerisation aids | n/a |
| 1-Dodecene 112-41-4 | max. 20 % as starting material in silicone elastomers. For silicone elastomers, starting material | 0.05 mg/kg. Additives | n/a | n/a |
| Carbon black 1333-86-4 | n/a | Annex 1, list III.9.5. Additives | max. teneur extractable-fraction = 0,15 %. Additives | - Extractable fraction of carbon black, graphite or carbon fibers by toluene <0.15%. - benzo 3,4 pyrène content from carbon black < or = 30 µg/kg. Additifs : Charges |
| Graphite 7782-42-5 | n/a | Additives | Additives | - Extractable fraction of carbon black, graphite or carbon fibers by toluene <0.15%. - benzo 3,4 pyrène content from carbon black < or = 30 µg/kg. Additifs : Charges |
| Sulphuric acid, barium salt 7727-43-7 | n/a | 1 mg/kg (e.a. Ba, for all Ba salts). Additives | SML=1 mg/kg. Additives | - Part soluble in HCL N/10 should not contain > 0.01% Pb, 0.01% As, 0.0005% Hg, 0.01% Cd, 0.005% Sb, 0,01% Ba. - Zn content must be < additifs : Charges |
| Iron oxide 1332-37-2 | n/a | 25 mg/kg for 1314-13-2 (e.a. Zn). Additives | List 1.3 additives | - Part soluble in HCL N/10 should not contain > 0.01% Pb, 0.01% As, 0.0005% Hg, 0.01% Cd, 0.005% Sb, 0,01% Ba. - Zn content must be < additifs : Charges |
| Magnesium oxide 1309-48-4 | n/a | 25 mg/kg for 1314-13-2 (e.a. Zn). Additives | List 1.3 additives | - Part soluble in HCL N/10 should not contain > 0.01% Pb, 0.01% As, 0.0005% Hg, 0.01% Cd, 0.005% Sb, 0,01% Ba. - Zn content must be < additifs : Charges |
| Aluminium | n/a | 25 mg/kg | Additives | - Part soluble in HCL N/10 should not contain > 0.01% |

| Substance | DE Rec 15 | CH 23/11/2005 DFI | CoE PS Silicones 2004 | FR Arrêté du 25/11/1992 |
|--------------------------------|-----------|--|-----------------------|---|
| oxide 1344-28-1 | | for 1314-13-2 (e.g. Zn). Additives | | Pb, 0.01% As, 0.0005% Hg, 0.01% Cd, 0.005% Sb, 0,01% Ba. - Zn content must be < additifs : Charges |
| Calcium oxide 1305-78-8 | n/a | 25 mg/kg for 1314-13-2 (e.g. Zn). Additives | Additives | - Part soluble in HCL N/10 should not contain > 0.01% Pb, 0.01% As, 0.0005% Hg, 0.01% Cd, 0.005% Sb, 0,01% Ba. - Zn content must be < additifs : Charges |
| Titanium dioxide 13463-67-7 | n/a | 25 mg/kg for 1314-13-2 (e.g. Zn). Additives | Additives | - Part soluble in HCL N/10 should not contain > 0.01% Pb, 0.01% As, 0.0005% Hg, 0.01% Cd, 0.005% Sb, 0,01% Ba. - Zn content must be < additifs : Charges |
| Zinc oxide 1314-13-2 | n/a | 25 mg/kg for 1314-13-2 (e.g. Zn). Additives | Additives | - Part soluble in HCL N/10 should not contain > 0.01% Pb, 0.01% As, 0.0005% Hg, 0.01% Cd, 0.005% Sb, 0,01% Ba. - Zn content must be < additifs : Charges |

Annex 19. Frameworks and other documents on multimaterials

The overview table is presented.

| MS | definition | Positive/Negative list, SMLs, OMLs, QM | |
|----|---|---|--|
| FR | <p>DGCCRF note d'information 2004/64</p> <p>An update to this measure was published in 2013. The DGCCRF Note d'information n. 2013-186 (communicable au sens de la loi du 17/07/1978)</p> | <p>term "multimaterials" refers to composite materials and objects in which a plastic layer or a coated plastic layer is in direct contact with food (Section 1).</p> | <ul style="list-style-type: none"> - plastic and aluminium layers in multimaterials must be manufactured in compliance with the positive list for monomers, other starting substances and additives set in Regulation (EU) 10/2011 Annex I and the positive list for metals set in Arrêté du 27/08/87 (Section 4). - residual limits and maximum quantities of monomers, other starting substances and additives set for plastics, - limits for extractable substances such as PCP, polychlorinated biphenyls (PCBs) and metal ions defined for paper and paperboard - maximum amounts for metal impurities in aluminium layers (Section 4 in conjunction with Regulation (EU) 10/2011 Annex I, DGCCRF Note d'information n°2004-64 Ch. 4 and Arrêté du 27/08/87). - OM from multimaterials (Section 4) <10 mg/dm² or <60 mg/kg (infants/toddlers) - SMLs for plastic monomers, other starting substances and additives as in Reg. (EU) 10/2011, Arrêté du 2/01/2003 Art. 7 and Annex Ch. I. (Ch. 3 Section 4) - SMLs for epoxy derivatives as in Arrêté du 02/04/2003 (Ch.3, Section 4). - SMLs for P&B as in DGCCRF Note d'information n°2004-64 Ch.4 (Ch.3, Section 4). - OM and SM tests including the selection of time-temperature conditions and simulants, shall be performed as laid down in Regulation (EU) 10/2011 Ch. V and Annex III and V, NF EN 1186, EN 13130, XP CEN/TS 14234 and CEN TC 194 TENAX (Section 5). |
| IT | <p>D.M. of 21/03/1973 (and amendments)</p> | <p>The Nota del Ministero della Salute n. 20072 20/05/2014 also includes multimaterials under its umbrella.</p> | <ul style="list-style-type: none"> - residual content of substances for the preparation of coatings, resins, varnishes, multimaterials, mainly based on the EU positive list for plastics. (Allegato II). - OML for multimaterials (where the material in contact with food is plastic), mainly based on the EU regulation for plastics. (Allegato II), - SMLs for substances used for the preparation of coatings, resins, varnishes, also mainly based on the EU regulation for plastics. (Allegato II). |

As regards to GMP only FPE provided a reply related to the use of FPE "Code for GMPs for Flexible and Fibre-based Packaging for Food" and the Italy Cast Project

Annex 20. National provisions in relevant non-EU countries

The legislative frameworks on FCM were investigated for EEA and non-EU countries (or group of countries such as Norden or Mercosur) with significant legislation on FCM. The study analysed similarities and/or differences with the EU structure. Only the most relevant information is reported.

EEA countries

The section summarises the measures on FCM available in the European Economic Area (EEA) countries (Norway, Iceland and Liechtenstein), which based on the agreement of 1 January 1994 can participate in the EU Internal Market.

Norway

The FCM legislative framework of Norway was included with the data of EU countries, due to some commonalities with MSs adhering to the Nordic Council.

Iceland

Iceland implements the EU legislation on FCM. General provisions on FCM are reported in the Food Act (Lög um Matvæli, 1995 nr. 93, 28. Júní)²¹⁷. There are no additional specific national laws on FCM. One exception was Regulation (EU) No 284/2011, on imports from the People's Republic of China and Hong Kong, but an amendment to the Food Act No 93/1995 on its implementation has been submitted to the parliament²¹⁸. Iceland is part of the Nordic Council, and thus applies the Norden guidance documents, also applied by Denmark, Sweden, Norway and Finland. The Local Municipal Environmental Health and Protection Offices (the Local Competent Authorities, LCAs) are legally responsible for the controls of producers and importers of FCMs. Their legal powers to carry out official controls and to enforce the legislation are established according to the Food Act No 93/1995 (Art. 28, 29 and 30 for intermediate measures, and in Art.31 for penalties). In addition, in Art.14 it is stated that producers and importers of packaging used for food, or for products used in the production of food, shall ensure that such does not damage the product for which it is intended, in such a way that it would make the product hazardous or unsafe for human health, reduce its quality or make it unfit for consumption. The Icelandic Food and Veterinary Authority (MAST) is responsible for supervision and coordination of the LCAs, may issue guidelines for the LCAs. MAST has recently contacted Denmark's NRL in order to make an agreement for the Danish laboratory to serve as Iceland's NRL in the future.

Liechtenstein

As Norway and Iceland, in the frame of the EEA Agreement Liechtenstein implements EU legislation on FCM. Liechtenstein does not have any other specific national law on FCM.

Non-EU countries

This portion used several available sources from peer-reviewed publications²¹⁹, book sections^{220,221}, other materials^{222, 223} and web sites²²⁴ that provided dedicated reviews and state of the art of international and worldwide regulatory frameworks in place for FCMs.

United States of America (USA)

The regulatory authority in USA is the Food and Drug Administration (FDA). According to the Federal Food, Drug, and Cosmetic Act (FFDCA), foods are considered adulterated if they contain unsafe food additives or unsafe levels of impurities. Food additives are divided into three categories: direct (directly added to the foods), secondary direct (added during treatments of food), and indirect (chemicals that might be transferred to the food by its packaging or processing equipment). Thus FCM should comply with requirements of indirect additives. Food contact substances (FCS) are considered unsafe if they

²¹⁷ EU Accession Screening Report Iceland, Chapter 12 (11/2011)

²¹⁸ Final report - EFTA Surveillance Authority mission to Iceland From 3 to 7 December 2012 regarding the application of EEA legislation related to FCMs

²¹⁹ Review of the regulation and safety assessment of food substances in various countries and jurisdiction (Bernadene Magnuson, Ian Munro, Peter Abbot, Nigel Baldwin, Rebeca Lopez-Garcia, Karen Ly, Larry McGirr, Ashley Roberts and Susan Socolovsky), Food Additives & Contaminants: Part A, 2013, Vol. 30, No. 7, 1147-1220.

²²⁰ Chemical migration and FCMs (Ed. K.A. Barnes, C.R. Sinclair, D.H. Watson, 2007, ISBN-13:978-1-84569-209-4 / 209-8)

²²¹ Global Legislation for Food Packaging Materials (R. Rijk, R. Veraart, Wiley-VCH, c2010, ISBN 9783527319121 3527319123),

²²² Fathoming Food Packaging Regulation Revisited (Jerome H. Heckman), Keller & Heckman Special Focus 03/2001

²²³ The world law guide, <http://www.lexadin.nl/wlq/legis/nofr/eur/lxwelie.htm>

²²⁴ Decernis database, <http://decernis.com/>,

are not compliant with a food additive regulation or they do not have a food contact notification (FCN). FCN as pre-market FCM components approval program was introduced by the FDA Modernization Act of 1997 and is effective from 2000. It replaces petitions and regulations for new substances, that was established by Section 409(a)-(d) of the FFDCFA, and that was found often as a lengthy and burdensome process. The reference framework regulation for FCM is the Chapter I of the Title 21 of the Code of federal Regulation (CFR) (21 CFR Chapter I). The FCN process is described 21 CFR, 170.100-106 and is the primary method to authorise new substances for food contact²²⁵. The FCN must contain: chemistry data, toxicology data and environmental assessment (if needed). Whatever process is used for asking an authorisation, the burden of demonstrating that the intended uses of the substance are safe is on the notifier.

As a difference with the EU legislation, the US legislation uses the concept of Threshold of Regulation (ToR) exemption process established in 1995 as another pre-market authorisation system for FCM, which imposes limits to the application of the CFR. According to 21 CFR, 170.39, FDA can exempt food-contact material from regulation if:

- its use results in < 0.5 ppb in diet, or
- it is cleared as direct food additive and exposure from food-contact use is less than 1% of the "Acceptable Daily Intake" (ADI)
- it is not a carcinogen and it does not have impurities that are potent carcinogens (TD50 < 6.25 mg/kg bw/day)

A list of exemptions issued for substances used in FCM is also reported under 21 CFR 170.39. To get the approval for a new substance, that is not already considered "Generally Recognized As Safe" (GRAS, 21 CFR, Part 170) or that has not been prior-sanctioned (21 CFR, Part 181), or for which there is not an exemption available, a FCN must be presented. It must be verified if whether any food additive clearance covers the substance use. While a petition authorises generically a substance, the FCN system grants authorisation only to the manufacturers/suppliers cited in the FCN, and the ToR exemption is effective only for the manufacturers/suppliers of the substance.

In addition, 21 CFR, Chapter I, Section 174.5 reports measures for GMP for packaging. Housewares, beverage dispensers, tools used in households and restaurant are not covered by the CFR, but if a problem arises, the FDA can take action.

Canada

Food packaging is regulated by Division 23 of the Food and Drug Regulations that states that FCM cannot release harmful substances²²⁶. It reports some restrictions on some substances (admission, non-admission, limits). In Canada food packaging is intended as the packages into which foods are marketed and the articles that come into contact with foods during production and processing, but not all the other consumer products such as kitchen tools, utensils, etc. as they are not meant to be sold together with foods. Producers might on voluntary basis submit a food packaging evaluation to the Health Products and Food Branch (HPFB) for assessment of chemical safety that is then certified by an advisory opinion. This applies to finished products or intermediate materials, but also suppliers of substances (e.g.: additives) may ask for a letter of opinion. These documents are only opinions, they are not legally binding and the sellers remain solely responsible for their products. Approvals of FCS are not required. Articles and equipment intended to be used in registered food production industries have to be registered by the Canadian Food Inspection Agency (CFIA). The preparation of a list for additives is under discussion, but a publication date is not foreseen.

Mercosur

The Mercado Común del Sur (Mercosur²²⁷) is a regional group of countries that aims to promote trade. It is composed of Argentina, Brazil, Paraguay, Uruguay and Venezuela as regular members, Chile, Bolivia, Colombia, Ecuador and Peru as associate countries and New Zealand and Mexico as observer countries. It issues regulations as "Grupo Mercado Común" (GMC) that are applied by its MSs. In the field of food packaging the framework resolution on FCM is the GMC 3/92²²⁸ that sets general requirements for FCM (considered as food additives) such as that they should not pose risks for human health, alter unacceptably the composition or the taste of foods, be manufactured according to GMP,

²²⁵ US Government: <http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>

²²⁶ Government of Canada: http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-76.html#h-127, Regulation of Food Packaging in Canada (Keller & Heckman Special Focus 10/2014)

²²⁷ Mercosur: <http://www.mercosur.int/>; administración nacional de medicamentos, alimentos y tecnología médica, ministerio de salud de argentina: <http://www.anmat.gov.ar/principal.asp>

²²⁸ mercosur/gmc/res nº 03/92- criterios generales de envases y equipamientos alimentarios en contacto con alimentos

and be of suitable purity. It establishes positive lists for components of FCM (GMC 31/99²²⁹) and criteria for purity requirements and limits of migration. It also provides analytical methods for controls (GMC 10/95²³⁰ for overall migration, GMC 32/99²³¹). Mercosur's standards for food-contact materials apply to housewares (i.e. disposable cups, plates, utensils, and other articles used to serve or dispense food for fairly immediate consumption), and to equipment used with food. Besides this regulation, specific measures on plastics exist, such as GMC 30/92²³², 56/92²³³, 87/93²³⁴, 32/97²³⁵ on simulants amending 30/92. Specific measures also exist for metals such as GMC 30/99²³⁶, 46/06 – providing a positive list. Provisions are available for cellulose in the form of GMC 19/94²³⁷ amended by GMC 35/97, 20/00, as well as GMC 56/97²³⁸ – providing a positive list-, GMC N° 12/95²³⁹ – providing overall migration tests-, and GMC 52/99²⁴⁰ on recycled materials. In the case of adhesives, GMC 27/99²⁴¹ regulates indirect and 28/99²⁴² direct contact as pressure sensitive adhesives under the elastomers resolution. Elastomers are addressed in GMC 54/97²⁴³ and GMC 28/99 and glass and ceramics in GMC 55/92²⁴⁴. Positive lists are available for additives for plastics, cellulose and elastomers. Mercosur GMC defines FCS as any primary container or any primary wrapping or container in contact with food. Finished packages should be registered before being allowed on the market (not in Brazil). Thus, while the general principles of the Mercosur's standards are applied in all 5 MSs, national provisions for registration and approval of products might differ. Analytical methods to determine overall migration are regulated by GMC 32/99.

Argentina applies Mercosur measures and FCMs are regulated by the chapter IV of the Código Alimentario Argentino²⁴⁵ (CAA). All new substances to be inserted in positive lists must be sent for approval to the National Committee of Food (CONAL, Advisor scientific body, providing support and monitoring to the National Food Inspection System – SNCA- that enforces the Argentine Food Code) that submits the request to the dedicated working group of Mercosur.

Brazil applies Mercosur measures. All new substances to be inserted in positive lists must be sent for approval to the Agencia Nacional de Vigilancia Sanitaria (ANVISA) that submits the request to the dedicated working group of Mercosur. Brazil since 2000 does not require anymore the registration of the finished packaging before sale (unless it is manufactured with recycled materials).

Mexico

FCMs in Mexico are not defined per se but fall under a larger class as substances allowed as additives and processing aids in foods, beverages and nutritional supplements²⁴⁶. They are regulated by the provisions título 24 of Reglamento de Control Sanitario de Productos y Servicios²⁴⁷ that establishes general principles, such as that any substance that might migrate from FCM into foods, without endangering human health, is considered as indirect additive²⁴⁸. The Reglamento classifies packaging based on their physical, chemical, toxicological characteristics through specific norms (such as to be inert, or be insoluble in foods, not be toxic, be free from heavy metals). No specific procedure exists for positive list or authorisation of substances, and producers might consult with authorities to ensure their products are allowed on the market. New standards will be based on FDA documentation.

²²⁹ Regl. Técnico Mercosur sobre criterios generales de actualización de listas positivas de componentes de envases y equipamientos en contacto con alimentos. SGT N° 3

²³⁰ 10/95 Determinación de la migración total de materiales plásticos en aceite de oliva como simulante graso.

²³¹ Regl. Técnico Mercosur sobre metodologías analíticas de referencia para control de envases y equipamientos en contacto con alimentos.

²³² 30/92 Envases y equipamientos plásticos en contacto con alimentos: clasificación de alimentos y simulantes

²³³ 56/92 Disposiciones generales para envases y equipamientos plásticos en contacto con alimentos.

²³⁴ 87/93, 05/95 Lista positiva de polímeros y resinas para envases y equipamientos plásticos en contacto con alimentos

²³⁵ 32/97 Regl. Técnico Mercosur sobre la incorporación de la Tabla N° 1: clasificación de alimentos simulantes, como anexo de la res. n° 30/92 - GMC "envases y equipamientos plásticos en contacto con alimentos: clasificación de alimentos y simulantes".

²³⁶ 30/99 Regl. Técnico Mercosur Complementario de la Res. N° 27/93 - GMC, sobre migración de compuestos fenólicos en envases y equipamientos metálicos en contacto con alimentos.

²³⁷ 19/94 - Disposiciones Generales sobre envases y equipamientos celulósicos en contacto con alimentos.

²³⁸ 56/97 Regl. Técnico Mercosur sobre lista positiva para envases y equipamientos celulósicos en contacto con alimentos.

²³⁹ 12/95 ensayo de migración total de envases y equipamientos celulósicos.

²⁴⁰ 52/99 Regl. Técnico Mercosur sobre material celulósico reciclado.

²⁴¹ 27/99 Regl. Técnico Mercosur sobre adhesivos utilizados en la fabricación de envases y equipamientos destinados a entrar en contacto con alimentos.

²⁴² 28/99 Regl. Técnico Mercosur sobre la lista positiva para envases y equipamientos elastoméricos en contacto con alimentos

²⁴³ 54/97 Regl. Técnico Mercosur sobre envases y equipamientos elastoméricos destinados a entrar en contacto con alimentos.

²⁴⁴ 55/92 Envases y equipamientos de vidrio y cerámica destinados a entrar en contacto con alimentos.

²⁴⁵ http://www.anmat.gov.ar/alimentos/normativas_alimentos_caa.asp

²⁴⁶ ACUERDO por el que se determinan las sustancias permitidas como aditivos y coadyuvantes en alimentos, bebidas y suplementos alimenticios) (Secretaría de Salud México 1999)

²⁴⁷ <http://www.salud.gob.mx/unidades/cdi/nom/compi/rcsps.html>

²⁴⁸ Secretaría de salud, Mexico: <http://portal.salud.gob.mx/>

Australia and New Zealand

FCM are defined as any material that come into contact with foods and they are regulated by standard 1.4.3 (that recalls provisions of Standard 1.4.1) of the Australia New Zealand Food Standards Code²⁴⁹, that only sets that FCM should not cause any harm²⁵⁰. Standard 1.4.1 then fixes maximum levels of contaminants in foods that might also come from FCM. At present submitting an application for FCM is not mandatory if substances are approved in EU or in USA. Current discussions may render future compliance with EU or FDA requirements under the Standard Code mandatory. The Australian Standard AS 2070-1999²⁵¹ on Plastics materials for food contact use provides measures on plastics, including processing aids, additives/colorants, printing inks, coatings and manufacture of multilayer products. Compliance with this standard though is not mandatory but voluntary.

China

FCM in China are regulated under the Chinese food safety law (2009) that states that it is not allowed to sell food products (including FCM) that do not comply with one of the Chinese standards²⁵². They are defined as any material in contact with food, including containers, packaging and any other manufacturing or transporting or sales material that come into contact with foods.

There are more than 100 standards, among which GB 9685 Standard (version 2008) contained a positive list for 958 substances used in paper, bamboo, wood, metal, enamelware, ceramics, plastics, rubber, natural fibers, synthetic fibers, glass, compound packaging materials, and coatings in contact food, including machinery, pipes, conveyor belts, containers, tools, utensils, etc., used in the production and distribution of food. In addition, there have been standards for resins, plastic articles, metal articles, coatings, paper (GB 11680), ceramic containers (GB 13121), rubber articles (GB 4806.1), composite laminated food packaging bag (GB 9683). To cover also the substances already on the market that were not included in any standard, the Ministry of Health authorised a petition process, under which three more lists (for 107 resins in 2011, for 301 additives in 2012 and for other 258 additives in 2013) were authorised.

New standards have been in development and it was expected that existing standards will be converted to Food Safety National Standards (end 2015-early 2016). A standard on migration testing (based on Regulation (EU) 10/2011) was in preparation. In January 2015, a revised draft of GB9685, under the terms "National Food Safety Standard for Uses of Additives in Food Contact Materials and their Products" was released by the National Health and Family Planning Commission (NHFPC). The Standard defines "food contact materials and articles" to include various materials and articles, including food packaging materials, containers, utensils, coatings that may directly or indirectly contact with food, and coating layers, ink, adhesives, etc., as well as machines, pipes, conveyer belts, containers, utensils, tableware, etc., but does not include detergents, disinfectants or public water facilities. The term "Additives" includes monomers or other starting materials of polymerisation for certain base polymers used during the manufacture of FCMs. The draft contains 1316 FCMs additives permitted to be used in China (vs. 958 in the 2008 version). Significant amendments were made regarding the maximum content, SML, names of substances. The standard includes tables of additives permitted in FC plastics, coatings, rubber, inks, adhesive paper and silicone rubber and other FCMs and their products. It includes appendices for SML(T) and special restriction provisions for metallic element. Further explanations are available on line²⁵³.

The Ministry of Health issued the Management Rules for the Administrative Approval of New Varieties of Food Related Products (new food packaging materials, expanded use of approved additives and packaging materials, food use disinfectants, detergents, food contact tools and equipment) in 2011. To petition for a new material, information such as the physicochemical properties, the technical necessity, use, and conditions of use, the manufacturing process, the quality specifications, the test method, and test report, the toxicological assessment, the migration values, the estimated dietary exposure and the method of determination, the approvals in other countries and relevant documentation must be submitted and the petition will be reviewed by an experts panel (government officials from various disciplines).

²⁴⁹ <http://www.foodstandards.gov.au/code>

²⁵⁰ Supporting document 2 International regulations for FCMs – P1034 Chemical Migration from Packaging into Food (Australia New Zealand Food Standards); Australia New Zealand Food Standards Code: <http://www.foodstandards.gov.au/code>

²⁵¹ <https://www.saiglobal.com/PDFTemp/Previews/OSH/As/as2000/2000/2070.pdf>

²⁵² China's online legal research: <http://www.lawinfochina.com/display.aspx?lib=law&id=7344&CGid=>

²⁵³ <https://www.khlaw.com/China-Publishes-Draft-Amendment-to-the-GB-9685-Hygienic-Standard-on-the-Uses-of-Additives-in-Food-Containers-and-Packaging-Materials>, http://www.cirs-group.com/food/news/GB9685_FCM_additives.html, <https://food.chemlinked.com/news/food-news/chinas-key-food-contact-materials-standard-gb-9685-revision>

Japan

No specific law on FCM exists in Japan. The Food Sanitation Law (1947) forbids the sale of food packaging that can be harmful for human health²⁵⁴. The Ministry of Health, Labour, and Welfare (MHLW) issued specifications (e.g.: end tests, heavy metals limits, extraction limits, etc., but not positive lists) for 12 plastic materials, for synthetic resins, metal cans, glass, ceramic, enamel, and rubbers. Specific restrictions exist on packaging of milk and milk products, on colorants and on DEHP plasticised PVC. So far, MHLW has only set specifications on finished food utensils, containers and packaging materials. The Japan Hygienic Olefin and Styrene Plastic Association (JHOSPA) prepared in 1973 a standard containing a positive list of raw materials to be used for food packaging and utensils and the Standard Methods of Analysis with specifications for each resin. Positive lists were also prepared for PVC, polyvinylidene chloride (PVdC), waxes and rubbers. Negative lists were issued for printing inks and adhesives. The application of such standards though is on voluntary basis (but broadly accepted and followed) and the Ministry is evaluating the possibility of implementing the lists, complementing them to regulate more materials.

Gulf states (Saudi Arabia, Kuwait, Qatar, United Arab Emirates, Oman)

In the Gulf States FCM is regulated by the framework regulation GSO 839/1997²⁵⁵. This standard gives the general requirements for all packages of FCMs, including metal, glass, plastic, paper, carton, multilayered textile, and wood packages, in addition to any other materials for packaging foodstuffs. This regulation defines as food grade materials all materials allowed for food contact and that do not cause any hazards or health threat. It stipulates that potential migration shall not contaminate foodstuffs. Plastics are regulated by GSO 1863/2013²⁵⁶ which includes a positive list of authorised monomers, starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids, with some restrictions (taken from the EU regulation). It also includes information on specific migration (QMA and SML for vinyl chloride, styrene and acrylonitrile) and overall migration (less than 10 mg/dm² or 60 mg/kg). A GSO "Food Packages – Methods of Testing of Plastic Packages" is under preparation.

Customs Union (Russia, Kazakhstan and Belarus)

The Customs Union (CU) includes Russia, Kazakhstan and Belarus: it includes provisions economic integration, remove custom barriers, assure free circulation of goods, and harmonise conformity assessment and certification systems. In this frame it issues Technical Regulations²⁵⁷. The Technical Regulation (TR) of the Russia-Kazakhstan-Belarus Customs Union (CU) on Safety of Packaging (TR CU 005/2011) is a key CU regulation covering standards and requirements for packaging, including that of food products, produced both as a finished product and as part of the products' manufacturing process. The TR was adopted by the CU Commission decision No. 769 of August 16, 2011, and has been in effect since July 1, 2012. It is applicable to all packaging materials, utensils and food production equipment. It introduces the concepts of PQM (Permissible Quantities of the Migration, in mg/L) and MPCw (Maximum Permissible Concentrations of chemicals in potable Water, in mg/L). For foods that have less than 15% content of water the daily average MPC (Maximum Permissible average daily Concentrations of pollutants in ambient air of populated areas, in mg/m³) is calculated. It does not contain a positive list, but it fixes limits for PQM, MPCw, and/or MPC for some substances. The main principles are compliance with rules (technical regulations or Standards), safety (migration should not endanger human health and should not exceed migration limits and the materials should not contain any carcinogenic or mutagenic substance) and hygiene requirements. It also stipulates labelling of FCM, state registration of new materials, and declaration of Conformity.

Thailand

In Thailand FCM are regulated by the Food Act B.E. 2522 (1979)²⁵⁸, issued and enforced by the Ministry of Public Health. It is the major law aimed at protecting and preventing consumers from health hazards occurring from food consumption. According to the Food Act, the Ministry of Public Health is designated to be in charge of the execution of this act. The controls are under the responsibility of the FDA of the Ministry of Public Health that among other tasks sets up food standard, specification and hygienic and labelling requirements, sets and executes controls, approves FCM, and issues GMP certification. Note N°92/2528 of 1985²⁵⁹ on Prescription of quality of standards for food containers sets

²⁵⁴ Japan's Food Sanitation Act: <http://www.cas.go.jp/jp/seisaku/hourei/data/fsa.pdf>

²⁵⁵ Gulf Standardisation Organisation: <http://www.gso.org.sa/standards> UAE.S GSO 839:1997 Food Packages - Part 1

²⁵⁶ UAE.S GSO 1863:2013 Food packages - Part 2: Plastic package - General -requirements

²⁵⁷ Technical Regulation of Customs Union: <https://trcu.eu/>

²⁵⁸ Thai Laws: <http://thailaws.com/>

²⁵⁹ No.92 / 2528(1985) prescription of quality or standard for food containers, use of food containers and prohibition of use

restrictions for plastics, lead and cadmium from ceramics and enamelled metals. Notification No. 117/2532 of 1989 regulates baby bottles (regarding BPA, the types of plastics used and specifications and restrictions for natural rubbers and synthetic rubbers), but it is under revision at the moment. Notification No. 295/2548 of 2005 regards the Qualities or standard for container made from plastic and sets restrictions for migration of lead and cadmium for foods and as well as specific SMLs for milk and milk products. The Thai Industrial Standards Institute (TISI) of the Ministry of Industry issues standards for FCM for which compliance is mandatory, such as the TIS 1136-2535 (1993) on Cling Film (that bans DEHP) and the TIS 2440-2552 (2009) Stainless steel: Seamed Stockpots (that regulates the specific release of lead, Sn, Cr, Zn, cadmium), and voluntary standards (on plastics, resins, metals, ceramics, glass, rubber). Since 2011 the Department of Science Service (DSS) issues Certificates of analysis of FCM for Thai exporters of the ministry of commerce.

India

In the past decade India has developed a framework for FCMs²⁶⁰ regulated under the Food Safety and Standards Act (FSSA). In 2006 it repealed and replaced all the former legislation on food and established the Food Safety and Standards Authority of India (FSSAI). The Food Safety and Standards (Packaging and Labelling) Regulation of 2011 provides measures and restriction on FCMs and sets general requirements for utensils and containers used in the "preparation, packaging and storing" of food. The requirements are broad but the underlying principle is that FCMs should not endanger foods. The Bureau of Standards is the official body that issues standards and methods for the evaluation of food and FCMs as well as guidelines for the accreditation and certification of testing laboratories. At present standards exist for glass, metals, paper/board and plastics (10 standards). Given the recent publication of the legislation, implementation and enforcement of specific provisions are not completely developed yet.

²⁶⁰ Food Safety and Standards Authority of India: <http://www.fssai.gov.in/GazettedNotifications.aspx>

Annex 21. Cases where national measures taken in part the plastics Regulation.

The summary of mentions of uptake of substances from 10/2011 for other materials was tabulated (non exhaustive).

| Sector | Mentions of applicability of Regulation EU 10/2011 to the sector's measures |
|--------------------------|---|
| ADHESIVES | <p><u>Germany</u>:</p> <ul style="list-style-type: none"> - BfR Recommendation LII: "In so far as the present Recommendation contains substances from the list of additives in Regulation (EU) No 10/2011, these have been labelled" (substances with "1") - BfR Recommendation XXVIII: "For starting materials already regulated by the Commission Regulation (EU) No 10/2011, the specific limits laid down therein apply" <p><u>The Netherlands</u>: Commodities Act Regulation: some substances are taken from the Plastic Regulation –</p> <p><u>Croatia</u>: does not mention using Regulation 10/2011 but seems to reflect Annex I.</p> |
| PRINTING INKS | <p><u>Germany</u>: "Einundzwanzigste Verordnung zur Änderung der Bedarfsgegenständeverordnung" (DRAFT!), (implementation of 10/2011)</p> |
| COATINGS | <p><u>Belgium</u>: Royal Decree on varnishes and coatings intended to come into contact with food (DRAFT!) for monomers and starting substances are those of the EU 10/2011</p> <p><u>Italy</u>: D.M. 21/3/73 takes the whole 10/2011 Annex I list</p> <p><u>The Netherlands</u>: Commodities Act Regulation: some substances have a reference to the chapter where some of the substances are taken from the EU 10/2011 are mentioned</p> <p><u>Slovakia</u>: 1799/2003: "plastics pursuant to the requirements of Division Five" (a list with the implementation of EU 10/2011, even if not clearly stated)</p> <p>CoE ResAP2004: substances from List 1 of additives and List 1 of monomers from the CoE document that are also present in the COMMISSION REGULATION (EU) No 10/2011</p> |
| WOOD & CORK | <p><u>The Netherlands</u>: Commodities Act Regulation: "epoxy polymers and softeners", contains a reference to a chapter where some of the substances are taken from the EU 10/2011</p> |
| PAPER & BOARD | <p><u>Czech Republic</u>: 38/2001: "Fibrous raw materials, fibres from synthetic polymer and copolymer compounds, if they comply with the requirements for plastics intended for contact with food" (the chapter on plastics of 38/2001 inserts a list that recalls EU 10/2011, even if not clearly stated)</p> <p><u>Germany</u>:</p> <ul style="list-style-type: none"> - BfR Recommendation XXXVI: "Fibrous materials: Fibres of synthetic high polymers, provided they comply with the prevailing requirements of food law". "Plastics dispersions, provided they comply with amended Recommendation XIV on Polymer dispersions" (where substances of EU Regulation 10/2011 are included, added to other substances); - BfR Recommendation XXXVI/1 "Fibrous materials: Synthetic fibres made of a) plasticizer-free copolymer of vinyl chloride and vinyl acetate, b) Polyethylene, c) Polypropylene, d) Polyester provided they comply with the prevailing requirements of food law"; <p><u>Slovakia</u>: 1799/2003: "Fibrous raw materials: fibres from synthetic polymer and copolymer compounds, if they comply with the requirements for plastics intended for contact with food" The plastic section is the implementation of the EU Regulation, even if not clearly stated</p> |
| RUBBERS | <p><u>Germany</u>: BfR Recommendation XXI: some polymers and copolymers have to comply with the restrictions laid down in Regulation (EU) No 10/2011</p> <p><u>The Netherlands</u>: Commodities Act Regulation: three substances make reference to 10/ "phenol-formaldehyde condensation products, containing no auxiliary materials other than those permitted in Chapter I (where some of the substances are taken from the EU 10/2011)", "polyethene, according to Chapter I*", molecular weight > 200", "polypropene, according to Chapter I*", "polystyrene, according to Chapter I*"</p> |
| SILICONES | <p><u>Germany</u>: BfR Recommendation XV: "Dispersions based on copolymers of acrylic and methacrylic acid esters, butadiene and styrene, provided they comply with Recommendation XIV on Polymer dispersions (where substances of EU Regulation 10/2011 are included, added to other substances)</p> <p><u>Italy</u>: D.M. 21/03/73 takes the whole 10/2011 Annex I list</p> |

Annex 22. Sensory issues and standards

A brief overview of sensory issues from FCMs is given below.

| Sector affected | Sources of taint | Examples of chemical | Cause of taint |
|-----------------------------------|---|---|---|
| Adhesives | - isocyanate hardener in solvent free polyester or polyurethane - Cold seals from styrene butadiene acrylate copolymer latex | - reaction of alcohols or diols with aldehydes or ketones into to (cyclic) ketals/and acetals (e.g. dioxanes) - Residual ethyl benzene, styrene and butyl and ethyl acrylate (cold seals) | - result of solvent/adhesive interaction - impurities in poor quality solvents. |
| Printing inks varnishes | surface or from secondary packaging | - residual solvents - residual acrylate monomers, photoinitiators (incl. benzophenone) - reaction by-products from polymerisation process (benzaldehyde, alkyl benzoates), | - Printing process - Insufficient drying after printing. |
| Printing inks varnishes | surface or from secondary packaging | - residual solvents - residual acrylate monomers, photoinitiators (incl. benzophenone) - reaction by-products from polymerisation process (benzaldehyde, alkyl benzoates), | - Printing process - Insufficient drying after printing. |
| Paper and board | - Multilayers: adhesives/varnishes/plastics - Recycled sources - Free metals ions as catalyst for oxidation - Surface coatings - higher fat content foods | Decarboxylation and oxidation of lignin Hexanal | - bacteria, moulds, - oxidation of residual resins - degradation of processing chemicals (incl. synthetic resin binder) |
| Wood, fibreboard/board jute sacks | - Fungicides – : microbial methylation of halophenols - paper regenerated from waste paper/board - bleaching of wood pulp for paper manufacture, | - Chlorophenols into chloroanisoles - Pentachlorophenol into trichloroanisole - Bromophenols into bromoanisoles - reaction of phenols from decomposition of lignin with source of bromine or chlorine - reaction of some biocides with phenol into tribromophenol | - Treatment of soft wood, - storage - timber treatment of food production buildings |
| Plastics | Residual monomers Degradation products from monomers (PET) Oxidation of residual monomers (PE/PP) | PS- Styrene PET – acetaldehyde PE/PP – aldehyde/ketone | excessive heat is used in processing manufacturing process |

In general, foods with high fat content or dry foods with a high surface area are most vulnerable. For direct contact, more migration will occur with fatty foods, where the oil and fat components can penetrate into the packaging and their low polarity makes them a good matrix to absorb many organic contaminants.

Standards for taint transfer testing are available from an overall sensory testing standpoint. Some are also specifically aimed at food packaging materials. The table below summarises the standards found.

| source | standard name | Standard title |
|--------|--|---|
| CEN | EN 1230-1:2009 EN 1230-2:2009 | Sensory analysis - Part 1: Odour Sensory analysis - Part 2: Off-flavour (taint) |
| BS | BS 6920-2.2.1:2000+A2:2008 BS 6920-2.2.1:2000+A3:2014 BS 6920-2.2.3:2000+A2:2014 | Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water. <u>Odour and flavour of water</u> . - General method of test - Method of testing odours and flavours imparted to water by hoses and composite pipes and tubes - Method of testing tastes imparted to water by hoses for conveying water for food and drink preparation |
| CEN | EN 1420-1:1999 EN 14395-1:2004 | Influence of organic materials on water intended for human consumption. - Determination of odour and flavour assessment of <u>water in piping</u> systems. Test method - Organoleptic assessment of water in storage systems. Test method |
| CEN | EN 14944-1:2006 | Influence of cementitious products on <u>water</u> intended for human consumption. Test methods. Influence of factory made cementitious products on organoleptic parameters |
| ASTM | E1432 - 04(2011) | Standard practice for defining and calculating individual and group <u>sensory thresholds</u> from forced-choice data sets of intermediate size |
| ASTM | E1697-05(2012) | Standard test method for <u>unipolar magnitude estimation</u> of sensory attributes |
| ASTM | E1810 - 12 | Standard practice for evaluating effects of <u>contaminants on odor and taste</u> of exposed fish |
| ASTM | E1870 - 11 | Standard test method for odor and taste transfer from polymeric packaging film |
| ASTM | E1885 - 04(2011) | Standard test method for sensory analysis triangle test |
| ASTM | E1909 - 13 | Standard guide for time-intensity evaluation of sensory attributes |
| ASTM | E2139 - 05(2011) | Standard test method for same-different test |
| ASTM | E2164 - 08 | Standard test method for directional difference test |
| ASTM | E2262 - 03(2014) | Standard practice for estimating thurstonian discriminial distances |
| ASTM | E2263 - 12 | Standard test method for paired preference test |
| ASTM | E253 - 16 | Standard terminology relating to sensory evaluation of materials and products |
| ASTM | E2609 - 08 | Standard test method for odor or flavor transfer or both from rigid polymeric packaging |
| ASTM | E2610 - 08 | Standard test method for sensory analysis—duo-trio test |
| ASTM | E460 - 12 | Standard practice for determining effect of packaging on food and beverage products during storage |
| ASTM | E544 - 10 | Standard practices for referencing suprathreshold odor intensity |
| ASTM | E619 - 09 | Standard practice for evaluating foreign odors in paper packaging |
| ASTM | E679 - 04(2011) | Standard practice for determination of odor and taste thresholds by a forced-choice ascending concentration series method of limits |

| source | standard name | Standard title |
|--------|--|---|
| ISO | EN ISO 10399:2004 | Sensory analysis. Methodology. duo-trio test |
| ISO | EN ISO 11035:1994 | Sensory analysis-identification and selection of descriptors for establishing a sensory profile by a multidimensional approach |
| ISO | EN ISO 11036:1994 | Sensory analysis-Methodology-texture profile |
| ISO | EN ISO 11037:2011 | Sensory analysis. guidelines for sensory assessment of the colour of products |
| ISO | EN ISO 11056:1999 | Sensory analysis. Methodology. magnitude estimation method |
| ISO | ISO 13299:2016 | Sensory analysis. Methodology. general guidance for establishing a sensory profile |
| ISO | EN ISO 4120:2004 | Sensory analysis. Methodology. triangle test |
| ISO | EN ISO 5492:2009 | Sensory analysis. vocabulary |
| ISO | EN ISO 5495:2005 | Sensory analysis. Methodology. paired comparison test |
| ISO | EN ISO 5496:2006 | Sensory analysis. Methodology. initiation and training of assessors in the detection and recognition of odours |
| ISO | EN ISO 6658:2005 | Sensory analysis. Methodology. general guidance |
| ISO | ISO 8586:2012 | Sensory analysis - General guidelines for the selection, training and monitoring of selected assessors and expert sensory assessors |
| ISO | EN ISO 8587:2006 | Sensory analysis. Methodology. ranking |
| ISO | EN ISO 8588-1987 | Methods for sensory analysis of food. 'a'-'not a' test |
| ISO | EN ISO 8589:2010 | Sensory analysis. General guidance for the design of test rooms |
| ISO | ISO 13300-1:2006 ISO 13300-2:2006 | Sensory analysis. General guidance for the staff of a sensory evaluation laboratory. - staff responsibilities - recruitment and training of panel leaders |
| ISO | ISO 13302:2003 | Sensory analysis. methods for assessing modifications to the flavour of foodstuffs due to packaging |
| ISO | ISO 16820:2004 | Sensory analysis. Methodology. sequential analysis |
| ISO | ISO 22308:2005 | cork stoppers. sensory analysis |
| ISO | ISO 22935-1:2009 ISO 22935-2:2009 ISO 22935-3:2009 | Milk and milk products. Sensory analysis. - general guidance for the recruitment, selection, training and monitoring of assessors - recommended methods for sensory evaluation - guidance on a method for evaluation of compliance with product specifications for sensory properties by scoring |
| ISO | ISO 29842:2011 | Sensory analysis. Methodology. balanced incomplete block designs |
| ISO | ISO 4121:2003 | Sensory analysis. guidelines for the use of quantitative response scales |
| ISO | ISO13301:2002 | Sensory analysis- methodology- general guidance for defining and calculating individual and group sensory thresholds from three alternative forced-choice data sets |
| UNI | UNI 10192:2000 | Condizionamento alimentare - Procedure per la valutazione dell'eventuale difetto organolettico derivante agli alimenti dal contatto con gli imballaggi |

Annex 23. Safety data

Reports of issues based on HFAA (ex- FVO) audits

The HFAA reports aims to summarise the transposition of EU measures into national law, presence of national legislation, and parameters of interest for this baseline study including registration of food contact operators, DoC and supporting documents, Details on GMP, basis for enforcement and for sanctions, certification/accreditation/ quality system, systems of controls/ Sampling, traceability and laboratory performance.

Summary outcome on findings of HFAA audits on FCM:

| Type of provision | Countries compliant with EU legislation (thus with provisions/systems in place) | Countries with issues on provisions | Countries with no provisions |
|---|--|--|------------------------------|
| Transposition of EU legislation into national legislation | HU(2011), DE(2008), UK(2009), FI(2009), LV(2009), FR(2007), DK(2008), EL(2009), LT(2009), SI(2009), PT(2009), RO(2009), PL(2010), BG(2010), MT(2010), IT(2010), LV(2011), SE(2011), PT(2011), AT(2011), BE(2011) | CZ(2010) | |
| National legislation on non-harmonised materials | HU(2011), DE(2008), UK(2009), FI(2009), LV(2009), FR(2007), DK(2008), EL(2009), LT(2009), SI(2009), RO(2009), CZ(2010), SE(2011) | | |
| Registration of food contact operators | HU(2011), DK(2008), CZ(2010), PL(2010), BG(2010), MT(2010), LV(2011), SE(2011), PT(2011), AT(2011), BE(2011) | RO(2009) | IT(2010), LV(2009) |
| DoC & supporting documents | HU(2011), FI(2009), EL(2009), PT(2009), RO(2009), PL(2010), BG(2010), IT(2010), SE(2011) | DE(2008), SI(2009), CZ(2010) | |
| Details on GMP | FI(2009), FR(2007), EL(2009), LT(2009), LT(2009), SI(2009), PT(2009), AT(2011) | HU(2011), UK(2009), LV(2009), RO(2009), CZ(2010), IT(2010) | |
| Basis for sanctions | HU(2011), FI(2009), CZ(2010), PL(2010), BG(2010), IT(2010), SE(2011), PT(2011), AT(2011), BE(2011) | ES(2008), RO(2009), MT(2010) | |
| Basis for enforcement | HU(2011), FI(2009), CZ(2010), PL(2010), BG(2010), MT(2010), IT(2010), LV(2011), SE(2011), PT(2011), AT(2011), BE(2011) | ES(2008), RO(2009) | |
| Certification/accreditation/quality system | DE(2008), UK(2009), FI(2009), LV(2009), FR(2007), DK(2008), EL(2009), LT(2009), SI(2009), PT(2009), CZ(2010), LV(2011), PT(2011), BE(2011) | ES(2008), RO(2009), MT(2010) | |
| System of controls/ Sampling | HU(2011), DE(2008), UK(2009), FI(2009), DK(2008), CZ(2010), PL(2010), BG(2010), MT(2010), LV(2011), | ES(2008), FR(2007), LT(2009), PT(2009), RO(2009), CZ(2010), AT(2011), BE(2011) | LV(2009), SE(2011) |
| Traceability | UK(2009), FI(2009), LV(2009), FR(2007), SI(2009), PT(2009), PL(2010), MT(2010), LV(2011), SE(2011) | DK(2008) | |
| Laboratory performance | HU(2011), UK(2009), FI(2009), FR(2007), DK(2008), CZ(2010), PL(2010) | ES(2008), LV(2009), LT(2009) | |

The main issues that were highlighted by the auditors during their visits and are pertinent to the present project were also summarised in the table below.

Main areas of issues noted by the HFAA audits (period 2007-2011):

| Type of non-conformity (lack of or insufficient) | Countries |
|---|--|
| resources for controls | HU(2011), ES(2008), MT(2010) |
| training | HU(2011), ES(2008), UK(2009), FR(2007), EL(2009), LT(2009), RO(2009), CZ(2010), PL(2010), MT(2010), IT(2010), LV(2011), SE(2011), AT(2011), BE(2011) |
| controls | HU(2011), ES(2008), LV(2009), DK(2008), EL(2009), LT(2009), PT(2009), RO(2009), PL(2010), BG(2010), SE(2011), PT(2011), AT(2011) |
| documentation and/or DoC | HU(2011), DE(2008), UK(2009), LV(2009), RO(2009), CZ(2010), PL(2010), BG(2010), IT(2010), LV(2011), SE(2011), AT(2011), BE(2011) |
| GMP implementation | HU(2011), FI(2009), LV(2009), LT(2009), SI(2009), PT(2009), CZ(2010), PL(2010), BG(2010), MT(2010), IT(2010), SE(2011), BE(2011) |
| provisions/follow-up for corrective actions | ES(2008), CZ(2010), SE(2011) |
| participation in proficiency testing | LV(2009), LT(2009), RO(2009), BG(2010), IT(2010) |
| validated methods | LV(2009), FR(2007), RO(2009), CZ(2010), PL(2010), BG(2010), MT(2010), IT(2010) |
| controls on FCM other than packaging | EL(2009) |
| certification/accreditation | RO(2009), BG(2010), MT(2010) |
| organisation of national PT by NRL | CZ(2010) |
| controls on FCM other than those in (EC)1935/2004 | DK(2008) |

Annex 24. Cost data

Professional associations also cite or provide a number of documents testifying to their self-guidance or self-regulation. These are reported here for the associations who gave feedback.

FEICA: FEICA Food Contact Status Paper

APEAL: Trade Association and individual company experts' participation in member state, national authority and inter-industry meetings

EMPAC: Central and individual company experts' participation in member state, national authority and inter-industry meetings. Self-auditing.

ECMA stated to have:

- *Well-functioning Technical Committee within the association.A14*
- *Regular food contact update mails to all national associations represented in ECMA and to all companies, direct members of ECMA. (indicative 20/year)*
- *Sector specific GMP (updated annually).*
- *Register with all self-declared compliant carton manufacturing plants."*

FPE:

- *FPE Q&A Swiss Ink Ordinance.*
- *FPE Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food.*
- *FPE Guideline on Use of Isocyanate-based Adhesives in Packaging Laminates.*
- *FPE Template for declaration of compliance*
- *Sharing of best practice through conferences and circular emails on a wide variety of issues such as migration testing and modelling, hygiene standards, taint and odour evaluation, functional barrier.*

EuPIA:

- *Information leaflet: Printing Inks for Food Packaging*
- *Frequently Asked Questions on the legal status of Printing Inks, Coatings and Varnishes for the non-food Contact Surface of Food Packaging (food packaging inks)*
- *EuPIA Guideline on Printing Inks applied to the non-food Contact Surface of Food Packaging Materials and Articles*
- *Inventory List Comprising Packaging Ink Raw Materials Applied to the Non-Food Contact Surface of Food Packaging*
- *EuPIA Suitability List of Photo-Initiators for Low Migration UV Printing Inks and Varnishes*
- *Explanatory Note: Update mechanism for the EuPIA Inventory List of Raw Materials for Food Packaging Inks, Coatings and Varnishes*
- *Template file as referred to in the Explanatory Note above*
- *GMP for the Production of Packaging Inks Formulated for Use on the Non-Food Contact Surfaces of Food Packaging and Articles intended to Come Into Contact with Food*
- *Customer Information Note regarding the use of sheet fed offset inks and varnishes for the manufacture of food packaging*
- *Customer Guidance Note for Using Ink Statements of Composition when Considering Compliance of Food Packaging*
- *Explanatory Note for Suppliers of Ink Raw Materials Regarding Regulatory Compliance of Printed Food Packaging*
- *Information Note: Resistance Requirements of Printing Inks and Coatings Applied to the Non-Food contact Surface of Food Packaging Materials and Articles*
- *Food Packaging Inks and Swiss Ordinance on FCMs and Articles - Questions & Answers Swiss Ordinance on Packaging Inks Substance Evaluation and Detection Limits: Frequently Asked Questions*
- *EuPIA Statement on Recycled Plastics and Inks (Commission Regulation (EC) No 282/2008)*
- *EuPIA Statement: Food Packaging made from Recycled paper and board*
- *EuPIA Statement on Recyclability of Printed Paper and Board Articles for Use in Primary Food Packaging*
- *EuPIA Contribution to Mineral Oil Reduction in paper and board*
- *EuPIA Position on the Commission Regulation (EC) 2023/2006 on GMP for Materials and Articles Intended to Come into Contact with Food*
- *EuPIA Information leaflet on Printing Inks and Varnishes intended to come into Direct Contact with Foodstuffs*
- *Standard Glossary of Packaging Inks and Coatings Terms*
- *EuPIA Statement on Benzophenone*

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