Institute for Health and Consumer Protection

European Chemicals Bureau

MANUAL OF DECISIONS FOR IMPLEMENTATION OF THE SIXTH AND SEVENTH AMENDMENTS TO DIRECTIVE 67/548/EEC ON DANGEROUS SUBSTANCES (DIRECTIVES 79/831/EEC AND 92/32/EEC)

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MANUAL OF DECISIONS FOR IMPLEMENTATION OF THE SIXTH AND SEVENTH AMENDMENTS TO DIRECTIVE 67/548/EEC ON DANGEROUS SUBSTANCES (DIRECTIVES 79/831/EEC AND 92/32/EEC)

(NON-CONFIDENTIAL VERSION)

FOREWORD

This document is a collection of the explanations and views of the Commission and the Committee of Competent Authorities for the implementation of Council Directive 79/831/EEC (the 6th Amendment of Directive 67/548/EEC) and Council Directive 92/32/EEC (the 7th Amendment). It also includes all the decisions taken during the meetings of Competent Authorities and the Commission over the period 1981 to 2002 (1st to 63rd meetings of Competent Authorities). These decisions, explanations and views, which relate primarily to the notification of new substances, have been systematically recorded over the period, to provide a harmonised guide for the Competent Authorities.

Many of the decisions, explanations and views taken under the 6th Amendment are equally applicable under the 7th Amendment, and have been included in this document (decisions, etc. taken prior to the 45th meeting of Competent Authorities, December 1993). Other decisions, etc. apply specifically to rules existing under the 6th Amendment, which no longer exist under the 7th Amendment. Since, however, a number of these decisions are important for the view of the Directive, they have also been included in the document.

The meetings of Competent Authorities and the Commission related to the notification of new substances are confidential in nature, since matters of commercial sensitivity related to individual notifications or prospective notifications may be discussed. For example, a common question posed to the Competent Authorities and the Commission is “does substance X need to be notified?”. Attendance at the meetings is restricted and the summary reports are similarly confidential. It is for this reason that the Commission, together with the Member States, has undertaken to publish this non-confidential version of the Manual of Decisions, for the guidance of industry and other bodies involved in the notification of new substances.

It should be noted that from time to time decisions taken in the past may be re-discussed. The Commission and the Competent Authorities may in certain cases come to a different conclusion, due to advances in technical understanding of certain problems and other reasons. For this reason, the decisions, explanations and views provided in this document should not be regarded as absolute. In cases of doubt, prospective notifiers should always contact the Competent Authority in the country in which they are located for further guidance on matters related to notification and classification, packaging and labelling of dangerous substances. A list of Competent Authorities is included as Section 4 of this document.

Key words: New substances, notification, ELINCS, EINECS, Polymers, No-longer polymers, Sole representative, Risk assessment

CONTENTS

1 LEGAL FRAMEWORK FOR THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS SUBSTANCES, INCLUDING NOTIFICATION AND RISK ASSESSMENT

1.1 INTRODUCTION

Directive 67/548/EEC[1] provides an approximation of the laws, regulations and administrative procedures relating to the classification, packaging and labelling of dangerous substances within the European Economic Community. The 6th Amendment of the Directive, Directive 79/831/EEC[2], introduced a procedure for notification of new substances within the Community, whereby notification to a competent authority in one Member State was valid for the whole Community. A new substance was defined within the Directive as a substance which was not listed in the EINECS inventory (European Inventory of Existing Commercial Chemical Substances) of chemical substances on the Community market on 18 September, 1981. New substances notified in the Community after 18 September, 1981, the date of entry into force of Directive 79/831/EEC in Member States are listed in ELINCS (European List of Notified Chemical Substances).

The current legal text of Directive 67/548/EEC is the 7th Amendment, Directive 92/32/EEC[3], which became binding on Member States on 31 October 1993. Council Directive 96/56/EC[4] further amended Directive 67/548/EEC to require use of the term "EC label" rather than "EEC label". Additional to the classification, packaging, labelling and notification requirements of the 6th Amendment, the 7th Amendment introduced inter alia a requirement for Member States to carry out a risk assessment on any new substance notified to a competent authority. The principles for risk assessment are established in Directive 93/67/EEC[5] and detailed technical guidance on carrying out risk assessment of both new and existing substances has been developed and published by the European Commission[6].

1.2 TITLES OF THE ANNEXES TO COUNCIL DIRECTIVE 92/32/EEC

Directive 67/548/EEC, as amended by Directive 92/32/EEC, contains a number of technical Annexes related to the practical implementation of the Directive, as shown in Table 1.

1 OJ No. 196, 16. 8. 1967, p. 1.
2 OJ No. L 259, 15. 10. 1979, p. 10.
3 OJ No. L 154, 5. 6. 1992, p. 1. Corrigendum in OJ No. L 317, 18. 12. 1993, p. 83 (DE version only)
4 OJ No. 236, 18. 9. 1996, p. 35.
5 OJ No. 227, 8. 9. 1993, p. 9.
6 Technical Guidance Documents in support of Commission Directive 93/67/EEC on risk assessment of new notified substances and Commission Regulation (EC) No.488/94 on Risk Assessment for Existing Substances. Office for Official Publications of the European Communities, Luxembourg, 1996. ISBN 92-827-8011-2

Table 1a Titles of the Annexes to Directive 92/32/EEC

Annex No.	Title
I	List of dangerous substances
II	Symbols and indications of danger
III	Nature of the special risks attaching to dangerous substances
IV	Safety advice concerning dangerous chemical substances
V A	Methods for the determination of physico-chemical properties
V B	Methods for the determination of toxicity
V C	Methods for the determination of ecotoxicity
VI	General classification and labelling requirements for dangerous substances
VII A	Information required for the technical dossier ("base set") referred to in Article 7(1)
VII B	Information required for the technical dossier ("base set") referred to in Article 8(1) and 8(3)
VII C	Information required for the technical dossier ("base set") referred to in Article 8(2)
VII D	Information required for the technical dossier ("base set") referred to in Article 12 (polymers)
VIII	Additional information and tests required under Article 7(2)
IX A	Provisions relating to child-resistant fastenings
IX B	Provisions relating to tactile warnings of danger

The current Annexes of the Directive can be found in the following Adaptations of Directive 67/548/EEC (see Section 1.2).

Table 1b. Adaptation of the Annexes of Directive 67/548/EEC to technical progress

Annex No.	Official Journal reference	Adaptation to Technical Progress (ATP)
I	OJ L 258 A, 16.10.1993	19th ATP
	OJ L 13, 15.1.1994	20th ATP
	OJ L 381, 31.12.1994	21st ATP
	OJ L 248, 30.9.1996	22nd ATP
	OJ L 343, 13.12.1997	23rd ATP
	OJ L 305, 16.11.1998	24th ATP
	OJ L 355, 30.12.1998	25th ATP
	OJ L 136, 8.6.2000	26th ATP
	OJ L 225, 21.8.2001	28th ATP
II	OJ L 225, 21.8.2001	28th ATP
III	OJ L 225, 21.8.2001	28th ATP
IV	OJ L 225, 21.8.2001	28th ATP
V	OJ L 133, 30.5.1988	9th ATP
	OJ L 383A, 29.12.1992	17th ATP
	OJ L 110A, 4.5.1993	18th ATP
	OJ L 248, 30.9.1996	22nd ATP
	OJ L 305, 16.11.1998	24th ATP
	OJ L 136, 8.6.2000	26th ATP
	OJ L 136, 8.6.2000	27th ATP
	OJ L 225, 21.8.2001	28th ATP
VI	OJ L 225, 21.8.2001	28th ATP
VII	OJ L 154, 5.6.1992	7th ATP
	OJ L 294, 30.11.1993	Directive on Annex VIID
	OJ L 225, 21.8.2001	28th ATP
VIII	OJ L 154, 5.6.1992	7th Amendment
	OJ L 225, 21.8.2001	28th ATP
IX	OJ L 228, 17.8.1991	14th ATP

1.3 ADAPTATIONS TO TECHNICAL PROGRESS OF DIRECTIVE 67/548/EEC

These Annexes are amended from time to time by formal vote of the Committee for Adaptation to Technical Progress of Directive 67/548/EEC, the Committee comprising representatives of each Member State in the Community. By August 2001 the Annexes of the Directive had been adapted to technical progress 28 times, and a consolidated text of the Directive containing all of the current legal Adaptations is currently under consideration in Council. Table 2 provides a listing of the Adaptations to Technical Progress that are currently relevant.

TABLE 2 CURRENTLY RELEVANT ADAPTATIONS TO TECHNICAL PROGRESS OF DIRECTIVE 67/548/EEC

Annex No.	Official Journal reference	Adaptation to Technical Progress (ATP)
V	Commission Directive of 18 November 1987 (Dir. 87/302/EEC), OJ L 133, 30.5.1988, p. 1.	9th ATP
IX	Commission Directive of 28 July 1991 (Dir.91/410/EEC), OJ L 228, 17.8.1991, p. 67.	14th ATP
V	Commission Directive of 31 July 1992 (92/69/EEC), OJ L 383, 29.12.1992, p. 130 & L 383A, p. 1.	17th ATP
I, II, III, IV, V, VI	Commission Directive of 27 April 1993 (93/21/EEC), OJ L 110, p. 20 and L 110A, 4.5.1993, p.1. Note that adaptations related to Annex I in this Directive have been superseded by the 19th ATP. Note that adaptations related to Annexes II, III, IV & VI in this Directive have been superseded by the 28th ATP.	18th ATP
I	Commission Directive of 1 September 1993 (93/72/EEC), OJ N L 258 and L 258A, 16.10.1993, p.1.	19th ATP
I	Commission Directive of 11 November 1993 (93/101/EEC), OJ L 13, 15.1.1994, p. 1.	20th ATP
I	Commission Directive of 19 December 1994 (94/69/EEC), OJ L 381, 31.12.1994, p.1.	21st ATP
I, III, V, VI	Commission Directive of 30 July 1996 (96/54/EC), OJ No L 248, 30.9.1996, p. 1. Note that adaptations related to Annexes III and VI in this Directive have been superseded by the 28th ATP.	22nd ATP
I	Commission Directive of 5 December 1997 (97/69/EC), OJ L 343, 13.12.1997, p.19.	23rd ATP
I, V	Commission Directive of 18 September 1998 (98/73/EC), OJ L305 16.11.1998, p. 1.	24th ATP
I, II, IV, VI	Commission Directive of 15 December 1998 (98/98/EC), OJ No L 355, 30.12.1998, p. 1. Note that adaptations related to Annexes III, IV and VI in this Directive have been superseded by the 28th ATP.	25th ATP
I, III, IV, V, VI, IX	Commission Directive of 19 May 2000 (2000/32/EC), OJ No L 136, 8.6.2000, p. 1. Note that adaptations related to Annexes III, IV and VI in this Directive have been superseded by the 28th ATP.	26th ATP
V	Commission Directive of 25 April 2000 (2000/33/EC), OJ No L 136, 8.6.2000, p. 90.	27th ATP
I, II, III, IV, V, VI, VII, VIII	Commission Directive of 6 August 2001 (2001/59/EC), OJ No L 225, 21.8.2001, p. 1.	28th ATP

2 EINECS (EUROPEAN INVENTORY OF EXISTING COMMERCIAL CHEMICAL SUBSTANCES)

2.1 ESTABLISHMENT AND PUBLICATION OF EINECS

The basis for the introduction of EINECS was Article 13 of Council Directive 79/831/EEC, which provided for the drawing up of an inventory of chemical substances existing on the Community market on 18 September 1981. In addition to Article 13 the following Commission Decisions and Communications are also relevant to EINECS:

2.1.1 Commission Decision 81/437/EEC, laying down the criteria in accordance with which information relating to the inventory of chemical substances is to be supplied by the Member States to the Commission. OJ No L 167, 24.6.1981, p. 31.

2.1.2 Commission Communication 90/C146A/0181/437/EEC pursuant to Article 13 of Council Directive 67/548/EEC - EINECS. OJ No C 146A, 15.6.1990, p. 1.

2.1.3 Commission Decision 92/3/EEC, establishing the conditions governing the notification of chemical substances existing on the market of the former German Democratic Republic prior to 18 September 1981 which do not appear on the inventory provided for in Article 13 of Directive 67/548/EEC. OJ No L 3, 8.1.1992, p. 26.

2.2 FOLLOW-UP TO THE PUBLICATION OF EINECS – EINECS CORRECTIONS

The document "Comments on Official EINECS" is a synthesis of all the questions (plus replies) submitted directly or indirectly to the European Chemicals Bureau (ECB) of the Joint Research Centre, Ispra. It was decided[7] to finalise the list of errors in EINECS and to publish an erratum. It was also agreed to publish any other changes at more or less regular intervals as and when necessary. As to any subsequent changes to CAS numbers, it was decided that these modifications, which do not affect the content of EINECS, would be introduced into the CD ROM version of the inventory and also in updates of the publication "How To Notify". The most reliable entry in the inventory would continue to be the EINECS number·

It was agreed[8] that corrections should not be made when the IUPAC nomenclature has not been followed precisely (use of prefixes such as "neo" or "iso", fractions of metal ions in the formula) if this does not cause any doubt about the identity of the substance. In the list of EINECS corrections circulated to Competent Authorities it will be indicated what corrections were made and why. Competent Authorities asked that EINECS on CD-ROM should include synonyms to the neo/iso /metal ions etc. entries.

7 38th meeting of Competent Authorities, Copenhagen, 21-22 /5/1991, NOTIF/31/91

8 Technical and Scientific Meeting, Ispra, 11-12/9/1995

The Commission has published several papers[9] [10] [11] [12] in scientific journals explaining the rules behind the formation and interpretation of EINECS. The agreed EINECS corrections have been published[13].

2.3 CRITERIA FOR REPORTING SUBSTANCES FOR EINECS[14]

As indicated above, the Commission has published several papers in scientific journals explaining the rules behind the formation and interpretation of EINECS. An excerpt from the reporting rules which were used for compiling EINECS is also included, as follows:

2.3.1 General Remarks

Each substance reported for inclusion in EINECS should meet all of the following minimum requirements:

1 It should be a substance, meaning chemical elements and their compounds as they occur in the natural state or as produced by industry, including any additives required for the purpose of placing them on the Community market.

2 It should have been placed on the Community market between 1 January 1971 and 18 September 1981.

3 It should be reported on an official EINECS Reporting Form (A, B, C).

4 It should not be excluded from Supplementary Reporting by any of the criteria cited in this chapter or in the Commission Decision.

The criteria listed in this chapter are intended to assist persons in determining which substances can be reported and which should not. When you have determined which substances should be reported, refer to chapter IV for detailed instructions on how to describe them using the official EINECS Reporting Forms.

2.3.2 Criteria

1 Substances already included in ECOIN should not be reported.

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9 The EINECS inventory of existing chemical substances on the EC market. F. Geiss et al (1992), Toxicological and Environmental Chemistry, Vol. 37, pp. 21-23

10 Compilation of EINECS: Descriptions and Definitions used for UVCB Substances: complex reaction products, plant products, (post-reacted) naturally occurring substances, micro-organisms, petroleum products, soap and detergents and metallic products. K. Rasmussen, G. Vollmer, D. Pettauer, J.B. Davis (1999), Toxicological and Environmental Chemistry, Vol. 69, pp. 403-416

11 Compilation of EINECS: Descriptions and definitions used for substances, impurities and mixtures, G. Vollmer, K. Rasmussen, G. Christ, O. Norager, J.B. Davis, A. van der Wielen, C. Haas and A. Fasey (1998), Toxicological and Environmental Chemistry, Vol. 65, pp. 113-122

12 Registration of Polymers in accordance with Directive 67/548/EEC, K. Rasmussen, G. Christ and J.B. Davis (1998), Toxicological and Environmental Chemistry, Vol. 67, pp. 251-261

13 Notification of New Chemical Substances in Accordance with Directive 67/548/EEC on the Classification, Packaging and Labelling of Dangerous Substances - EINECS Corrections. Office for Official Publications of the European Communities, 1997, Luxembourg. ISBN 92-828-0196-9

14 Except from “How to report for EINECS”

2 Substances placed on the market before but not after 1 January 1971 or placed on the market for the first time after 18 September 1981 should not be reported.

3 Substances placed on the market exclusively for research, development and/or analytical purposes should not be reported.

4 Substances rendered radioactive by either natural or artificial nuclear transformation should not be reported.

5 Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight should not be reported.

6 Substances which result from a chemical reaction that occurs incidental to storage of another substance, mixture or article should not be reported. For example, partially polymerised drying oils or other degradation products formed incidental to storage should not be reported.

7 Substances which result from a chemical reaction occurring upon end use of other substances, mixtures or articles (e.g. adhesives, paints, miscellaneous cleansers or housekeeping products, fuels, fuel additives, water softeners, photographic films, batteries, matches) and which are not themselves placed on the market should not be reported. Only substances which are components of adhesives, paints, cleansers, etc. can be reported.

8 Substances which result from a chemical reaction that occurs when: (i) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (ii) a substance solely in tended to import a specific physico-chemical characteristic function as intended should not be reported.

9 Impurities should not be reported.

10 By-products should not be reported, unless they are placed on the market. Substances such as reaction residues, sludges, fly ashes, dusts and slags, commonly termed as by-products, can be reported if they are placed on the market.

11 Medicinal products, cosmetic products and pesticide products, if placed on the market as intentional mixtures, should not be reported as such. The individual components, however, can be reported separately.

12 Substances placed on the market exclusively as food or feedingstuff should not be reported. Additives or substances produced by processing of food and feedingstuff can be reported.

13 Articles should not be reported. Articles which undergo chemical surface reactions to increase their stiffness, strength, flame resistance or to improve their ion-exchanging capacity, chromatographic behaviour, resilience, bacterial resistance, etc. while maintaining their bulk structure retain their status as articles. Fluids and particles are not considered articles regardless of shape or design, but rather mixtures or

substances. Examples of articles include batteries, brake linings, chips, fabrics, fibres, filaments, films, flares, glass wool, leather, paper, pencils, rock wool, chromatographic supports and yarns. Components of articles and substances used in the finishing process of an article (e.g. dyes and fire retardants) can be reported if they have a separate commercial identity from that of the article.

14 Hydrates of a substance or hydrated ions, formed by association of a substance with water should not be reported. The anhydrous form can be reported and will, by implication, represent all hydrated forms. The products of discrete chemical reactions in which water is a reactant, i.e. a metal hydroxide formed by the reaction of a metal oxide and water can be reported.

15 Homogeneous and heterogeneous alloys should not be reported. Intermetallic compounds of well-defined stoichiometry such as NbAl3 can be reported.

16 Intentional mixtures produced by the mixing or blending of ingredients which do not chemically react should not be reported. Examples of intentional mixtures or blends include a coating material prepared by mixing linseed oil and titanium dioxide, a solution of n-hexane and methanol, and a blended gasoline to which a corrosion inhibitor has been added. The components of such an intentional mixture can be reported separately.

17 Fertilisers, whether produced by intentional blending or by a method involving a chemical reaction, should not be reported. The components or starting materials of fertilisers can be reported separately.

18 Special categories have been established and included in ECOIN covering all of the component substances intentionally produced in certain common commercial reaction mixtures.

Examples:

Cement, Portland, chemicals [65997-15-1 *]

Cement, alumina, chemicals [65997-16-2*]

Glass, oxides [65997-17-3*]

Frits, chemicals [6.997-18-4*)

Ceramic materials and wares, chemicals [66402-68-4*]

Steel manufacture, chemicals [65997-19-5*]

Definitions for these examples can be found in the "Chemical Substance Definitions Section" of ECOIN. Only substances or categories not fitting those included in ECOIN can be reported.

19 Substances occurring in nature as such, unprocessed, or processed only by manual, mechanical or gravitational means; by dissolution in water, by flotation, or by heating solely to remove water, or which are extracted from air by any means, will be listed in

EINECS under the collective name "naturally occurring substances" and should not be reported individually. However, substances as such or as part of mixtures which are produced by chemical modification of naturally occurring products or are separated from them by physical processing can be reported.

Enzymes can be reported if synthesised or if obtained after processing of a natural product. Substances which are produced by chemical modification of bacteria, fungi, yeasts and their metabolic products (or are separated from the living materials by physical processing) can be reported. This will apply whether the substance is isolated or is a component of a mixture. Bacteria, fungi and yeasts themselves, being living materials should not be reported.

The following list of examples is intended to provide guidance in determining the reportability of natural products and their derivatives. Chapter IV should be consulted for instructions on how to describe reportable substances.

Should Not Be Reported	Can Be Reported	
Phosphate rock	Superphosphates	[8011-76-5*]
Cedar wood	Cedarwood oil, epoxidized	[68648-34-0*]
Corn	Corn steepwater	[66071-94-1*]
Pine needles	Pine needle oil	[8000-2-6-8*]
Coal	High temperature coal tar	[65996-89-6*]
Crude oil	Catalytic dewaxed light petroleum paraffin oils	[64742-71-8*]
Castor bean (Ricinus communis)	Castor oil	[8001-79-4*)]
Carbohydrate isomerases	Glucose isomerase (E.C.S.3.1.18)	[9055-00-9]
Kaolinite clay (natural)	Kaolinite (synthetic)	[1318-74-7]
Tobacco products	Nicotine	[54-11-5]

20 Mixtures obtained as the result of a chemical reaction and placed on the market without separation into component parts can be reported as such in terms of their starting materials or by reporting separately the individual components if known. (Examples and instructions in chapter IV, page 49).

21 Inorganic catalysts should not be reported as such. The component metals or metallic compounds can be reported separately without specification of use.

Examples:

Should not be reported	Can be reported individually
Raney nickel	Nickel
Cobalt oxide-aluminium oxide catalyst	Cobalt II oxide
	Cobalt III oxide
	Aluminium oxide
	Aluminium cobalt oxide
Supported platinum catalyst	Platinum metal

22 Polymers, polyadducts and polycondensates should not be reported. Instead, starting materials for polymer production (monomers) can be reported. Polymers which have been post-reacted (undergone reactions after polymerisation) should not be reported as such. Instead, the monomer substances from which the polymer is manufactured and the post-treating reagent(s) can be reported separately.

A natural polymer used as a starting material can be reported unless already included in EINECS under the collective name "naturally occurring substances". (Criteria 19, page 11).

Examples:

Should not be reported	Can be reported individually
Polyvinyl chloride	Vinyl chloride
Phenol-formaldehyde resin	Phenol
Brominated polyethylene	Bromine
	Ethylene
Ethanol homopolymer, reaction	Ethanol
product with chloromethane	Chloromethane
Linseed oil, polymer with vinyltoluene	Linseed oil
	Vinyltoluene
I-Octene polymer	I-Octene
n-Lauroyl terminated collagens	Lauric acid
	Collagen
Ethoxylated, propoxylated glycerol	Oxirane
	Methyloxirane
	Glycerol
Potassium polymethacrylate	Potassium hydroxide
	Methacrylic acid
Propoxylated tall-oil fatty acids	Methyloxirane
	Tall-oil fatty acids

General remark

As a result of the procedure used to build ECOIN and the Compendium some substances may have been included in either publication though belonging to categories which are excluded from supplementary reporting. This fact should not be interpreted as an authorisation to report similar substances for EINECS.

2.4 EINECS AND MIXTURES

Generic EINECS entries for mixtures do not cover the individual substances within a mixture[15]. It was restated at the 51st meeting of Competent Authorities[16] that one isomer is not covered by EINECS if the EINECS entry is for the mixture.

15 49th meeting of Competent Authorities - 30-31/3/95

2.4.1 Gasoline, Lubricating Oils and Lubricating Greases

As a matter of principle, general definitions of this type, of which there are many examples in EINECS, cannot be interpreted as covering all possible constituents which could be contained in these products.[17]

2.4.2 Substituted Alkyl-Benzenesulphonates

Generic entries in EINECS such as "sulphonic acids, petroleum" or "sulphonic acids of petroleum, calcium salts" etc. cannot be regarded as "umbrella" entries covering each particular well defined alkyl-benzenesulphonate as marketed by a company.[18]

2.4.3 Mixtures in EINECS - Should traces be considered as components in a substance?

The issue related to the need to notify a particular substance, namely a mixture of mono-, di-, tri- and tetraesters, where one component is present only in traces.

A substance (being a mixture of different components) must contain all components listed in an EINECS entry to be covered by this entry.

In the specific case of an EINECS entry which is a mixture A, B, C, D of mono-, di-, tri- and tetraesters of the same acid, the CA decided that all components A, B, C and D need to be present and each at a level ≥ 0.01 % for the mixture to be covered by the EINECS entry relating to the mixture A, B, C, D.

This conclusion is not applicable if one component is present at 80 % or more (in this case the substance is regarded as a 'mono-component' substance).[19,20]

2.5 ISOMERS AND EINECS

- Entries in EINECS covering a reaction mixture containing several different isomers cannot be used as a basis for not notifying the isolated isomers if they are placed on the market individually.[21]
- It was agreed that under the EINECS rules the entry "C5-C9, fatty acids" describes linear saturated chain only. Therefore, substances containing branched or unsaturated chains should be notified.[22]

2.6 A DERIVATIVE OF ROSIN

On the basis of the information provided by the manufacturer it was decided[23] that a product derived from rosin

- is a different substance from rosin;

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16 51st meeting of Competent Authorities, Rome, 5-7/6/1996
17 28th meeting of Competent Authorities- 15-16/3/96 - NOTIF/10/89
18 28th meeting of Competent Authorities- 15-16/3/96 - NOTIF/10/89
19 6th Technical and Scientific Meeting, Ispra, 10-11/03/98, NOTIF/5/98-rev.1
20 55th Meeting of Competent Authorities, Edinburgh, 23-24/06/98, NOTIF/16/98-rev.1
21 29th meeting of Competent Authorities - 16-17/5/89, NOTIF/16/89 rev. 1
22 49th meeting of Competent Authorities - 30-31/3/95
23 40th meeting of Competent Authorities – 17-18/12/91, NOTIF/9/92rev 1

- could be considered as a polymer according to EINECS rules and therefore not notifiable.

2.7 PHOSPHATE CATALYST DOPED WITH METAL IONS

The question was raised as to the need to notify a metal phosphate doped with metal ions (a catalyst).

From the information available and after consultation with the JRC, Ispra, it was agreed that a notification should be required for this substance. Inorganic catalysts were excluded as such from reporting for EINECS because they were supposed to be a mixture. In this case, however, since this metal phosphate was not a mixture but a defined substance, it should be notified.[24]

2.8 CO-ORDINATION COMPLEX

The question concerned the need to notify a complex product consisting of an equilibrium mixture of two EINECS substances and a resulting "new" substance:

Chelating Agent + Metal Salt = Metal Chelate

If a marketed chelating agent (not listed in EINECS) subsequently in use generates a metal chelate, only the chelating agent would be notifiable but not the metal chelate. If the metal chelate (not listed in EINECS) is marketed it must be notified as a new substance.[25,26]

2.9 COMPLEX REACTION MIXTURE OF PARTLY EINECS-LISTED, PARTLY NEW COMPONENTS

A question raised at the 41st meeting of Competent Authorities[27] concerned the need to notify a complex mixture of phosphates made from a mixture of EINECS-listed and non-EINECS-listed components and containing small quantities of non-EINECS-listed phosphates in the eventual product. It was subsequently agreed that this was a complex mixture containing components which would have been reportable for EINECS and was therefore notifiable[28]

2.10 CRYSTALLINE MATRIX

2.10.1 Luminescent Materials

The question of whether or not luminescent doped materials should be notified was discussed at the 42nd meeting of Competent Authorities[29]. According to the JRC, Ispra, such substances were included in EINECS if they were known to form a crystalline matrix; if not, they were treated as mixtures.

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24 40th meeting of Competent Authorities - 17-18/12/91, NOTIF/9/92 rev.1
25 8th Technical and Scientific Meeting, Ispra, 9-10/03/99, NOTIF/4/99-rev.1
26 57th Meeting of Competent Authorities, Berlin, 17/06/99, NOTIF/8/99 rev.?
27 41st meeting of Competent Authorities, 5-6/3/92, NOTIF/24/92 rev.1
28 42nd meeting of Competent Authorities, 5-6/5/92, NOTIF/42/92 rev.1
29 42nd meeting of Competent Authorities, 5-6/5/92, NOTIF/42/92 rev.1

It was therefore agreed that the potential notifier and the Competent Authority must decide in what form the substances are present. If they are present as a crystalline matrix they should be notified.

2.10.2 Co-precipitate of two metals oxides (Solid solutions?)

This question was also tabled at the 42nd meeting in Lisbon. The meeting noted that if a substance was a solid solution it would probably have been included in EINECS since making such substances requires a high temperature implying the formation of new species.

The substance should be notified if there is a crystalline matrix.[30]

2.10.3 Double salts

A query concerning double salts had been received by the Competent Authorities. According to the JRC, Ispra, solid solutions having a crystalline matrix were reportable for EINECS. It was decided that these double salts were therefore notifiable as they form a crystalline matrix.[31]

2.10.4 EINECS entries specifying only one ionic component of a salt

A question was raised whether EINECS entries for ions covered all possible counter ion combinations. It was recognised that only complete substances physically existed and that a marketed substance not identical to an EINECS entry would be notifiable as new. Therefore EINECS entries of anions or cations without specifying the counter ion are not valid as generic cover for all corresponding salts, which would be notifiable.

Entries for benzenediazonium cations without specified anions form typical examples (EINECS numbers listed below):

229-758-2	247-877-8	248-648-5
238-340-9	248-280-5	249-584-0
239-490-8	248-281-0	249-779-0
239-549-8	248-282-6	249-780-6
240-190-4	248-283-1	250-721-1
241-355-3	248-284-7	251-046-5
241-356-9	248-543-4	251-047-0
244-422-5	248-545-5	256-261-8
244-653-1	248-642-2	256-279-6
246-530-8	248-643-8	256-306-1
247-334-5	248-646-4	263-285-2

30 42nd meeting of Competent Authorities, 5-6/5/92, NOTIF/42/92 rev.1
31 49th meeting of Competent Authorities – Brussels, 30-31/3/1995

2.11 SURFACE-TREATED METAL OXIDE POWDER

A product to be placed on the market included a substance which is made of a metal oxide powder with a surface treatment designed to hydrophobe the powder. The question was raised as to whether this "substance" was notifiable.

This case was discussed at the 40th[32] and 41st[33] meetings of Competent Authorities. The substance would not have been declarable for EINECS as it was the product of an unintentional reaction (Article 8 of the reporting rules for EINECS). At their 42nd meeting[34] Competent Authorities came to the decision that the substance should not be notified.

2.12 FATS, OILS AND EXTRACTS

EINECS definitions for substances of biochemical origin, specified by source organism, do not permit modification to production process. In cases where alkyl chains isolated from tallow (animal fat) are covered by EINECS, replacement of animals by plants for chemical extraction would require new substance notification of products. Data sharing and/or read-across would be possible where adequate data are available.[35][36]

2.12.1 Linseed oil extractives

A Competent Authority was contacted by a company which wanted to place on the market an extract obtained from linseed (extraction in a water/ethanol mixture and elimination of insoluble fractions). This extract is rich in mucilages and contains, in particular, polysaccharides. The extract is covered by the EINECS entry 232-278-6 and therefore not notifiable.[37]

2.13 EINECS-PROBLEMS, NOTIFICATION OF PLANT EXTRACTS[38]

Fats, fatty acids, oils and extracts

2.13.1 Introduction

Fats are the main constituents of the storage fat cells in animals and plants. Vegetable fats are, due to the presence of unsaturated fatty acid side-chain, often liquid at room temperature and hence referred to as oils. Whether a fat or an oil, they are poorly soluble in water but can be extracted from cells by organic solvents of low polarity such as ether or hexane or by pressure (e.g. rape oil from rapeseed). Examples are: corn oil, coconut oil, cottonseed oil, palm oil, tallow, bacon grease, and butter.

Chemically, fats are carboxylic esters, known as glycerides, of the trihydric alcohol glycerol with three carboxylic (or "fatty") acid residues, typically of C12-C20 chain length, attached.

32 40th meeting of Competent Authorities, 17-18/12/92, NOTIF/9/92
33 41st meeting of Competent Authorities, 5-6/3/92, NOTIF/24/92
34 42nd meeting of Competent Authorities, 5-6/5/92, NOTIF/42/92 rev.1
35 58th Meeting of Competent Authorities, Helsinki, 22/11/99
36 9th Technical and Scientific Meeting, Ispra, 7-8/9/99, NOTIF/99 rev.3
37 Technical and scientific meeting, Ispra, 11-12/9/1995, NOTIF/26/95
38 Technical and scientific meeting, Ispra, 11-12 September 1995, Notif/26/95

The natural fats and oils are always mixtures of different glycerides in which the glycerol carries a mixture of different such acids. Some of these products are of great economic importance and the composition of the vegetable oils is sometimes greatly influenced by the particular variety (e.g. those produced by selection, by plant breeders, so as to yield desired fatty acid components) of plant from which the oil has been extracted and also to some extent by the region (cultivation area, climate) in which the plants were grown.

2.13.2 Principles for reporting oils, resins and other plant extracts in EINECS

(i). Those plant-derived oils which are well known commercially (e.g. linseed oil, coconut oil, rape oil) are listed in EINECS with the following definition:

Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids (the different types of the fatty acids are listed followed by the genus, species, and family name of the plant concerned)

(Besides that such entries also cover any other extract that can be derived from the same plant)

Animal fats (e.g. tallow, EINECS No. 263-099-1) are listed similarly but omitting the plant detail.

(ii). Resins are listed in EINECS with the following definition:

Extractives and their physically modified derivatives. It is a resinous product which may contain resin acids and esters, terpenes, and oxidation or polymerisation products of these terpenes. (Genus, species, where appropriate).

Natural gums and resins are exudations of various trees and shrubs. They differ in their chemical composition and their physical properties.

(iii) Natural polymers

Synthetic polymers were not reportable as such for EINECS. However natural gums, resins, and other plant-derived materials containing polymeric products (natural polymers) were, and are listed in EINECS. (Besides that any post-reacted products derived from them are listed under the post-reactant and the natural polymer entry itself whereas substances extracted from natural gums are listed as extracts as under iv.).

(iv) Plant extracts which are not covered by (i) - (iii) are listed in EINECS with the following definition:

Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc. obtained from (Genus species, family name)

Plant extracts and their physically modified derivatives are listed in EINECS under genetic heading, covering all products extracted from the same plant irrespective of the part of the plant or the physical process used. Each plant extract identified with genus and species has its own EINECS entry. They are named with common names or the genus and species.

Annex 1 gives examples of different EINECS entries, for example, plant-derived oils, rosins, resins, plant extracts, and modified substances. Most of the EINECS entries are for spices, fruits, petroleum and plants.

2.13.3 Decisions on some EINECS entries concerning fats, oils and extracts

The CA's agreed upon the following definitions:

1. Extractives obtained from plants using water only are not listed in EINECS as such but covered by the general entry, 310-127-6. Substances extracted by a solvent consisting of water and another solvent (e.g. ethanol) are listed as individual entries using the procedures outlined under (i). above giving the Genus, species, and family name of the plant from which the extractive was obtained.

2. Extraction methods carried out at different temperatures do not result in different EINECS entries, even if the composition of the extracts is different.

3. EINECS entries do not distinguish between different procedures for processing the same type of oil (e.g. cold and hot pressing of olive oil or extracting the olives with a solvent).

4. There are no different EINECS entries for the same plant extract or oil obtained with a different yield or with a different composition (e.g. different percentage of fatty acids) because of its geographical origin.

5. Rape oil epoxides/soya bean oil epoxides. At the time when substances could be reported for EINECS, the epoxidised rape oil was not reported. It is therefore considered to be a new substance and must be notified. Epoxidised soya bean oil was reported for EINECS and is listed with the number 232-391-0. Similarly all such chemically modified plant extractives (except where the extractive is a natural polymer - for which see under (iii) above) are listed as such.

6. Linseed oil extracts. Linseed oil extracted from the species Linum usitatissimum with a mixture of water and alcohol is covered by the EINECS entry 232-278-6 (see paragraph (1) above).

ANNEX 1

Examples of EINECS entries:

1. Plant derived oils:

CAS No	EINECS No	Substance
68783-89-1	272-212-3	Soyabean oil, hydrated The complex combination consisting primarily of phosphatides, neutral oil and water obtained by hydration of soyabean oil with water, salt solutions, or dilute acids followed by recovery of precipitated gum
8002-75-3	232-316-1	Oils, palm
8021-56-5	232-420-7	Waxes, and waxy substances, palm Extractives and their physically modified derivatives. It consists primarily of the fatty acids lauric, oleic and palmitic.
8023-79-8	232-425-4	Oils, palm kernel Extractives and their physically modified derivatives. It consists primarily of the fatty acids linoleic, and oleic acid
68308-60-1	269-661-2	Oils, mixed lard, palm and tallow, mixed with soyabean oil, hydrogenated
68440-15-3	270-438-7	Fatty acids, palm oil
67784-87-6	267-057-3	Glycerides, palm oil mono- and di-, hydrogenated
61790-79-2	263-162-3	Fatty acids, palm oil, sodium salts
61789-89-7	263-097-0	Fatty acids, palm kernel-oil, sodium salts
68937-87-1	273-098-8	Fatty acids, C14- 16 palmitic acid distillate residues
68938-37-4	273-124-8	Glycerides, mixed coco, palm, palm kernel and soya, hydrogenated
68424-45-3	270-304-8	Fatty acids, linseed oil
68154-76-7	268-920-7	Fatty acids, linseed oil, sodium salt
8001-26-1	232-278-6	Linseed oil Extractives and their physically modified derivatives. It consists primarily of glycerides of the fatty acids linoleic, linolenic and oleic.
8554-56-3	271-404-4	Linseed oil, sodium salt
68649-95-6	272-038-8	Linseed oil, oxidised
8016-11-3	232-401-3	Linseed oil, epoxidised
68440-35-7	270-452-3	Glycerides, linseed oil, mono-, di- and tri-
68554-72-3	271-406-5	Soaps, stocks, linseed oil A complex combination of aqueous alkali salts of fatty acids, proteins, neutral linseed oil, phospholipids, and other minor components produced by the treatment of crude linseed oil with dilute aqueous alkali.
70983-82-3	275-094-1	Fatty acids, linseed oil, epoxidised, Me-esters

91770-17-1	294-801-4	Linseed oil, epoxidised, reaction products with tetraethylenepentamine
8002-13-9	232-299-0	Rape oil Extractives and their physically modified derivatives. It consists primarily of glycerides of the fatty acids erucic, linoleic and oleic.
68201-56-9	269-226-7	Rape oil, potassium salt
100403-30-3	309-572-9	Fatty acids, rape oil, distn. residues
91001-53-5	292-823-1	Fatty acids, C1 2-22 and C1 6-18 unsatd, Me-esters, mixed with rape oil and tallow, sulfurised
91001-54-6	292-824-4	Fatty acids, C1 2-22 and C1 6-18 unsatd, Me-esters, mixed with rape oil, sulfurised
61788-72-5	263-001-7	Fatty acids, tall oil, epoxidised, octyl ester
61789-01-3	263-024-2	Fatty acids, tall oil, epoxidised, 2-ethylhexylesters
68082-355-9	268-371-3	Fatty acids, soya, epoxidised, Me-esters
0983-82-3	275-094-1	Fatty acids, linseed oil epoxidised, Me-esters
91051-90-0	293-146-1	Fatty acids, tallow Me esters, epoxidised
93384-53-3	297-264-4	Waxes and waxy substances, orange roughy, epoxidised
97404-45-0	306-811-9	Fatty acids, rape oil, erucic acid-low, iso-Bu-esters, epoxidised
97404-46-1	306-812-4	Fatty acids, rape oil, iso-Bu-esters, epoxidised
97553-12-3	307-167-1	Fatty acids, rape oil, Bu-esters, epoxidised
97533-16-7	307-171-3	Fatty acids, rape oil, iso-octyl esters, epoxidised
97765-92-9	307-849-9	Fatty acids, rape oil, C7-9 alkyl esters, epoxidised
68554-74-5	271-407-0	Soyabean oil, deodorised distillate, sapod, extn. residue. The tocopherol residue obtained by the saponification of soybean deodoriser distillate. Containing the fraction from which the sterol hydrocarbons have been extracted.
84603-53-2	283-254-7	Butternut, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc. obtained from Juglas cinerea, Juglandaceae
84650-11-4	283-493-7	Ginseng, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc. obtained from Panax pseudo Ginseng, Arliaceae
84696-07-1	283-623-9	Cypress, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc. obtained from Cypress.

2. Rosins, Resins:

CAS No	EINECS No	Substance
8050-09-7	232-475-1	Rosin A complex combination derived from wood, especially pine wood. Composed primarily of resin acids and modified rosin acids, such as dimers and decarboxylated resin acids. Includes rosin stabilised by catalytic disproportion
8002-16-2	232-300-4	Rosin oil
68425-08-1	270-333-6	Rosin distn, overheads The low-boiling fraction obtained by the distillation of rosin. Contains decarboxylated rosin, decarboxylated resin acids, resin acids, terpenes and hydrocarbons derived from decarboxylated fatty acids
68783-82-4	272-209-7	Rosin, low-boiling fraction A complex combination obtained by the distillation of rosin.. This low boiling fraction consists primarily of decarboxylated rosin, resin acids, decarboxylated, resin acids, terpenes and hydrocarbons derived from decarboxylated fatty acids.
68477-28-1	270-718-9	Waxes and waxy substances, rosin
68512-65-2	270-986-7	Resin acids and Rosin acids, esters with ethylene glycol
8050-31-5	232-482-5	Resin acids and Rosin acids, esters with glycol
85566-49-0	287-660-5	Resin acids and Rosin acids, esters with pentaerythritol
68425-12-7	270-334-1	Calcium, resin acids and tall oil fatty acids complexes
91081-20-8	293-622-9	Resin acids and rosin acids, epoxidised
94114-23-5	302-657-1	Resin acids and rosin acids, tall oil

3. Plant extracts:

CAS No	EINECS No	Substance
94333-75-2	305-055-7	Hyacinth (plant) ext. Extractives and their physically modified derivatives such as tintures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc. obtained from Hyacinthus orientalis, Liliaceae.
97488-71-6	307-008-6	Charcoal, plant, ext.
93333-79-0	297-049-5	Ashes (residues), plant The residue from the burning of a combination of plants
9000-01-5	232-519-5	Gum arabic
9000-05-9	232-523-7	Gum benzoin Extractives and their physically modified derivatives. It is a product which may contain resin acids and their esters, terpenes and their oxidation or polymerisation products of these terpenes
9000-14-0	232-527-9	Copals Extractives and their physically modified derivatives. It is a product which may contain resin acids and their esters, terpenes and their oxidation or polymerisation products of these terpenes
9005-25-8	232-679-6	Starch High polymeric carbohydrate, material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pre-gelatised by heating in the presence of water.
9000-16-2	232-528-4	Dammar
8008-60-4	232-368-5	Opium
8050-07-5	232-474-1	Olibanum
9005-90-7	232-688-5	Turpentine Extractives and their physically modified derivatives Pinus palustris, Pinaceae

4. Modified substances:

CAS No	EINECS No	Substance
68525-85-9	271-198-6	Corn, flour, acid-modified Substances produced by heating refined corn flour in an acid medium followed by neutralisation
70084-94-5	274-308-0	Proteins, soy, enzyme-modified
100085-62-9	309-204-7	Protein hydrolysates, micro-organism Substances obtained by acidic, alkaline, or enzymatic hydrolysis of mixed micro-organisms composed primarily of amino acids, peptides, and proteins. It may contain impurities consisting chiefly of carbohydrates and lipids along with smaller quantities of miscellaneous organic substances of biological origin
68442-85-3	270-493-7	Cellulose, regenerated The product obtained by treating cellulose with caustic soda, reacting this with carbon disulphide, and extruding into an acid to form a continuous viscose tube.

2.13.4 Soya bean fatty acid derivative[39]

A question was raised concerning a substance based on soya bean fatty acid, initially considered to correspond to an EINECS entry, 281-991-9 (1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl,N-C8-22-acyl derivatives, hydroxides, inner salts). Subsequently, it was found that the soya-based product had a narrower carbon chain distribution, technically disqualifying exemption from notification. However, manufacture could incorporate a compatible material with broader chain distribution, to provide a final product similar to the EINECS entry. Addition of 5-20% tallow fatty acid into the reaction would broaden the chain length distribution to a degree, but with perceptible discrepancy in the proportions of each chain length.

An EINECS listing of the marketed substance would qualify exemption from notification, where production process would be neither relevant nor necessarily known. It was agreed that the soya bean fatty acid derivative in question was not covered by EINECS, and therefore notifiable.

2.14 NOTIFICATION OF EXTRACTS FROM GENETICALLY-MODIFIED PLANTS

A Competent Authority had received a query from a company asking whether the oil extracted from a genetically modified form of Brassica napus was covered by the EINECS entry for the extract from “natural” B. napus? Following discussion at the 3rd Technical & Scientific Meeting, it was decided at the 53rd meeting of Competent Authorities that the oil has to be notified[40]. The description in ELINCS will include the plant name and the “extra” gene. Competent Authorities agreed that it was important to distinguish between “new” plant extracts obtained from hybrids by normal agriculture techniques and those from plants in which another gene is introduced deliberately.

2.15 ROSIN/TALL OIL ROSIN

The 43rd meeting of Competent Authorities considered a request made by a company to delete one entry (Tall Oil Rosin) in EINECS on the basis that the substances covered by this entry were in fact the same as those covered by the "Rosin" entry. The consequences of the current listing are that the derivatives from these two entries, even if they are chemically the same substances, may need to be notified.

It was agreed that EINECS could not be changed and that - on a case by case basis - one notification would be sufficient for the derivative made from the two rosins if the notifier could prove, to the satisfaction of the Competent Authorities, that both substances derived from the two entries were the same. This conclusion was based on the fact that EINECS (and ELINCS) are substance-related and not process-related even if, for the purpose of EINECS, some substances were described by the process of production.[41]

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39 Technical and scientific meeting, Ispra, 14-15/3/2000, NOTIF 3/2000; 61st CA meeting, Stockholm 27 June 2001, NOTIF 45/2001

40 53rd meeting of the Competent Authorities, the Hague, 11-12/6/1997

41 43rd meeting of Competent Authorities - 14-16/12/92 - NOTIF/5/93 rev.1

2.16 PROTEIN HYDROLYSATES OBTAINED FROM OATS

At the 43rd meeting of Competent Authorities the question was raised as to the need to notify a protein hydrolysate made from oats. Although no specific mention was made in EINECS of products based on oats (or on "cereals"), it was agreed that no notification was needed for this particular protein hydrolysate since in EINECS it is covered by the general entry "Proteins, hydrolysates obtained from plants, microorganisms, animals and fish".[42]

2.17 NOTIFICATION OF A POLYGLUCURONATE

The need to notify a polyglucuronate, produced by genetically engineered bacteria, was discussed at the 44th meeting of Competent Authorities. On the basis of the information available it was agreed that notification of this substance, if not yet on EINECS, should be required, since it would have been reportable for EINECS.[43]

2.18 PETROLEUM PRODUCTS AND HYDROCARBONS IN EINECS[44]

As indicated in Section 2.2, the Commission has published several papers in scientific journals explaining the rules behind the formation and interpretation of EINECS, including the rules in relation to petroleum products. The Commission also produced a policy document in relation to petroleum products and hydrocarbons in EINECS, which is reproduced as follows:

42 43rd meeting of Competent Authorities - 14-16/12/92 - NOTIF/5/93 rev.1

43 44th meeting of Competent Authorities - 5-7/5/93 - NOTIF/18/93

44 46th meeting of Competent authorities, Brussels, 22-23 /2/1994

EINECS POLICY DOCUMENT ON PETROLEUM PRODUCTS AND HYDROCARBONS

Petroleum products submitted for EINECS were processed according to the guidelines and processing rules that were used for similar substances on TSCA. These guidelines and processing rules were developed with the joint co-operation of the American Petroleum Institute, US Environmental Protection Agency and Chemical Abstracts Service.

The TSCA guidelines for petroleum products were adopted for EINECS in agreement with the European petroleum industry, consulted through Member States Contact Points (MSCP), CEFIC and CONCAWE in 1982. Because many TSCA petroleum products were included in ECOIN and the content of ECOIN had legal value, it was agreed that the TSCA guidelines would be used. Minor changes in the interpretation of carbon and boiling ranges were made after the publication of the Provisional EINECS in agreement with the MSCP's, CONCAWE and industry in 1986.

Petroleum products are listed in EINECS with a name and definition that identifies each substance. The names and definitions are listed in accordance with CAS nomenclature, the established processing guidelines for petroleum substances, general petroleum chemistry, and literature of speciality product manufacturers.

The definitions identify:

- starting materials (stream source),

- process,

- boiling range or other appropriate physical characteristics,

- carbon (alkyl) range,

- typical chemical composition.

1. STARTING MATERIALS

The starting materials used in the petroleum refinery industry may be crude oil (petroleum) or any specific, refinery stream obtained by one or more processes.

2. REFINERY PROCESSES

The following processes and refinery streams may be used to identify substances for EINECS:

Crude oil distillation process

Hydrocracking process

Catalytic cracking process

Thermal cracking process.

Steam cracking process

Catalytic reforming process

Sweetening process

Solvent refining process

Acid treatment process

Chemically neutralising process

Clay treatment process

Hydrotreatment process

Solvent dewaxing process

Catalytic dewaxing process

Complex dewaxing process

Hydrodesulfurisation process

Special solvent process

Oxidising process

Alkylation process

Isomerisation process

Carbon-treatment process

Alumina treatment process

De-asphalting process

De-aromatising process

Hydrogenation process

Heat-soaking process

Generally, different processes used for identical starting materials result in different refinery streams and different EINECS-entries. However, for specific petroleum substance identification, it is important to consider also the other specific substance information, such as carbon range, boiling range and composition. For example, the following streams are obtained from crude oil with different processes:

EINECS Nr. 294-454-9 CAS RN 91722-55-3

Distillates (petroleum) solvent-dewaxed straight-run middle

A complex combination of hydrocarbons obtained by removal of normal paraffins from a petroleum fraction by solvent crystallisation. It consists of hydrocarbons having carbon numbers predominantly in the range of C11 through C20 and boiling in the range of approximately 205^{o}C to 345^{o}C (401 ^{o}F to 653^{o}F)

EINECS Nr. 309-695-8 CAS RN 100684-24-0

Gas oils (petroleum), straight-run, carbon-treated

A complex combination of hydrocarbons obtained by treatment of straight run petroleum gas oils with activated charcoal for the removal of traces of polar constituents and impurities. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C11 through C25

EINECS Nr. 296-468-0 CAS RN 92704-36-4

Gas oils (petroleum), straight-run, clay-treated

A complex combination of hydrocarbons resulting from treatment of a petroleum fraction with natural or modified clay in either a contact or percolation process to remove the trace amounts of polar compounds and impurities present. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C11 through C25 and boiling in the range of approximately 160^{o}C to 410^{o}C (320^{o}F to 770^{o}F)

The petroleum products listed above describe two different processes. A straight-run stream has been further processed; in one case it has been solvent dewaxed, in the second case it has been carbon-treated, in the third case it has been clay treated.

Also, a substance processed further results in a different EINECS-entry, e.g.:

EINECS Nr. 265-044-7 CAS RN 64741-44-2

Distillates (petroleum), straight-run middle

A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C11 through C20 and boiling in the range of 205^{o}C to 345^{o}C (401^{o}F to 653^{o}F).

EINECS Nr. 295-320-2 CAS RN 91995-58-3

Distillates (petroleum), straight-run middle, sulfurised

A complex combination of hydrocarbons produced by the distillation crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C11 through C20 to which elemental sulphur is added at an elevated temperature.

No distinction (different EINECS-entries) has been made in using different materials for specific processes, except the acid treatment process.

While the solvent refining process does not specify the type of solvents used (e.g. phenol, sulphur dioxide, etc.), the type of acids is specified for petroleum products obtained from the acid treatment process.

No type of catalyst is specified for the catalytic cracking process, the catalytic reforming process and the catalytic dewaxing process.

No difference has been made for the substances used for the sweetening process, e.g. sodium hypochlorite, sodium hydroxide, etc. They are not listed in EINECS for this process.

The crude oil is separated in different fractions by the crude oil distillation process and further treated by different refining processes: for example, the sweetening process is used in order to remove acidic or sulphur-containing components or to convert mercaptans. Also the hydrodesulfuration process is used to remove sulphur.

The clay treatment process, as well as the acid treatment process, is used for the removal of trace polar constituents and impurities.

Also the cracking processes are considered refining processes. For example, a distillate treated by catalytic cracking with hydrogen is carried out in order to convert organic sulphur to hydrogen sulphide, which is then removed.

A solvent dewaxing process is a solvent-deparaffination process.

3. CARBON RANGES

Petroleum substances obtained from identical starting materials through the same process (e.g. distillation but different fractions) may result in substances with different carbon ranges. For the purpose of EINECS they are considered different substances, for example:

EINECS Nr. 265-046-8 CAS RN 64741-46-4

Naphtha (petroleum), light straight-run

A complex combination of hydrocarbons produced by distillation of crude oil. It consists predominantly of aliphatic hydrocarbons having carbon numbers predominantly in the range of C4 through C10 and boiling in the range of approximately minus 20^{o}C to 180^{o}C (-4^{o}F to 356^{o}F).

EINECS Nr. 265-041-0 CAS RN 64741-41-9

Naphtha (petroleum), heavy straight-run

A complex combination of hydrocarbons produced by distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C6 through C12 and boiling in the range of approximately 65^{o}C to 230^{o}C (149^{o}F to 446^{o}F). After Provisional EINECS, it was agreed between the Commission, the MSCP's, CONCAWE and consulted industry (submitters) that narrower carbon ranges were covered by broader carbon ranges, except for very small ranges.

No new EINECS entry would have resulted in the case of a substance reported as:

Naphtha (petroleum), straight run, C6-9 fraction.

A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C6-C9 and boiling in the range of approximately 80^{o}C to 145^{o}C.

The following table specifies (idealised) carbon ranges for specific processing streams:

1. Primary petroleum fractionation - crude distillation

A. Naphtha (petroleum), straight run

1. Full-Range : C4-C11

2. Light : C4-C10

3. Heavy : C6-C12

4. Narrow ranges are merged into the above broad ranges

B. Distillates (petroleum), paraffinic

1. Light : C15-C30

2. Heavy : C20-C50

3. Narrow ranges are merged into the above broad ranges

C. Kerosine : (C9-C16)

1. Narrow ranges are merged into the above broad range

2. Catalytic reforming

A. Naphtha (petroleum), catalytic reformed

1. Full-range : C4-C12

2. Light : C5-C11

3. Heavy : C7-C12

4. Narrow ranges are merged into the above broad range

3. Dewaxin

A. Distillates (petroleum), solvent-de waxed, paraffinic

1. Light : C15-C30

2. Heavy : C20-C50

3. Narrow ranges are merged into the above broad ranges

4. Hydrocracking

A. Naphtha (petroleum), hydrocracked

1. Light : C4-C10

2. Heavy : C6-C12

3. Narrow ranges are merged into the above broad ranges

5. Hydrodesulfurisatio

A. Naphtha (petroleum), hydrodesulfurised

1. Light : C4-C11

2. Heavy : C7-C12

3. Narrow ranges are merged into the above broad ranges

B. Kerosine (petroleum), hydrodesulfurised: C9-C16

1. Narrow ranges are merged into the above broad range

6. Hydrotreating

A. Naphtha (petroleum), hydrotreated

1. Light C4-C11

2. Heavy C6-C13

3. Narrow ranges are merged into the above broad ranges

B. Distillates (petroleum), hydrotreated, naphthenic

1. Light : C15-C30

2. Heavy C20-C50

3. Narrow ranges are merged into the above broad ranges

7. Solvent refining

A. Naphtha (petroleum), solvent-refined

1. Light C5-C11

2. Heavy C7-C12

3. Narrow ranges are merged into the above broad ranges

B. Distillates (petroleum) solvent-refined, paraffinic

1. Light C15-C30

2. Heavy C20-C50

3. Narrow ranges are merged into the above broad ranges

4. BOILING RANGES AND OTHER APPROPRIATE PHYSICAL CHARACTERISTICS

The boiling ranges or viscosities, etc., are further characteristics for the specific identification of petroleum products included in EINECS, for example:

EINECS Nr. 265-04 1-0 CAS RN 64741-41-9

Naphtha (petroleum), heavy straight-run

A complex combination of hydrocarbons produced by distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C6 through C12 and boiling in the range of approximately 65°C to 230°C (149°F to 446°F)

EINECS Nr. 265-046-8 CAS RN 64741-46-4

Naphtha (petroleum), light straight-run

A complex combination of hydrocarbons produced by distillation of crude oil. It consists predominantly of aliphatic hydrocarbons having carbon numbers predominantly in the range of C4 through C10 and boiling in the range of approximately minus 20°C to 180°C (-4°F to 356°F).

As for the carbon ranges, it was agreed between the Commission, the MSCP's, CONCAWE and industry (submitters), after Provisional EINECS, that broader boiling ranges cover the narrower boiling ranges, except for very small ranges.

The following table gives some examples of carbon and boiling ranges associated with specific petroleum products:

Name	Carbon Range	Boiling Range (approx.) °C
Naphtha, full range	4-11	-20 to 220
Naphtha, light	4-10	-20 to 180
Naphtha, heavy	6-12	65 to 230
Kerosine	9-16	150 to 290
Middle distillate	11-20	205 to 345
Gas oil	11-15	205 to 400
Residuum	>20	>350
Vacuum condensate	11-25	205 to 400
Paraffinic distillate, light	15-30	*
Paraffinic distillate,.heavy	20-50	*
Naphthenic distillate, light	15-30	*
Naphthenic distillate,heavy	20-50	*
Vacuum gas oil, light	13-30	230 to 450
Vacuum gas oil, heavy	20-50	350 to 600
Vacuum residuum	>34	>495

***** Paraffinic distillate is saturated aliphatic, while Naphthenic distillate contains very little normal paraffins. The distinction is also based on viscosity (over or under 100 SUS or 19cST at 40°C).

More importance was given to the carbon range than the boiling range in order to associate a submitted petroleum substance for EINECS with an already existing CAS Registry Number.

5. TYPICAL CHEMICAL COMPOSITION

Petroleum (crude oil) consists predominantly of hydrocarbons in almost all their chemical variations: they are present in chain and ring form, in different chain lengths, and in various ring and chain combinations.

These complex combinations of hydrocarbons are separated, converted and recovered through the refinery processes to obtain refinery feed stocks and streams.

Therefore, specific refinery streams have their specific chemical composition as carbon ranges, and the predominant hydrocarbon type.

This typical chemical composition is listed in the definition of the EINECS petroleum products.

For example, it is specified for many refinery streams that "they consist predominantly of branched-chain saturated hydrocarbons", or "they consist predominantly of paraffinic and cyclic compounds". If the substance contained more than 5% wt. of 4-6 membered condensed ring aromatic hydrocarbons, then this information was included in the definition.

The composition listed for the petroleum products is a typical composition, which means that the compounds listed is only a representative list of the type of compounds that may he present.

6. NAMES

The names of the petroleum products listed in EINECS specify the type of substances as well as the composition (e.g. "Light naphtha", "Kerosine", "Gas oil", "Middle distillate") and any appropriate modifications (e.g. "full range", "C4-rich", C5-unsatd. fractions) and reflects the process stream (e.g. "steam cracked", "straight-run", "dewaxed").

Examples:

EINECS Nr. 295-434-2 CAS RN 92045-53-9

Naphtha (petroleum), hydrodesulfurised light, de-aromatised

A complex combination of hydrocarbons obtained by distillation of hydrodesulfurised and de-aromatised light petroleum fractions. It consists predominantly of C7 paraffins and cycloparaffins boiling in a range of approximately 90^{o}C to 100^{o}C (194^{o}F to 212^{o}F).

EINECS Nr. 295-315-5 CAS RN 91995-53-8

Distillates (petroleum), naphtha steam cracking-derived, solvent-refined light hydrotreated

A complex combination of hydrocarbons obtained as the raffinates from a solvent extraction process of hydrotreated light distillate from steam-cracked naphtha.

Specifically defined petroleum streams which were further processed have been named after the type of processing. If the process was a separation procedure (e.g. distillation), the petroleum stream was named as "Distillates, ...", although the distillation process was the last process. If the post-treatment was a chemically-modifying procedure, the petroleum stream was named after the unmodified fraction with the chemical modification at the end of the name.

There are petroleum products listed in EINECS with only a generic name without petroleum origin and stream, e.g.:

EINECS Nr. 295-421-1 CAS RN 92045-40-0

Lubricating oils, used, distd.

A complex combination of hydrocarbons obtained by distillation of used lubricating oils. It boils in the range of approximately 80°C to 365°C (175°F to 689°F).

These substances were described on the EINECS reporting forms with only a generic name. They were accepted if the process description and the composition agreed with the generic name. Such substances are for example:

Absorption oils (syn. wash oils)

Fuel gases

Fuel oils

Gasoline

Hydraulic oils

Lubricating oils

Naphthenic acids

Naphthenic oils

Paraffinic oils

Wastes

Waste solids

7. CONCLUSIONS

Petroleum substances were determined to be unique based on their chemical composition, the boiling range, and the refinery stream or process; different CAS Registry Numbers were assigned to each substance that was determined to be unique. For determining the unique character of a substance the chemical composition (carbon range) was considered to be more important than the boiling range.

HYDROCARBONS

1) Hydrocarbon streams:

Hydrocarbon substances have often been submitted for EINECS without specification of petroleum origin, but with a stream origin (e.g. "steam cracked"). These substances are named in EINECS hydrocarbons with the chemical composition and the process. Mostly they are listed with a definition, e.g.:

CAS RN 702110-14-5

Hydrocarbons C3-6 C5-rich, steam-cracked naphtha

A complex combination of hydrocarbons obtained by distillation of steam-cracked naphtha. It consists predominantly of hydrocarbons having carbon numbers in the range of C3 through C6, predominantly C5.

2) Complex hydrocarbon reaction mixtures:

Complex hydrocarbon-containing reaction mixtures submitted for EINECS with a process description and/or name, which specified the chemical composition of the mixture including a

carbon ring and/or the starting materials, are listed in EINECS with names based on the composition or the reaction product:

a) Specific hydrocarbons, linear; branched; branched and linear, e.g.:

CAS RN 110-54-3 Hexane

CAS RN 92112-69-1 Hexane, branched and linear

CAS RN 92112-69-1 represents a substance which was reported as a complex mixture of n-hexane and hexane isomers.

b) Specific hydrocarbons with a specific carbon range which include all members of the mixture without being broader, e.g.:

CAS RN 93762-78-8 Alkenes, C12-14

CAS RN 93821-12-6 Alkenes, C 10-14, branched and linear, C12-rich

CAS RN 68920-70-7 Alkanes, C6-18,chloro

These type of substances have been reported for EINECS as a complex mixture of one class of hydrocarbons, e.g. all alkanes, all alkenes, all alkynes, and aromatic hydrocarbons with a defined carbon range.

c) Complex mixtures of more than one class of hydrocarbons (e.g. alkanes and alkenes; alkenes and alkynes; aliphatic and aromatic), e.g.

CAS RN 68606-28-0

Hydrocarbons, C5 and C10-aliph and C6-8-arom

A complex combination of hydrocarbons produced by the thermal cracking of ethane and propane. It contains predominantly cyclic hydrocarbons having carbon numbers predominantly in the range of C5 through C10 primarily benzene, cyclopentadiene, dicyclopentadiene, toluene, and xylenes.

CAS RN 68606-26-8 Hydrocarbons, C3

CAS RN 93924-43-7 Hydrocarbons, C11

d) Hydrocarbon oils

Mineral oils containing aliphatic and/or aromatic hydrocarbons are named in EINECS as hydrocarbon oils with any chemical modification. They are listed with a definition which identifies generally the process, the starting materials and the typical chemical composition, and often the boiling range, e.g.:

CAS RN 100801-64-7

Hydrocarbon oils, arom, mixed with polyethylene and polypropylene, pyrolysed, middle oil fraction.

The oil obtained from the heat treatment of a polyethylene/polypropylene mixture with aromatic oils. It consists predominantly of naphthalene and its homologues, 1,3 diphenylpropane and other polynuclear aromatic hydrocarbons boiling in a range of approximately 200^{o}C to 400^{o}C (392^{o}F to 752^{o}F). Substances reported for EINECS which

listed their compositions as "hydrocarbon oils" or "petrolatum" or "mineral oil" and for which the word “ petroleum" was not specified, are named in EINECS as "hydrocarbon oils".

e) Hydrocarbon streams which are the by-product of a specified reaction, e.g.:

CAS RN 93763-36-1

Hydrocarbons, C5-7, C6-rich, heat-soaked, steam-cracked ethylene-manufacturing by-product

The names of these types of substances specify that the hydrocarbons are obtained by specific processes as a by-product of a specific manufacturing process. In addition the composition of the hydrocarbons is indicated. For example, the substance listed above with CAS RN 93763-36-1 represents a substance produced by the fractionation of products of a cracking process in the ethylene plant after recovery from a heat soaking process. This type of substance is often listed with a definition in EINECS.

f) Specific substances, described as being chemically modified to produce a reaction mixture which is then further separated into cuts, e.g.

CAS RN 68515-29-7

Benzene, di-C10-14-alkyl derivs., fractionation overheads, middle cut

The overhead middle cut from fractionation boiling in a range of approximately 446^{o}C to 482^{o}C (835^{o}F to 900^{o}F).

g) Hydrocarbons obtained by hydroformylation. The post-treated hydrocarbons are listed without definition, e.g.

CAS RN 68989-33-3

Alkenes, C2-3, hydroformylation products

The complex combination of hydrocarbons obtained by the hydroformylation of ethylene and propylene. Contains alcohols, esters, ethers, acetals, ketones, aldehydes and hydrocarbons.

CAS RN 68890-87-9

Alkenes, C2-3, hydroformylation products, hydrolysed

(Although this type of hydrocarbons is not obtained from a petroleum refinery process, it is listed here for consistency).

<u>Definitions for Hydrocarbons</u>

Hydrocarbons Content

Alkanes aliphatic hydrocarbons, straight or branched carbon chain; also included, cycloalkanes

Alkenes unsaturated aliphatic hydrocarbons, straight or branched carbon chains; contain one or more double bonds; also included, cycloalkenes

Alkynes unsaturated aliphatic hydrocarbons, straight or branched carbon chains; contain one or more triple bonds; also included, cycloalkynes

Aromatic hydrocarbons	conjugated, unsaturated cyclic hydrocarbons containing one or more rings; often contains fused ring systems (typified by benzene, naphthalene and anthracene)
Hydrocarbon oils	mineral oil containing aliphatic and/or aromatic hydrocarbons
Hydrocarbons	contains members from two or more of the above classes of hydrocarbons
Paraffin waxes and Hydrocarbon waxes	long-chain aliphatic hydrocarbons of non-specified or mixed saturation

2.19 REACTION OF SUBSTANCES VERSUS PROCESSING OF PETROLEUM STREAMS[45]

A query was raised posing equivocal interpretation between reaction of chemical substances versus processing of petroleum streams. Production of the substance in question is initiated by catalytic polymerisation of feedstock alkenes. Subsequent stream processing results in a final product mixture of C11 – C15 alkane isomers. The product also contains ~20% naphthenes. A proposed change of polymerisation catalyst (replacing disposal by regeneration) would result in an increase of final naphthene content to 25-30%. Noteworthy is that while the original product comprised carbon chain lengths within C11-C15, catalyst replacement resulted in a product comprising only C11 and C15, including 18% as cyclic.

In this case, it was considered that the feedstock components undergo chemical reaction rather than stream processing, and that the final product is not a mixture of polymers due to absence of molecular weight distribution. It was agreed that the alternative product should be treated as a new substance, as defined by the Directive, and would be notifiable.

45 Technical and scientific meeting, Ispra, 14-15/3/2000, NOTIF 3/2000; 61st CA meeting, Stockholm 27 June 2001, NOTIF 45/2001

3 ELINCS (EUROPEAN LIST OF NOTIFIED CHEMICALS SUBSTANCES)

3.1 ESTABLISHMENT AND PUBLICATION OF ELINCS

The basis for the establishment of ELINCS, the European List of Notified Chemical Substances was Article 21 of Council Directive 79/831/EEC. In addition to Article 21 the following Commission Decisions and Communications are relevant to ELINCS:

1. Commission Decision 85/71/EEC on 21 December 1984, concerning the list of substances notified pursuant to Council Directive 67/548/EEC. OJ No L 30, 2.2.1985, p. 33.
2. Commission Communication - 4th publication of ELINCS. OJ No C 361, 17.12.1994, p. 1.

Commission Decision 85/71/EEC laid down the procedure for the preparation of the ELINCS list. In addition it was decided that the list will include the notification number and the EC number for each substance; where a substance has been the subject of several notifications the number of each notification will be given.[46] In the event that a substance has been notified on several occasions and the Competent Authorities concerned have divergent views, the publication in ELINCS will be in the form assuring greatest confidentiality.[47]

All trade names under which the substance is marketed in the Community should appear in ELINCS. In those cases where a Colour Index name is given, this should not be translated. While Member States agreed to verify the IUPAC names to the extent that their expertise allowed, it was considered that the final responsibility for control rested with the Commission.[48]

Only the main component, or in the case of a reaction mixture, the major components should appear in ELINCS. [49]

3.2 PROPOSAL FROM THE COMMISSION FOR THE PUBLICATION OF ELINCS[50]

This proposal, NOTIF/20/89, follows below. The categories defined in point A of the document were accepted. As regards point C of the document, the criteria decided upon were:

Criteria (i): > 50% and $\geq$ 2/1 and criteria (ii) = 3/1. This latter criterion might be modified in the light of practical experience.

Trade names:

A formal update will be requested of the notifier whenever it is envisaged to change the trade name of the substance.

Confidentiality of the trade name of the substance:

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46 28th meeting of Competent Authorities - 15-16/3/89 - NOTIF/10/89

47 28th meeting of Competent Authorities - 15-16/3/89 - NOTIF/10/89

48 29th meeting of Competent Authorities - 16-16/5/89 - NOTIF/16/89 rev 1

49 29th meeting of Competent Authorities - 16-16/5/89 - NOTIF/16/89 rev 1

50 31st meeting of Competent Authorities - 4-5/12/89 - NOTIF/20/89

In the case of dangerous substances the length of time for which the notifier may claim confidentiality for the chemical name may only extend until such time as the substance is introduced into Annex 1. For non-dangerous substances on the other hand justification must be provided by the notifier; there are however divergent approaches among the competent authorities as to how to evaluate those justifications. In any event the decision concerning the granting of confidentiality rests with the authority receiving the notification; this responsibility is clearly indicated in the Directive. The final decision on the question of confidentiality, once taken by the authority, should be communicated to the Commission.

It was also agreed to limit to three years the period for which the chemical name will be regarded as confidential for non-dangerous substances for which the notifier has either not responded to an enquiry from the competent authority or has responded in an equivocal manner.

As to the desirability or otherwise of listing all notifications for a substance manufactured or imported by different companies which may not be aware of each other, when at least one of the notifiers has claimed confidentiality of the chemical name of its substance, the ELINCS decision (85/77/EEC) foresees the publication of a list with entries by substance, not by notification. The Commission and the Member States are obliged to respect this decision. This was also the advice of DG XI's legal service circulated at the 33rd meeting of Competent Authorities.[51]

51 33rd meeting of Competent Authorities 24-25/4/90 - NOTIF/17/90)

PROPOSAL FROM THE COMMISSION FOR THE PUBLICATION OF ELINCS

a) Trade Name

In accordance with the decision taken at the Madrid meeting[52] all the trade names relating to a substance which appears in the files will be listed in ELINCS.

In cases where no trade name has been proposed for a substance In the file, the Competent Authority head of file must request the missing Information from the notifier. If the latter does not provide any trade name, the substance will be identified by the IUPAC name, in accordance with Decision 85/7/EEC of the Commission.

b) IUPAC Name

The procedure adopted at the Madrid meeting will be applied.

c) Multiple notifications

There are several possibilities, depending on the producer's situation (within or outside of the EEC), the number of producers and/or notifiers (one or several) and whether they know each other or not.

In taking account of the legal basis for the publication of ELINCS (Decision 85/71/EEC), the objective of the publication and the possible confidentiality of certain data (e.g. IUPAC name), the Commission proposes that the following rule should be followed for the publication of the list of the notified substances.

publication on basis of the notified substances, that is to say a single entry per substance;

the list ought to contain as much information as possible (openness), without prejudice to Point 4 of the Appendix to Decision 85/71/EEC (possible confidentiality of the IUPAC name at the request of the notifier and in accordance with the decision of the CA);

application of the principle of maximum confidentiality. When one of the competent authorities claims confidentiality for the IUPAC name for a substance, the substance will be listed in ELINCS under the trade names only, even if the other competent authorities have not claimed confidentiality for the IUPAC name.

d) Substances which are no longer marketed

Substances which are no longer marketed or which have never been marketed will be included in the list, in accordance with Decision 85/71/EEC (list of the notified substances).

e) Substances/impurities

A. Notified substances can be classified into 4 categories in accordance with their composition:

52 29th meeting of Competent Authorities - 16-17/5/89

Substances which are a complex mixture of constituents which are not completely defined or the proportions of which are not known, the result of a complex reaction process. Mixtures of isomers in unknown proportions will also form part of this category.

Substances containing a single principal "functional" constituent, impurities and/or additives.

Substances containing several "functional" constituents, one of which is preponderant and the others present in a relatively small quantity, impurities and/or additives.

Substances containing several "functional" constituents present in similar quantities, impurities and/or additives.

B. The entry in ELINCS for these different types of substances should present as follows in cases where confidentiality of the IUPAC name is not requested or cannot be claimed.

Category 1.

It is not possible to allocate a precise IUPAC name for these substances. The latter will be defined as well as they can be, taking account of the rules set out for EINECS.

For example: files 87-02-0018, 86-06 0040, 88-04-0098

About fifteen similar cases have been identified by the Commission to date.

Category 2.

These substances will be entered in accordance with the IUPAC name for the principal "functional" constituent, whatever the percentage of the latter in the "mixture".

For example: file 87-06-0067.

Category 3.

Only the IUPAC name of the preponderant "functional" constituent will be mentioned.

For example: files 87-05-0031 and 89-01-0094.

Category 4.

The substance will be presented as a mixture of the different "functional" constituents indicated under their respective IUPAC names. The constituents present in (very) small quantities should not be listed.

For example: files 87-06-0079 and 83-01-0003.

C. Distinction between categories

It is up to the notifier, under the control of the CA, to specify, from among the constituents in the notified substance, those which are considered as "functional" constituents (which will be taken up in Point 1.1.1. of the notification summary) and those considered as impurities (listed in Points 1.3.2 and 1.3.3).

Locating the substances in Categories 1 and 2 does not raise any problem.

It is proposed that the following criteria be used to differentiate between substances belonging to Category 3 and those in Category 4:

a) ratio between the percentage of the two most important "functional" constituents. (if a range is mentioned, then the mean is taken into consideration);

b) relative percentage of the most important constituent with reference to the sum of the "functional" constituents (thus ruling out Impurities and any additives).

Tables 1 and 2 show, for different types of theoretical mixtures and as a function of the criteria adopted, those which will be considered as substances with 1 preponderant "functional" constituent (Category 3) and those which will be considered as a mixture of "functional" constituents (Category 4). Table 3 gives the number of dossiers in each category (3 and 4) for 32 files examined, as a function of the criteria adopted, as well as a few examples.

Proposal:

A ratio of 2/1 and a minimum percentage of 50% appear to be adequate.

D. Limitation of the number of constituents listed (for Category 4)

For the substances in Category 4, which will be listed as a mixture of several constituents, it seems advisable to limit the number of constituents cited by applying a new criterion.

Criteria

a) Either by fixing a minimum percentage (relative or absolute);

b) Or by citing the constituents until a minimum cumulated percentage is obtained (70 or 80 % for example);

c) Or, for example, by considering the ratio between the 1st constituent in order of importance and the 3rd, then the 4th, etc.

Proposal:

The 3/1 ratio could be considered adequate in this case. (In the cases observed, this limits the number of constituents cited to 3 in practically every case).

E. The procedure could be simplified as follows:

Procedure **Publication in ELINCS**

IUPAC name ⟶ YES ⟶ as it is, EINECS rules

cannot be defined precisely (complex mixture)

NO

One single clearly defined ⟶ YES ⟶ IUPAC name

"functional" constituent

NO

Calculation of the relative %

of the different "functional" constituents

Application of the criteria (I)

Mixture → NO → IUPAC name of the principal constituent

YES

Application of the criteria (11) → mixture of several IUPAC names

It should be remembered that whatever way the IUPAC name is published, the substance notified will remain the one as it is described in full in the files, the number(s) of which appear opposite the substance (and not solely the constituents cited in ELINCS).

Table 1 **Theoretical mixtures. Distribution between Category 3 (1C= 1 principal constituent) and Category 4 (M = mixture) for substances with 2 principal constituents**.

Type of mixture	Criteria					
	≥ 3/1 ≥ 50% (1)	≥ 2/1 ≥ 50% (2)	≥ 2/1 > 50% (3)	> 2/1 > 50% (4)	≥ 1.8/1 ≥ 50% (5)	≥ 1 5/1 ≥ 50% (6)
75/25	1C	1C	1C	1C	1C	1C
70/30	M	1C	1C	1C	1C	1C
66.6/33.3	M	1C	1C	M	1C	1C
65/35	M	M	M	M	1C	1C
60/40	M	M	M	M	M	1C
55/45	M	M	M	M	M	M
50/50	M	M	M	M	M	M

Table 2 Theoretical mixtures. Distribution between Category 3 and category 4 for substances with 2 principal constituents.

Type of mixture	Criteria					
	> 3/1 > 50% (1)	> 2/1 > 50% (2)	> 2/1 > 50% (3)	> 2/1 > 50% (4)	> 1.8/1 > 50% (5)	> 1.5/1 > 50% (6)
75/20/5	1C	1C	1C	1C	1C	1C
70/15/15	1C	1C	1C	1C	1C	1C
70/20/10	1C	1C	1C	1C	1C	1C
70/25/5	M	1C	1C	1C	1C	1C
65/30/5	M	1C	1C	1C	1C	1C
60/20/20	1C	1C	1C	1C	1C	1C
60/25/15	M	1C	1C	1C	1C	1C
60/30/10	M	1C	1C	M	1C	1C
60/35/5	M	M	M	M	M	1C
55/25/20	M	1C	1C	1C	1C	1C
55/30/15	M	M	M	M	1C	1C
55/35/10	M	M	M	M	M	1C
55/40/5	M	M	M	M	M	M
50/25/25	M	1C	M	M	1C	1C
50/30/20	M	M	M	M	M	1C
50/35/15	M	M	M	M	M	M
50/40/10	M	M	M	M	M	M
50/45/5	M	M	M	M	M	M

Note difference between columns (2) and (3): 50/25/25 mixture (type 2:1:1) which is or is not considered as a mixture.

Table 3

A) Distribution of substances in accordance with Categories 3 and 4 (32 files)

Criteria			Category 3 (1 principal constituent)	Category 4 (mixture)
≥ 3/1	and	≥ 60%	8	24
≥ 3/1	and	≥ 50%	8	24
≥ 2/1	and	≥ 60%	12	20
≥ 2/1	and	≥ 50%	18	14
≥ 2/1	and	> 50%	16	16
> 2/1	and	> 50%	14	18
≥ 1.8/1	and	≥ 50%	20	12
≥ 1.5/1	and	≥ 50%	20	12

B) Some concrete examples (1 = Impurities; A = Additive, according to the file)

Absolute % of the constituents	Relative % of the constituents (without impurities or constituents)	≥ 2/1 ≥ 60%	≥ 2/1 ≥ 50%	≥ 2/1 > 50%	> 2/1 > 50%	≥ 1.8/1 ≥ 50%
18-25	50	M	1C	M	M	1C
9-12,5	25					
9-12,5	25					
40-62 (1)						
10 (1)						
47,5	50	M	M	M	M	M
47,5	50					
2,5 (1)						
2,5 (1)						
25,5	30 +/- 10	M	M	M	M	M
25,5	30 +/- 10					
17,0	20 +/- 10					
12,7	15 +/- 5					
4,2	5 +/-5					
10 (1)						
5 (1)						
0,025 (1)						
40,6-38,2 30,5-28,7 13,5-12,7	48 36	M	M	M	M	M
5-10 (1)	16					
0,32 (l)						
10 (A)						
73,2-61,0	78-65 (71,5)	1C	1C	1C	1C	1C
20,6-32,8	22-35 (28,5)					
6 (1)						
0,1 (1)						
0, 1 (A)						
39,5	50	M	1C	M	M	1C
19,75	25					
19,75	25					
17 (1)						
1 (1)						
2 (1)						
1 (1)						
55,5-74	60-80 (70)	1C	1C	1C	1C	1C
18,5-37	20-40 (30)					
2 (1)						
2 (1)						
0,5 (1)						

Absolute % of the constituents	Relative % of the constituents (without impurities or constituents)	≥ 2/1 ≥ 60%	≥ 2/1 ≥ 50%	≥ 2/1 > 50%	> 2/1 > 50%	≥ 1.8/1 ≥ 50%
3 (1)						
35	66,6	1C	1C	1C	M	1C
17,5	33.3					
2,5 (1)						
2,5 (1)						
2 (1)						
25 (A)						
16 (A)						
33,7-35	52-54	M	M	M	M	1C
< 18,8	< 29					
< 14,9	< 23					
7,8-13,6	12-21					
< 0,6	< 1					
0-2	0-3					
20-25 (1)						
10-15 (1)						
0,1-0,30 (I)						
59,9	65	M	M	M	M	1C
32,3	35					
4,4 (1)						
1,75 (1)						
1,7 (1)						

3.3 ELINCS RULES – IDENTIFICATION OF MIXTURES

Intentional mixtures made by mixing or blending with other substances were neither reportable for EINECS nor are covered by Directive 92/32/EEC. Mixtures listed in EINECS or notified as new substances are reaction products not being separated into individual components, including additives to preserve the stability of the product and any impurity deriving from the production process used. These mixtures are placed on the market as such, e.g. mixed isomers and plant extracts.

The rules for listing these mixtures are different in EINECS and ELINCS:

In EINECS only the main component is listed, if the substance consists of at least 80% of this component. Otherwise, several components are listed.

Up to now, in ELINCS mixtures consisting of less than 80% of the main component are listed only by the main component under certain conditions, in some cases even if the main component is less than 50% (see Annex).

These different rules lead to inconsistencies: e.g. a mixture of 70% of an existing substance and 30% of a new substance has to be notified as it is not covered by the corresponding EINECS entry. However the mixture is not listed in ELINCS under the existing rules for reporting for ELINCS, as it would be described as an (existing) mono-substance.

To solve these inconsistencies the participants of the 3rd Technical & Scientific Meeting recommended a change in the ELINCS rules. The 53rd CA meeting[53] agreed that the new ELINCS rules should follow EINECS, as follows:

A notified substance listed as a (mono-) substance must contain at least 80% of this component. If not, it is a mixture and several components have to be listed in ELINCS. These rules are foreseen to come into force with the 5th ELINCS publication. This change in the ELINCS rules will not affect any notification requirements.

3.4 NOTIFICATION BY IMPORTERS/SOLE REPRESENTATIVES[54]

All notifications must remain on ELINCS, even if superseded by a sole representative notification; the "original" notification should be able to be "reactivated" if the importer responsible recommences placing the substances on the market independently of the sole representative.

53 53rd meeting of Competent Authorities, the Hague, 11-12/6/1997
54 50th meeting of Competent Authorities, Madrid, 22-23/11/1995. NOTIF/13/95 rev.1

4 COMPETENT AUTHORITIES

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4.2 COMPETENT AUTHORITIES MEETINGS[55]

4.2.1 Papers

At the 49th meeting of CAs it was agreed that:

- issues should normally not be placed on the agenda for a CA meeting unless they are presented in a paper prepared by the body responsible for raising the issue (i.e. DG XI, ECB, CAs) and clearly stating:
    - the issue raised in the paper;
    - the background to the issue (e.g. why has it been raised now, has the issue been considered previously);
    - the relevant views of CAs, ECB and DG XI (if known); and
    - proposals for dealing with the issue.
        - The exception to the above rule should be when an urgent and important issue has arisen that needs to be addressed immediately. Even in this case the body raising the issue (e.g. DG XI, ECB, a CA) should present to the meeting all available relevant information;
        - All papers should be sent to DG XI who will circulate them to all CAs with a deadline for comments (usually four to six weeks from the date of circulation). Comments should be sent directly to the author of the paper and copied to DG XI. DG XI and ECB will comment as necessary (i.e. on policy and technical/scientific points respectively);
        - If information is required from other CAs, ECB and DG XI before a paper can be prepared the request for information should be made through DG XI. DG XI will circulate the request to all CAs and ECB with a reasonable deadline for responses. Responses should be made to the author of the request and copied to DG XI;
        - Papers should not be tabled without prior consultation with, and the agreement of DG XI. This agreement will not normally be given unless DG XI has received at least 24 hours notice. This is to avoid papers being "tabled on the day" as this can be confusing to the organisers and CAs;

This procedures, to be reviewed in the light of experience, would have to be used flexibly but should be adhered to as far as possible and form the basis for the consideration by CAs.

4.2.2 Meetings[56]

It was agreed that there should be each year at least two (preferably three) CA meetings, all of two days duration. If necessary, new substances CA meetings could be held 'back to back' with existing substances meetings. This was, however, difficult for some CA representatives as they would have to prepare for and attend two meetings with no break in between.

Greater emphasis should be placed on resolving issues by written procedure and discussions in CA meetings should concentrate on written comments.

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55 49th meeting of Competent Authorities, Brussels, 30-31/3/95, NOTIF/7/95

56 50th meeting of Competent Authorities, Madrid, 22-23/11/1995

4.3 TECHNICAL AND SCIENTIFIC MEETINGS[57]

The meetings in Ispra have to consider only technical and scientific issues associated with the notification of new substances. The CAs are however ultimately responsible for all decisions taken on the implementatives of Directive 67/548/EEC. It is agreed the CAs should be asked to endorse the decisions recorded in summary records of " Technical and Scientific Meetings" as the decisions of the CAs.

Care needs to be taken to ensure the agendas dealt with appropriate issues and that, wherever possible, issues were only discussed in one forum; flexibility would however be required e.g. when urgent issues needed to be addressed.

It was agreed that there should be two technical and scientific meetings per year, all of two days duration.

57 50th meeting of Competent Authorities, Madrid, 22-23/11/1995

5 APPLICABILITY OF THE DIRECTIVE

5.1 APPLICABILITY OF THE DIRECTIVE AS REGARDS THE OBLIGATION TO NOTIFY

Articles 7(1), 1(2), 8(1), 13 and 16 of the 7th Amendment, Directive 92/32/EEC, define which substances must be notified within the meaning of Article 7(1). In general new chemical substances must be notified. The concept of "new substance" is twofold: a substance is new:

- if it is not in EINECS, and

if it is placed on the market for the first time by a given manufacturer or importer (Article 7(1))

Various substances are excluded from the scope of the Directive (Article 1(2)); the Directive grants various degrees of exemption for other substances (Article 1(2); Article 8(1)). In the case of some of these provisions there is no problem, e.g. as regards radioactive substances and wastes covered by Directives 75/442/EEC and 78/319/EEC; on the other hand in other cases a detailed examination of the situation has been necessary. These special cases are explained below in 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9 and 5.10.

5.2 MEDICINAL PRODUCTS

5.2.1 Substances incorporated into pharmaceutical products

Article 1(2)(a) of Directive 92/32/EEC specifies that the Directive shall not apply to medicinal products in the finished state, intended for the final user. [Medicinal products are defined in Directive 65/65/EEC, amended as Directive 87/21/EEC]. Article 13(1) of Directive 92/32/EEC exempts from notification active ingredients used exclusively in the medicinal products referred to in Article 1(2)(a).

New substances (not listed in EINECS) which are placed on the market as inactive ingredients of pharmaceutical products (e.g., additives such as 'excipients' and 'solubilisers') require notification according to Directive 92/32/EEC. This applies equally to substances supplied, either separately for formulation, or previously incorporated, into medicinal products.[58]

5.2.2 Intermediates in the synthesis of substances for incorporation in medicinal products[59]

As indicated in Section 5.2.1, Article 1(2) of Directive 92/32/EEC stipulates that the Directive does not apply to medicinal products in the finished state, destined for the final user.

It therefore follows that pharmaceutical products in general, along with their ingredients and additives, are exempt from the notification obligation imposed by Articles 7 and 8 of the

58 63rd meeting of Competent Authorities, 17/06/02, NOTIF/5/2002

59 "Communication of the Commission's Services on the interpretation of Article 1 (2) (c) of Directive 79/831/EEC (doc. XI/126/83 dated 24 February 1983). Note that the Commission's Services opinion is by no means final. The Court of Justice is the only authority empowered to interpret Community legislation.

Directive, as long as the substances are used exclusively for medicinal products. The question of whether intermediates used in the pharmaceutical industry are also exempt from this obligation has however been raised on a number of occasions. Intermediates are base substances and reagents converted in the course of synthesis and, therefore, not present in the final product·

The reason for the derogation made by Article 1(2) is because the substances concerned are already covered by special national, Community and international regulations. Pharmaceutical substances in particular have been exempted because they are subject to more rigorous controls than contemplated in the Directive.

Since the same does not apply to intermediates, the Commission feels these substances must be notified.

5.3 ARTICLE 1(2): FOODSTUFFS OR FEEDINGSTUFFS – FOOD ADDITIVES AND ANIMAL FEED ADDITIVES[60]

(Communication of the Commission's Services on the interpretation of Article 1(2)(d) and 1(2)(e) of Directive 92/32/EEC, Article 1(2)(c) of Directive 79/831/EEC)

During meetings of the Competent Authorities of the Member States responsible for the application of Directive 79/831/EEC, some discussion took place on the interpretation of the phrase "foodstuffs or feedingstuffs" which occurs in article 1(2)(c). Specifically, there is a question whether additives are included in this term. Article 1.2 of Directive 92/32/EEC stipulates that the Directive does not apply to foodstuffs or animal feedingstuffs. In the view of the Commission's Services, the phrase "foodstuffs or animal feedingstuffs" must be interpreted as including food additives and animal feed additives.

Within the structure of the Directive as it stands, this interpretation seems correct, despite the apparent ambiguity. Article 1(2) states that the Directive does not apply to certain substances. The definition of "substances" includes "any additives required for the purpose placing them (i.e. the substances) on the market". The term "foodstuffs and animal feedingstuffs" includes, therefore, reference to their additives.

It is important to note the practical effect of this interpretation. The substances referred to in Article 1(2) remain outside the scope of the exclusive Community competence established by this Directive; in particular, they do not benefit from the guarantee of free circulation provided by Article 30. The Directive does not, therefore, affect the possibility for the Member States to regulate these substances as they wish. They remain of course bound by Articles 30 and following of the Treaty as well as by specific Directives[61]

It should be noted that this interpretation applies only to substances used exclusively as food additives or as animal feed additives.

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60 Extract from "Communication of the Commission's Services on the interpretation of Article 1 (2) (c) of Directive 79/831/EEC (doc. XI/126/83 dated 24 /02/1983).

61 At present, the following directives (and their amendments) apply to food additives: Directive of 11/11/1962, Directive 64/54/EEC, Directive 70357/EEC, Directive 74/329/EEC. Other Directives are in preparation. For additives for feedingstuffs, there exists the Directive 70/524/EEC.

It was agreed at the 46th meeting of Competent Authorities that the new salts L-carnitine L-tartrate and L-carnitine magnesium citrate could be regarded as food additives and should not be considered as notifiable[62].

5.4 COSMETICS

Article 1(2) of Directive 92/32/EEC indicates that the Directive does not apply to substances or preparations for which Community notification or approval procedures exist and for which requirements are equivalent to those laid down in the Directive.

Directive 76/768/EEC relating to cosmetic products, as last amended by Directive 86/199/EEC, cannot be considered equivalent to Directive 92/32/EEC. Consequently, substances intended for use in a cosmetic fall within the scope of Directive 92/32/EEC and must therefore be notified, except if they are exclusively put on the market as cosmetic products in their final form, intended for the final user (according to Directive 92/32/EEC, Article 1).

The notification of cosmetic ingredients was also discussed at the 43rd meeting of Competent Authorities. On that occasion it was confirmed that ingredients used in cosmetics placed on the market and sold as the substance or as preparations (excluding cosmetic products in the final form, intended for the final user) would fall within the scope of the 7th Amendment as they did fall within the scope of the 6th.[63].

5.5 AROMATIC SUBSTANCES[64]

The Liaison Bureau of the European (EEC) Associations of the Flavour Industry requested that the requirements set out in Annex VII could be relaxed for aromatic products.

The Competent Authorities took the view that they could do nothing which was contrary to the aims of the Directive. Instead the flexibility allowed by the preamble to Annex VII would have to suffice. No particular application could warrant exemption from the obligations laid down in the Directive.

5.6 POLYMERS

5.6.1 Single substance definition for new polymers[65]

Article 2 (Definitions) (Directive 92/32/EEC) specifies meaning of “substances” and “polymer”. In conformity with the definitions, a polymer is characterised by molecular weight distribution coupled to variation of monomer content. A (co)polymer substance is defined by number average molecular weight (Mn) and composition, corresponding to similar blends of monomers. The definition allows for limited Mn and composition variations, either imposed by deliberate alterations to process conditions (e.g., temperature, pressure) or occurring by random fluctuations among production batches.

62 46th meeting of Competent Authorities, Brussels 22-23/2/1994

63 43rd meeting of Competent Authorities, London, 14-16/12/1992 - NOTIF/5/93 rev. 1

64 8th meeting of Competent Authorities, 6/10/1983 - Doc. XI/660/83

65 62nd meeting of Competent Authorities, November 2001, NOTIF/54/2001

A single polymer substance, equivalent to monomer combinations including alteration to process conditions, is defined by the following characteristic ranges:

Composition variation within ±10% (applicable to a specified polymerisation reaction chemistry);

Mn variation within 3-fold (applicable upwards only from the measured and tested Mn value).

Considering toxicological significance at lower molecular weight (Mw) a notification would cover an Mn range down to ~0.9 times the measured Mn of the tested polymer. In practice, arbitration would be justified (at the discretion of a Competent Authority) taking into account measurement precision and accuracy of Mn determination by Gel Permeation Chromatography (GPC).

Following similar principles of quality assurance and data evaluation, notifiers and regulators should confirm that a polymer (produced in the scope of normal process variability) to be placed on the market under the single substance definition, has an oligomer (Mn < 1000 Dalton) content within 1.1 times the oligomer content of the notified (tested) polymer.

In submitting a notification, notifiers should ensure data consistency through quality control. In registering a notification, regulators should judge acceptable batch variability of Mn and oligomer content from authenticated test reports.

Example 1 (notification of Polymer A)

GPC data are available for three different batches of polymer A, yielding mean values for Mn and Mw from four consecutive determinations for each sample:

Batch 1: Mn 2430, Mw 6740 (source of samples for polymer A notification tests)

Batch 2: Mn 2230, Mw 6680 (routine production of polymer A as single substance)

Batch 3: Mn 1990, Mw 6480 (routine production of polymer A as single substance)

Applying the guide to polymer A (batch 1) allowing 10% reduction of Mn (i.e., factor 0.9 times) would set a lower range limit for Mn of 2187. Relative to batch 1, Mn for batches 2 and 3 are low by ~8.2% (factor ~0.92 times) and ~18.1% (factor ~0.82 times) respectively.

Batch 2 (production) is within the recommended Mn range, relative to batch 1 (tested). Assuming oligomer content is also compliant (refer to example 2) notification of tested batch 1 would also cover production batch 2.

Batch 3 (production) is outside the recommended Mn range, relative to batch 1 (tested). Justification of any further testing would take account of the degree of Mn variance, respective of individual cases.

Example 2 (notification of Polymer B)

GPC data are available for three different batches of polymer B, yielding mean values for oligomer content (Mn < 1000 Dalton) from four consecutive determinations for each sample:

Batch 1: Oligomer content 15% (source of samples for polymer B notification tests)

Batch 2: Oligomer content 16% (routine production of polymer B as single substance)

Batch 3: Oligomer content 20% (routine production of polymer B as single substance)

Applying the guide to polymer B (batch 1) allowing 10% excess of oligomer content (i.e., factor 1.1 times) would set an upper range limit for oligomer content of 16.5%. Relative to batch 1, oligomer content for batches 2 and 3 are high by ~6.7% (factor ~1.07 times) and ~33.3% (factor ~1.33 times) respectively.

Batch 2 (production) is within the recommended oligomer content range, relative to batch 1 (tested). Assuming Mn is also compliant (refer to example 1) notification of tested batch 1 would also cover production batch 2.

Batch 3 (production) is outside the recommended oligomer content range, relative to batch 1 (tested). Justification of any further testing would take account of the degree of oligomer content variance, respective of individual cases.

5.6.2 2% rule for notification of new polymers[66]

Article 13 (Exemptions) (Directive 92/32/EEC) indicates 'polymers, with the exception of those which contain in combined form 2% or more of any substance which is not on EINECS, shall be considered as having been notified within the meaning of this Directive'.

The 2% refers to new substance final weight fraction incorporated by polymerisation, not initial reactant content, and exclusive of residual monomer component. Where more than one new substance occurs as a monomer, the 2% rule applies individually to each new monomer substance, not to the sum total content of new monomer weight fraction. In practice, a polymer incorporating two new monomer substances at a sum total of 3% weight fraction in combined form, but individually present at only 1.5% each, would satisfy the <2% exemption criterion of Article 13.

Two examples, a condensation reaction and a post-reaction halogen substitution (below) illustrate application of this concept, in particular, distinguishing between reactant and combined monomer units.

Methodology to determine combined unit versus free monomer quantitatively would depend on characteristic properties, where estimation by measurement or calculation would be the responsibility of a prospective notifier. Comprehensive guidance covering any reaction eventuality would not be feasible, but uncertainty in individual cases may be addressed to a Competent Authority for advice.

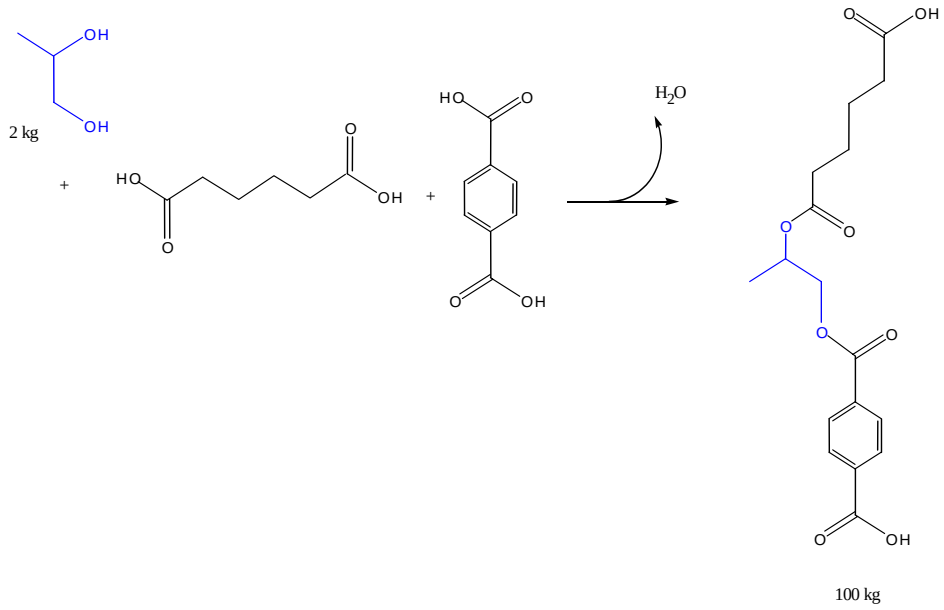
<u>Example 1</u>

Example 1 shows a condensation reaction where propylene glycol monomer (diol) is present as 2% reactant. Even in the ideal case of 100% yield, the combined form of the diol remains <2%, due to elimination of H_2O, originating partly from the diol monomer. In cases where the diol is introduced in excess of 2%, and/or where the reaction is incomplete, estimation of diol bound in the polymer should be determined, either directly by spectroscopic analysis or indirectly by calculation using measured residual diol content.

Propylene glycol (2%) + Adipic acid + Terephthalic acid

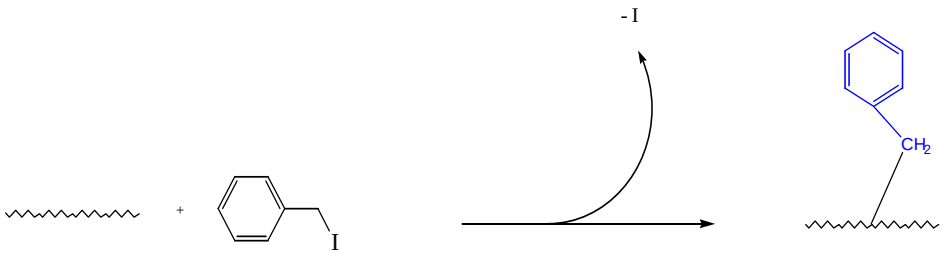
66 63rd meeting of Competent Authorities, 17/06/02, NOTIF/5/2002

→ Polymer - Water



Example 2

Example 2 shows a polymer post-reacted with benzyl iodide resulting in loss of iodine. The applicable content of reactant benzyl iodide monomer in combined form would be the proportion of polymerised benzyl functional group, not the percentage of benzyl iodide originally introduced.



5.6.3 Definition of new (notifiable) polymer[67]

1.1 A substance produced by polymerisation of one or more non-EINECS listed substance(s), present 2% or more in bonded form, will require notification.

1.2 A substance produced by polymerisation of substance(s), which are all listed on EINECS, will not require notification.

67 10th Technical & Scientific Meeting, March 2000, NOTIF/3/2000
59th meeting of Competent Authorities, June 2000, NOTIF/2/2001

1.3 A substance produced by post-reaction of an exempt polymer (1.2, above) with (a) non-EINECS listed substance(s), present 2% or more in bonded form, will require notification.

1.4 A substance produced by post-reaction of an exempt polymer (1.2, above) with (an) EINECS listed substance(s), will not require notification.

2. A polymer produced by either of the processes 1.1 or 1.3 (above) will require notification before placing on the EU-market. However, in the case competent authorities deem the notifiable polymer to be identical and therefore a duplicate of an existing polymer produced with (an) EINECS listed substance(s) and the existing polymer is already available on the EU-market, they may conclude that for this reason notification may not be required.

3.1 Identical polymers replicate all the following properties:

a) Chemical structure and composition

b) Identity of end groups

c) Number average molecular weight

d) Identity and percentage of all low molecular weight components (% MW<1000)

3.2 When only reactant identities are known, and the substance is made via polymerisation or post-reaction of a transient intermediate (not isolated during the polymerisation reaction) the resulting polymer may be considered exempt from notification if all the reactant(s) is (are) EINECS listed.

3.3 Cases which are not adequately covered under these rules should be considered individually by the competent authority(ies) of a member state and communicated subsequently to the competent authorities of the other member states.

5.6.4 Guidance document for the implementation of Annex VII D of Council Directive 67/548/EEC (Directive 93/105/EEC)

This Guidance document was originally endorsed and approved during the 47th meeting of Competent Authorities[68], and a revised version was adopted at the 54th meeting of Competent Authorities[69]. The revised version is reproduced below.

Note: This guidance document has been subject to further review, under Commission patronage, during the period 2000 – 2002. Comprehensive revision, respective of the latter review, is not available. However, specific issues have been endorsed by Competent Authorities in the course of the review, and which are definitive, viz: entries 5.6.1, 5.6.2, and 5.6.3 (above). In absence of a full more recent revision, the guidance document dated 1997 (below) remains valid, with refinement and/or revision of interpretation limited, as appropriate, to the scope of the adopted entries 5.6.1, 5.6.2, 5.6.3 (above).

Doc.XI/584/93 (rev. 3 FINAL)

NOTIF/20/97

68 47th meeting of Competent Authorities, June 1994
69 54th meeting of Competent Authorities, December 1997

Guidance document for the implementation of Annex VII D of Council Directive 67/548/EEC (Directive 93/105/EEC)

1. Introduction

The Directive 93/105/EEC[70] contains a specific test strategy for polymers. In addition to the test package, in analogy to Annex VII of Directive 67/548/EEC, it incorporates a concept for grouping polymers (including the family approach) and provides the concept of a reduced test package for polymers fulfilling various specific criteria. This guidance describes those concepts but has no legal status. It is intended to clarify notification of polymers.

2. Test package for polymers and testing methods.

2.1 Test package

The test package for polymers consists in principle of the normal test programme according to Annexes VII and VIII supplemented by some polymer-specific tests (but with the potential for no or fewer tests, as in sections 4 and 5 of the Directive and the scheme in figure 1). These tests permit the identification of substances as polymers in compliance with the polymer definition (cf. Art. 2, para 1 c of the Directive 67/548/EEC; number-average molecular weight, molecular weight distribution, identity and concentration of the starting monomers and starting substances which will be bound in the polymer). They also allow the performance of hazard assessment for polymers (based on indications of endgroups, identity of reactive functional groups, identity and percentage of main impurities and non-reacted monomers, statement concerning the intended environmental degradability with relevant information, extractivity in water and cyclohexane) on the assumption that possible effects should be mainly due to the low molecular weight and soluble components The tests at different pH-values in water are designed to reflect varying physiological/environmental conditions.

Additionally in certain cases and without delaying the decision on the acceptability of the notification, ecotoxicologically relevant test (light-stability, long-term extractivity) may be required if there is an exposure potential to man or environment.

The test for light-stability provides information about a potential danger to the environment as a result of the possible formation of reaction products. For polymers that are only placed on the market containing light-stabilisers this test provides no relevant information and should be omitted.

The long-term environmental extractivity should be estimated by leachate tests. The leachate test should reflect the fate of polymers in the environment (e.g. on waste disposal sites). Depending on the results of the leachate test, i.e. if the leachate is formed in relevant amounts (criteria to be developed), appropriate ecotoxicological tests on the leachate (e.g. acute toxicity test on either fish, Daphnia or algae, appropriate biodegradation test) may be requested on a case by case basis.

2.2 Testing methods

70 OJ L 294, 31.11.1993, p.21

Wherever possible, testing methods described in Annex V of Directive 67/548/EEC must be used. Where such methods are not available or are not appropriate, other internationally recognized methods are accepted, with appropriate justification. Thus the tests for molecular weight distribution, Mn(*) (by gel permeation chromatography or physico-chemical methods), % species with $M^+ < 1000$, and water extractivity generated by EU/OECD officials and available in draft-form May 1994 (and already in use) are due to be published by the EU during 1997. For test 3.1.6 under section C2.1 of the Directive (93/105/EEC), OECD test 113 can be used and for the leachate test, above, a UK draft method is available.

3. Grouping polymers

While maintaining the basic principle of 1 substance - 1 notification, there will be the possibility for notifiers to submit one technical dossier which will cover several polymers which are proposed to be marketed. This grouping is possible at two levels, covering (3.1 below) a narrow and (3.2) a wide range of variation.

3.1 Meaning of "substance"

In the particular case of polymers, the term substance is taken to mean a narrow group of (co)polymers of similar composition and/or similar Mn(*) values, even if the small variations are due to deliberate alterations to the process conditions, the process itself remaining unchanged.

Small variations include the following:

a) for homopolymers, the Mn can vary by up to 3-fold;

b) for co-polymers where,

   (i) the Mn remains approximately constant (variation up to 2-fold) while the composition varies by ± 10% absolute.

or

   (ii) the composition remains approximately constant (variation up to ± 3% absolute) while the Mn can vary up to 3-fold.

Each substance, as defined above, will be subject to one notification, with as a consequence, the cumulation of the tonnages, one entry in ELINCS etc. For (a) and (b) (ii), the tests are done on the polymer with lowest Mn (Examples 1 & 7) and for (b) (i) that with the mean composition.

In any case, information on the identity and quantities of the different polymers which are actually marketed and covered by the same substance definition, will need to be made available to the Competent Authorities. Examples are given in Annex 1.

Where a group of polymers to be marketed is too wide in composition or Mn to be a "substance", then it may be possible to consider the group as a "family", as follows:

3.2 Family approach

(*) Mn is Number average molecular weight, M is molecular weight

The concept of grouping polymers into families is based on the assumption that, in principle, the members of a family of polymers process a similar hazard potential. The decision to group polymers into a family is not mandatory and is left to the notifier.

A family of polymers is defined as a group of polymers/substances (in the meaning of 3.1), either homopolymers or copolymers, in which one parameter, e.g. the number-average molecular weight, Mn, is "fixed" while one (NB one) other (e.g. the composition) is allowed to vary, due to the differing ratios of monomer units, over a relatively large range. In this concept, "fixed" means confined to a narrow range consistent with the possibly wide variation of the variable parameter. In this and similar examples the variation in the Mn values or in the composition is due to not unintentional process-related fluctuations but to deliberate alterations to the process conditions, the process itself remaining unchanged. Another example would be where the same polymer chain is attached to a series of side-chains of varying length as in Annex 1 example 8, or to a series of closely related, for example, carbohydrates. Other examples may be possible but the prospective notifier should first enquire of the local Competent Authority.

It is assumed that the low molecular weight members of the family produce greater toxicological and/or ecotoxicological effects than the high molecular weight members because of their higher solubility and mobility. Although it is recognized that the effects might not be always linear throughout the family, testing of polymers on a family basis is accepted in order to reduce technical dossiers and tests to a reasonable and yet sufficient number.

The concept consists of testing representative members of the family. For example for a family with composition fixed, Mn varying, i.e. of homopolymers (i.e. in contrast to a "substance" under 3.1(a), Mn extending over more than a 3-fold range), the notifier proposes the Number average molecular weight range of the family and submits, in the first instance, two technical dossiers one for each end of the family. In the case of the low Mn end, the full test package has to be performed. As already mentioned the effects produced by the polymers normally decrease from the low to the high Mn, so if no toxicological/ecotoxicological effects are observed for the low Mn member no effects are expected in the case of the high Mn member. Therefore the technical dossier for the upper end of the family may be submitted without testing (a "nominal" notification) and the two dossiers cover the whole range (example 2). If, in contrast, certain effects are seen at the low Mn, these should be checked for at the upper end to see if they extend over the whole range (as in example 3) [if this is not done, the dossiers cover only the polymer substance at each end of the range - example 4].

For the more usual situation of a "new" copolymer in which the Mn is "fixed" and the composition varies or alternatively the composition is "fixed" and the Mn varies, similar principles apply. Thus with the first such case, two technical dossiers are needed, one for each end of the range of compositions with the tests to be done usually on the polymer with most "new" monomer present (or if good reason, e.g. that the new monomer has been fully tested and found not to be classified but one of the other, EINECS-listed, monomers is, then the test should be done at that end of the range instead). As for the homopolymers case, if the tests on the chosen end of family are negative, no tests are required at the other end and the whole family is covered (example 6). If some are positive, those tests should be repeated at the other end and if with the same result, again the whole family is covered. However in the case where toxicological/ecotoxicological effects are seen at one end of the range and no effects in/at the other, additional technical dossiers or tests on other (intermediate) representative members are required to maintain the necessary standard of safety while at the same time preserving the

simplified notification concept and avoiding over-classification. In the second case, tests are done at the low-Mn of the range and the family can extend upwards to any chosen Mn limit.

Either of the above procedures, 3.1 or 3.2 may also be used for those polymers for which a Reduced Test Package, see below, is acceptable (NB: where the Family Approach is used, the polymer at each end of the range must be of the RTP type if the omission of RTP-style test is to be allowed for the whole group. Otherwise one has the situation delineated in the next but one paragraph).

Some tests which are relevant for polymers with a high molecular weight (e.g. inhalation toxicity for polymer dusts) and some ecotoxicological tests (e.g. light-stability, long-term environmental extractivity) may be necessary post-notification for the respectively upper and lower end of the family.

In all cases, each “substance”, as under 3.1 above, within the family which is marketed, will have to be briefly reported, but without the submission of a technical dossier, to the Competent Authorities.

4. Polymer for which a reduced test package is acceptable (RTP-polymers)

The fundamental idea of this concept is the assumption that non-bioavailable substances as indicated by the three criteria of high Mn, <1% of species with M<1000 and low water extractivity are not able to cause systemic effects which are toxicologically and/or ecotoxicologically relevant. However, this concept has been extended post-Annex VII D such that where a polymer breaks one of those criteria, it may still be possible to reach RTP or similar status by balancing the presumed, but still low, bioavailability that implies with a knowledge of the properties of the component monomers. These possibilities are indicated in the attached scheme, figure 1, but first the following section gives in more detail the philosophy behind this concept for the original (Annex VII D) RTP polymer.

4.1 Criteria for the traditional Annex VII D RTP polymer

Polymers with a high Mn, low content of low molecular weight species as well as low solubility/extractivity in water are regarded as essentially non-bioavailable. Therefore, for polymers fulfilling the prescribed criteria, a reduced test package is acceptable.

A high molecular weight prevents, according to present knowledge, passage through biological membranes. As a guidance for this criterion a Mn > 10000 is used. Only when this value is not fulfilled, should polymers with Mn > 1000 be considered (on a case by case basis). The up-take in aqueous solution is limited by the required low solubility/extractivity in water. A low proportion in the polymer with M < 1000 represents a low toxicological/ecotoxicological activity of the polymer under the assumption that possible effects are due to low molecular weight species.

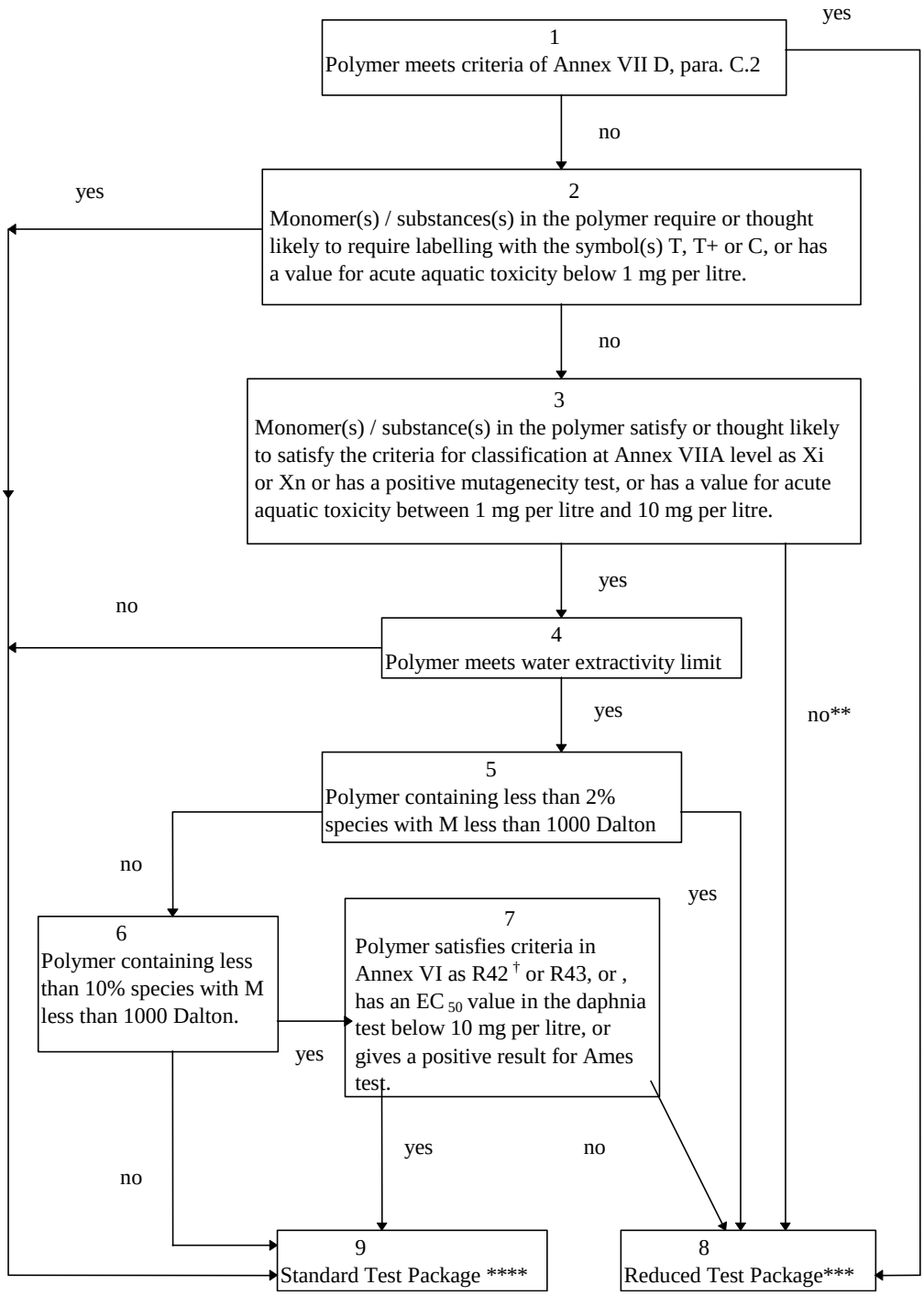


Figure 1. Routes to the Reduced Test Package (RTP)*

Footnotes to notification scheme:

* RTP route cannot be applied to polymers containing certain reactive groups as specified in Annex 2 to this guidance document (XI/584/93 rev.3) nor to respirable / high Molecular weight polymeric dusts.

** Providing the Mn is > 1000 and it can be demonstrated (not necessarily by testing) that on simulated ingestion the polymer cleaves to the same or equivalent non-classified fragments.

*** The usual caveats as to possible post-notification testing (as in 93/105/EEC, C.2.1 items 4 and 5) apply.

**** Tests for STP may be omitted if <u>all</u> the monomers and substances in the polymer do not satisfy or are not thought likely to satisfy the criteria for classification in Annex VI to Directive 67/548/EEC for a particular end-point. The evidence may be that derived from reliable literature (e.g. RTECS, non-confidential IUCLID etc.) test data on close structural analogues, in-house worker protection tests, etc. The notifier has to provide the data.

† When test methods becomes available in Annex V this test will be required.

Explanation of the terms used in the boxes:

'monomers' describes the building blocks of the polymers.

'substances' is defined in Directive 67/548/EEC as amended by 92/32/EEC. It is included in this scheme as the chemical synthesis of polymers may include other building blocks than 'monomers', e. g. networking agents, chain terminators, initiators etc. which will be chemically bound in the final polymer.

'species' cover the individual molecules in the polymer (the 'individual molecule' is a specific polymer chain [e.g. the hexamer] within the over all polymer distribution).

'M' is the molecular weight of a individual molecule in the polymer.

'T+' is the symbol of 'very toxic' substance as laid down in the Directive 67/548/EEC. It includes the substances labelled with R39 'Danger of very serious irreversible effects'.

'T' is the symbol of 'toxic' substance as laid down in the Directive 67/548/EEC. It includes the substances which are carcinogenic and/or genotoxic.

'C' is the symbol of 'corrosive' substance as laid down in the Directive 67/548/EEC.

R42 and R43 are sensitizing substances by inhalation and skin routes respectively (test results)

Data requirements:

The minimum data set which should be available for the new monomers/substances is the data requirements laid down in Annex VII A of Directive 92/32/EEC. These data would be obtained by testing as the substance is new and thus supposedly not described in literature.

The data set required for the monomers/substances listed in EINECS should be data set equivalent to the requirements laid down in Annex VII A of Directive 92/32/EEC, in consultation with the Competent Authority. The evidence may be that derived from reliable literature (e.g. RTECS, non-confidential IUCLID etc.) test data on close structural analogues, in-house worker protection tests, etc.

The data expected for Box 7 are test results of testing on the actual polymer or read across from close analogues.

If the criteria are fulfilled, the hazard potential of the polymer should be limited, so that a reduced test package is acceptable.

Up to now, the concept is limited to non-readily-degradable polymers, since the effect of the degradation products cannot be estimated based on the composition of the polymer.

For non-readily-degradable polymers, that are placed on the Community market in quantities of < 1 t/a or total quantities of < 5 t, it is sufficient that the criteria of a high molecular weight and a low solubility/extractivity in water are fulfilled, because only a few tests are required in Annexes VII B and VII C for other chemicals and it would be an unreasonable expenditure to prove that the other criterion (i.e. < 1% with M < 1000) is fulfilled.

4.2 Test package for RTP-polymers

The reduced test package for RTP-polymers contains most of the physico-chemical tests in addition to the common declarations concerning the manufacturer, notifier, identity of the substance and information on the substance. However, the determination of the melting range can obviously be combined with the (polymer-specific) test for thermal stability by DTA or DSC, using e.g. OECD Test Guideline 113, though it should be noted that that cannot replace the test for explosive properties/autoflammability. However, for explosive properties the escape clause is very likely for polymers.

Most polymers for which the reduced test package is acceptable require in principle no toxicological and ecotoxicological tests at base-set level. If it seems likely that toxicity effects are due to low molecular weight components, classification (and the possible need for confirmatory testing) may be determined by application of the rules in the Preparations Directive.

The structural and physical characteristics of the polymer (reactive functional groups, bio-available metals, aerodynamic particle size) are also to be taken into account (described in detail in Annex 2), but if it can be scientifically justified the tests can be omitted.

A similar treatment to determine the need for ecotoxicological test should be possible once the Preparations Directive is modified adequately. Anionic and cationic charge densities as well as biotic and abiotic stability are also of concern.

In addition, tests for inhalation toxicity may be required, if a potential for such exposure exists, because dusty high molecular weight polymers may cause inhalation toxicity by overloading the clearance mechanism of the lung. Some ecotoxicologically relevant tests such

as light-stability and long-term environmental extractivity may also be relevant. The reasons are already mentioned under 2.1.

4.3 Labelling of RTP polymers

Any polymer notified under one of the RTP procedures (see figure 1) must carry the "Caution-substance not yet fully tested" phrase in addition to any label required by testing.

5. Higher tonnage testing requirements.

The tonnages follow the usual trigger levels for New Substances as laid down in Directive 92/32/EEC, the tests for polymers at higher tonnage triggers are as follows:

- For a polymer notified as a 'Standard Test Package Polymer' the standard testing program is to be followed, so this type of polymer notification will contain the end-points required for the Annex VII A and D, and appropriate Annex VIII tests. If it can be demonstrated that the ultimate building blocks are all 'negative' with regard to a particular end-point then testing for that end-point can be delayed until the 100 tonnes/annum (or 500 tonnes cumulative) level has been reached.
- For polymers following a 'Reduced Test Package' the testing is shifted so that the Annex VII A and D package is expected at 100 tonnes/annum level (and not at 1 tonne/annum). Then at the next tonnage trigger, 1000 tonnes, relevant tests from annex VIII (level one and two) are defined. For the RTP polymers following the Annex VIID, para 2 route it is expected that tests from Annex VIIA and VIII would not be relevant; however it should be evaluated on a case by case basis; when scientifically justified tests may be omitted.

To give an overview table 1 was compiled giving a schematic comparison of the testing requirements for the different substance classes at the tonnage levels.

Annex 2 of this guidance note gives further explanation to the toxicological and ecotoxicological testing of polymers subject to the reduced test package in Annex VII D para C.2.

TABLE 1. Polymer Test Packages at Higher Tonnage Triggers

TONNAGE	STP+ POLYMER	RTP POLYMER	ANY NEW SUB-STANCE
≥ 1 tonne/annum or ≥ 5 tonnes cumulative	Annex VIIA testing and some polymer specific tests	None (unless CA specifically requests)	Annex VIIA testing
≥ 10 tonnes/annum or ≥ 50 tonnes cumulative	Annex VIIA testing and some Annex VIII (level 1) at CA request	None (unless CA specifically requests)	Annex VIIA testing and some Annex VIII (level 1) at CA request
≥ 100 tonnes/annum or ≥ 500 tonnes cumulative	Annex VIIA testing and full Annex VIII (level 1)	Annex VIIA testing*	Annex VIIA testing and full Annex VIII (level 1)
≥ 1000 tonnes/annum or ≥ 5000 tonnes cumulative	Annex VIIA testing and full Annex VIII (level 2)	Annex VIIA testing and Annex VIII (level 1 and 2) depending on dialogue between CA and notifier*	Annex VIIA testing and full Annex VIII (level 2)

+ If for a particular test end-points are negative for all monomers/substances in the polymer, then testing is not required on the polymer until 100 tonnes/annum or 500 tonnes cumulative threshold is reached.

* If omissions can be justified testing does not need to be performed (usual Annex VII preamble applies).

ANNEX 1.

Examples

Examples are grouped by type of polymers.

For the purposes of these examples the following abbreviations are used:

t+ : testing resulting in effects being seen

t- : testing resulting in no effects being seen

i : basic Mn etc. information on the substance but without tox/ecotox testing

rt+ : relevant tests with effects seen.

rt- : relevant tests no effects seen.

Firstly, there is the narrow-range type, a polymer "substance" (as defined under item 3.1), where a single notification dossier covers all the examples within that narrow-range of Mn and/or composition. Secondly, there are families, where there are two types of notification dossier - (a) one requiring the usual toxicological/ecotoxicological tests, except for RTP polymers, and carried out on the polymer with the lowest Mn or with composition highest in the (new) monomer or as indicated under item 3.2 para 5; (b) a "nominal" notification at the "other end" of the family which will either require (i) no testing to be done (if the tests done under the first notification were all "negative"), and signified by little i (information only) below; or (ii) where not all "negative", testing of those end points which were "positive" in the first notification (t+), and signified by the abbreviation rt+ or rt- below. Since the two individual dossiers represent a "substance", as defined under item 3.1, at each end of the family, the "validity" of that notification covers the substance actually tested but extending, for homopolymers for example, up to 3-fold its Mn whereas the two technical dossiers cover the whole range between the extremes of the family as indicated e.g. under example 2. Although "new" homopolymers will be rare, 3 examples (2-4) of the family approach for homopolymers are provided to illustrate the principle, which can be extended to "new" co-polymers.

HOMOPOLYMERS

Example 1, a polymer "substance"

mol. weight range proposed by the notifier:	Mn = 500 - 1500
testing at:	Mn = 500
validity of the technical dossier:	Mn = 500 - 1500
validity of the notification:	Mn = 500 – 1500

Graphic representation[*]

Technical dossier

500 1500

||==========||

t- or

t+

Notification

500 1500

|--------------------|

Example 2, a family showing no tox/ecotox effects

family proposed by the notifier in the range from:	Mn = 500 - 7000
testing for notification 1 (no effects seen) at:	Mn = 500
validity of notification 1:	Mn = 500 - 1500
a “nominal notification” (see introduction) giving information on the substance, without toxicological and eco-toxicological testing, at:	Mn = 7000
validity of nominal notification 2:	Mn = 7000 - 21000
combined validity of the two dossiers for the family:	Mn = 500 – 21000

Graphic representation of validity

Technical dossiers

500 7000 21000

||==================================||================|

t- i

[*]|| extremes proposed by the notifier
|====| validity range of the technical dossier(s)
|-------| validity range of the notification(s)

Notifications

500 1500 7000 21000

||----------| ||----------|

Example 3, a family showing tox/ecotox effects at both ends of the range

family proposed by the notifier in the range from:	Mn = 500 - 7000
testing for notification 1 (with effects seen) at:	Mn = 500
validity of notification 1:	Mn = 500 - 1500
relevant tests (see Introduction), for notification 2 and the same effects seen, at:	Mn = 7000
validity of notification 2:	Mn = 7000 - 21000
combined validity of the two technical dossiers for the family:	Mn = 500 – 21000

Graphic representation of validity

Technical dossiers

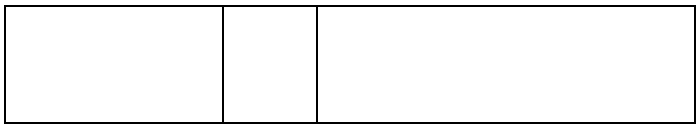
500 7000 21000

||==========||==========|

t_+ rt_+

Notifications

500 1500 7000 21000



Example 4, a family showing tox/ecotox effects at one end of the range but not the other

family proposed by the notifier in the range from:	Mn = 500 - 7000
testing for notification 1 (with effects seen) at:	Mn = 500
validity of notification 1:	Mn = 500 - 1500
relevant tests, and with no effects seen, at:	Mn = 7000
validity of notification 2:	Mn = 7000 - 21000

combined validity of technical
dossiers 1 and 2 for the family: Mn = 500 - 1500
and 7000 – 21000

Graphic representation of validity

Technical dossiers

500 1500 7000 21000
||==========| ||===============|

t+ rt-

Notifications

500 1500 7000 21000
|----------| |----------|

COPOLYMERS

Example 5, Copolymer A-B (Mn approximately constant and a narrow compositional range, a polymer substance)

Testing on the marketed polymer of composition 50% A - 50% B; a deviation of ± 10% absolute is acceptable. The variation in Mn acceptable will be a factor of 2.0. The notification (and technical dossier) is valid for the range from composition (1) to composition (2) and a molecular weight range from Mn to 2.0 Mn.

(1) 40% A - 60% B

(2) 60% A - 40% B

The notified polymer corresponds to one substance (see guidance, point 3.1), testing to be at the middle of the compositional range.

Example 6, Copolymer A-B (Mn approximately constant but a wide compositional range, family)

variations in composition: (1) 90% A - 10% B

(2) 25% A - 75% B

Two technical dossiers required for copolymers with composition (1) and (2), with testing first, as indicated under item 3.2 para 5, at one end of the range and if no effects seen, information only at the other end but if effects then those (relevant) tests repeated there.

Validity of notifications as under example 5 (composition variation of ± 10%). Each dossier covers the tested composition ± 10% (as for example 5), but providing the same, or no, effects are seen at the two ends of the range, the two dossiers cover the whole family as for Example 2 and 3. M.Wt. variation allowed = 3-fold across the family.

Example 7, Copolymer A-B (composition approximately constant and a narrow M.Wt.variation, a polymer substance)

Testing on the marketed polymer with Mn = 1000 and composition 50% A - 50% B; a deviation of ± 3% absolute is acceptable.

The notification (and technical dossier) is valid for the range from composition (1) to composition (2) and a molecular weight range from Mn to 3 x Mn.

	Composition	Mn
(1)	47% A - 53% B	1000 up to 3000
(2)	53% A - 47% B	1000 up to 3000

The notified polymer corresponds to one substance.

Example 8, a family of polymers in the form of a homologous series

This family consists of a group of molecules in which the polymer entity is the same and a homologous series of end-groups is attached; e.g.:

------- C_8

---------- C_{10}

"Fixed polymer" ---------- C_{12}

---------- C_{14}

---------- C_{16}

The lowest (C_8) example of the homologous series would then have to be tested and notified and a nominal notification with basic physico-chemical data, and possibly some (eco)toxicological data, provided for the C_{16} example.

ANNEX 2.

DETERMINATION OF FURTHER TESTING (TOXICOLOGY, ECOTOXICOLOGY) OF POLYMERS FOR WHICH A REDUCED TEST PACKAGE IS ACCEPTABLE.

(points 4 and 5 of section C2.1 of Annex VIID)

1. Introduction

In general toxicological, ecotoxicological tests are to be performed if required by the competent authority on a case by case basis. The tests required depend on structural and physical characteristics. They do not delay acceptance of the notification but must be performed within a reasonable timescale.

2. Toxicology

The following parameters should be considered when making a decision on the necessity of toxicological tests:

2.1 Presence of reactive functional groups

Polymers containing reactive functional groups may be capable of reacting with tissues or with other chemical constituents, and reactive groups may cause sufficient irritation to disrupt normal cell membrane barriers and therefore facilitate penetration. If those groups are present in the polymer, the higher possibility of presence of these effects should be taken into account when designing the test package. The kind of functional groups which may induce such effects are examplified in the following:

acid halides; acid anhydrides; aldehydes; hemiacetals; methylolamides,-amines or -ureas; alkoxysilanes (> C2); allylethers; conjugated olefines; cyanates; epoxides; imines; substances with unsubstituted ortho or para positions to phenolic hydroxyl. Groups of more concern are pendant acrylates and methacrylates; aziridines; carbodiimides; halosilanes; hydrosilanes; hydrazines; isocyanates; isothiocyanates; alpha or beta lactones; methoxy or ethoxy silanes; vinylsulfones or analogous compounds.

2.2 Presence of bioavailable metals, that are part of the polymer structure

The toxicological effects due to bioavailable metals should be taken into consideration when deciding on further toxicological testing of RTP-polymers.

2.3 Aerodynamic particle size

A (solid) polymer with particles of a respirable size may cause inhalation toxicity. If such an exposure potential exists, test on inhalation toxicity should be considered.

2.4 Low molecular weight content

The following procedural rules for the determination of further testing are based on the fact that a polymer is normally a mixture comprising a high molecular weight portion, a low molecular weight portion (monomers, oligomers; M < 1000), impurities and essential additives. Possible systemic effects can, in principle, be due to low molecular weight components.

2.4.1 Effects of the low molecular weight components are sufficiently known

If the effects of the low molecular weight components are sufficiently known the polymer should be classified in accordance with Article 4(1) of Directive 67/548/EEC. For this purpose additives should be treated as impurities.

2.4.2 Effects of the low molecular weight components are not sufficiently known

If the effects of the monomer, oligomers, impurities and/or additives are not sufficiently known (e.g. the chemicals are not included in Annex I of the Directive), they should be estimated (low molecular weight species with M < 1000 are considered to have the same properties as the monomer). In the case of untested effects a worst case assumption is made (that the effects are present). The default concentration limits of the Preparations Directive (88/379/EEC) are then applied to the estimated effects. The concentration limits have to be modified, if necessary, by SAR to a substance-specific lower value.

3. Ecotoxicology

The parameters mentioned in connection with toxicological tests under 2.1 and 2.2 (reactive functional groups, bioavailable metals) and anionic charge density may be also relevant for the decision on the necessity of ecotoxicological tests.

In addition, another factor is of relevance:

3.1 Cationic charge density

Cationic, water-soluble or dispersible polymers are available when in the aquatic environment and may therefore be able to cause toxicity to aquatic organisms. To estimate the possible effects of the polymer, the cationic charge density should be calculated on the basis of the polymer composition. Polymers with a cationic functional group-equivalent weight[72] of 5000 or greater are regarded as having not sufficient cationic characteristics to cause environmental effects. Consequently this value should be used as a guidance. All amines (primary, secondary, tertiary amine and quaternary ammonium), phosphonium and sulfonium should be included in the calculation. Nitrogen from amides, aromatic amines, aromatic triazines and melamines also need to be considered.

4. Overall assessment

The overall effects of a polymer are to be determined by the estimated effects of the low molecular weight components. If toxicological/ecotoxicological effects appear likely, relevant tests have to be carried out. Considerations about structural and physical characteristics of the polymer (e.g. reactive functional groups, bioavailable metals, aerodynamic particle size, anionic and cationic charge density) are also to be taken into account. If it can be scientifically justified the tests can be omitted.

Equivalent weight means the ratio of the Mn to the number of cationic functional groups

5.6.5 Specific questions concerning notification of polymers under the 6th Amendment rules[73]

Case 1: Homopolymer obtained from one monomer contained in the Inventory

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72 Equivalent weight means the ratio of the Mn to the number of cationic functional groups.

73 13th meeting of Competent Authorities, 6/12/1984 - doc. XI/31/85

Can an oligomer be considered a polymer or not?

The criterion applied for reporting for EINECS should be used: if the molecular weight is distributed, the substance is a polymer.

Case 2: Homopolymer obtained from a monomer not in the Inventory

Several polymers can have the same empirical formula but different structures. Are they all the same substance or several different ones?

A priori, if the physical properties are different, the substances are different. However, the escape clause set out in the preamble to Annex VII could be used on a case-by-case basis to avoid carrying out all the toxicological and ecotoxicological tests.

Case 3: Copolymer of which at least one of the monomers is not in the Inventory and makes up more than 2% of the polymer

According to a IUPAC draft[74], seven sequences of monomers are possible. Is a separate notification required for each type of polymer or will one notification cover all seven sequences? The conclusion is the same as for case 2.

5.6.6 Biodegradability for RTP polymers

Application of biodegradability testing relevant to support the acceptability of a Reduced Test Package (RTP) for polymers according to the conditions in Annex VIID (C.2) was discussed. Competent Authorities agreed that biodegradability could be inferred from the physico-chemical properties: high number average molecular weight, low content of low molecular weight species, and low solubility/extractivity in water.[75] [76]

5.6.7 No longer polymers[77]

Subject to inclusion of a short explanation on the position of oligomeric reaction products, the NLP list was adopted in 1995[78]. The Commission agreed to, when resources allow, inform Competent Authorities which applications to be on the NLP list had been rejected and why.

The Commission stressed that the list was not exhaustive, but should be a useful tool for Competent Authorities and industry. Other substances to those on the list could be considered to be NLPs if they satisfied the following criteria:

they could have been considered to be a polymer under the 6th Amendment definition;
they were not a polymer under the 7th Amendment definition and;
they were placed on the EU market between 18 September 1981 and 31 October 1993 (inclusive).

The final NLP list has now been published.[79]

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74 IUPAC provisional document. Source-based nomenclature for copolymers

75 58th meeting of Competent Authorities, Helsinki, 22/11/99

76 9th Technical and Scientific Meeting, Ispra, 7-8/9/99, NOTIF/99 rev.3

77 50th meeting of Competent Authorities, Madrid, 22-23/11/1995 - NOTIF/36/95

78 Ref. U11.2/185/Gv/gv, dated 7/11/95

79 Notification of New Substances in accordance with Directive 67/548/EEC on the Classification, Packaging and Labelling of

5.6.7.1 Corrigendum to No-Longer Polymer List

A corrigendum to the official Commission document "Notification for new chemical substances in accordance with Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances – No-longer Polymer List" (ISBN 92-827-8995-0) was agreed:[80, 81]

The entry with NLP No. 500-139-1 on page 19 is deleted.

The entry with NLP No. 500-313-7 on page 35 should read as follows:

NLP No. 500-313-7

CAS RN NYA

4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol,

2,4'-diisocyanatodiphenylmethane, 1,1'-methylenebis(4-isocyanatobenzene) homopolymer, [(methylethylene)bis(oxy)]dipropanol and propane-1,2-diol

The 2 substances listed with NLP No. 500-761-3 and NLP No. 500-762-9 on page 74 are synthesised from the same starting materials which are used in different concentrations. This is reflected in 2 different NLP-numbers. However, the Chemical Abstracts Service assigned only CAS No. 162567-74-0. Therefore, the NLP-No. 500-762-9 is deleted.

5.6.7.2 No-Longer Polymers as starting material – notification requirements for the resulting product

This issue concerned the notification requirements of substances created from No-Longer Polymers (NLPs) as starting material.[82,83]

Following the intention of the Council of Ministers, the change of the polymer definition from the 6th to the 7th Amendment of the Directive should have no negative impact on the producer or importer of polymers which were not reportable for EINECS. Therefore, substances which are "No-Longer Polymers" are excluded from the notification.

However, exemption from notification covers not only EINECS- and NLP-substances. Polymers created on the basis of EINECS-substances only are excluded as well. Following the intention of the Council of Ministers and the working criteria for NLP-substances, polymers created from:

- NLP-substances only or

- EINECS- and NLP-substances

are excluded as well.

Dangerous Substances. No longer Polymer List**.** /09/ 1996. Luxembourg: Office for Official Publications of the European Communities. CR-99-96-932-EN-C, ISBN 92-827-8995-0

80 8th Technical and Scientific Meeting, Ispra, 9-10/03/99, NOTIF/4/99-rev.1

81 57th Meeting of Competent Authorities, Berlin, 17/06/99, NOTIF/8/99 rev.?

82 5th Technical and Scientific Meeting, Ispra, 23-24/09/97, NOTIF/19/97-rev.1

83 54th Meeting of Competent Authorities, Brussels, 15/12/97, NOTIF/2/98-rev.1

5.6.7.3 Assignment of No Longer Polymer (NLP) status to unlisted substances

No Longer Polymer (NLP) status may be granted to substances upon application and submission of requisite evidence to a competent authority. Criteria for acceptance would follow the same principles adopted during compilation of the NLP list. In addition, claims for recent NLP status would be valid from companies able to substantiate previous marketing of the same substance.

The reporting form for the NLP inventory listed requirements for a submission. A declaration was requisite that the substance was on the market in the reference period, i.e., prior to entry into force of the 7th Amendment to Directive 67/548/EEC. The minimum analytical proof required was evidence of a MW distribution, which could be demonstrated by Gel Permeation Chromatography (GPC). A Commission guidance (NOTIF/36/92) indicated that a GPC trace was not essential. Alternative proof may be acceptable where relevant (e.g., a comprehensive description of the reaction process). The guidance recommended (but did not demand) that individual peaks in a chromatogram should be characterised by mass spectrometry (MS) analysis or a similar technique.

Data requirement would thus be as follows:

1. An invoice to prove that the substance was on the market in the reference period (18 September 1981 to 31 October 1993).

2. Evidence to show that the substance has a molecular weight distribution. If analytical data on molecular weight distribution is available only for the substance supplied post October 1993, data must be provided to show that this substance is the same as that placed on the market within the reference period.

Experience from two recent submissions has shown that invoices providing proof of supply and data on chemical identity may have uncertain compliance with the above criteria. Evidence in the form of original documents and absolute proof of the structure and MW distribution may be difficult for industry to provide. A standard of proof is needed to avoid speculative claims.

Information to be submitted in support of a request for NLP status is as follows:

1. Photocopies of invoices and spectra would be acceptable and do not necessarily have to be the original spectra of the substance placed on the market in the reference period.

2. Evidence other than analytical data can be provided which shows the substance was on the market in the reference period.

3. Evidence of molecular weight distribution by chromatograms appropriately annotated with identified peaks.

4. Photocopies should be countersigned as authentic.

Letters from competent authorities accepting NLP status should leave the applicant accountable for the submission, indicating that a false claim would be a breach of regulations. Unsuccessful submissions should be given justification of ineligibility. Rejected substances may be resubmitted for reconsideration. Acceptance letters, annexing a substance description, would take the following format (indicative only):

The information provided for the substance as described in your letter dated ..... indicates that it has a MW distribution and is produced from EINECS listed substances. We consider that you have provided sufficient proof for the substance to be considered a No Longer Polymer. Provided the substance placed on the market meets the description as given there is no requirement to provide a notification under the Notification of New Substances Regulations 1993.

If subsequent analysis of the substance shows that it is not identical to the specifications given below it cannot be considered a NLP. Under these circumstances the substance cannot be placed on the market unless a notification is in place.

In the event that a substance placed on the market under the NLP description is identified as different, the supplier would be considered to have breached the regulations and in such circumstances inspectors will be advised to take enforcement action.

Example of substance acceptance description:

The [Member State] competent authority declare the following substance to be a

No Longer Polymer:

Name: Oleic acid, ethoxylated

Cas No: 9004-96-0

Composition: >1 <2.5 mol EO

Molecular weight distribution:

Characterisation:

1.	HPLC	2.	NMR
	Column:		Frequency:
	Eluent:		Solvent:
	Temperature:		Peak position (delta)
	Peak retention time (Weight %)		

N.B: Identity of substances granted NLP status should be forwarded to ECB, for inclusion in the web version of the NLP list (http://ecb.ei.jrc.it/new-chemicals/).

5.6.8 Polymer or polycondensate?

A reaction product between substituted sulphonic acids and formaldehyde was discussed at the 42nd meeting of Competent Authorities. It was decided that it was similar to a previous case discussed at the 37th meeting of Competent Authorities.[84]

84 37th meeting of Competent Authorities, Brussels, 25-26/2/91 - NOTIF/15/91

The question was whether this substance should be notified, i.e. whether it was a polymer or a polycondensate.

Further to the advice from JRC, Ispra, and following an exchange of views between Competent Authorities, the possibility was mentioned that the substance might satisfy the OECD polymer definition. It was agreed by the meeting that the substance should not be notified.[85]

5.6.9 Mixture of esters

A query was received concerning a mixture of esters, which the company concerned wished to be considered a "polyadduct". After discussion and on the basis of the information supplied by the company, it was obvious that the product could not be considered to be a polymer but was simply a mixture of esters- which were almost certainly not on EINECS. It was agreed that the substance should be notified.[86]

5.6.10 Notification strategy using an extended family approach applied to the example of diol polyesters[87]

Notification duty for new polymers, relating to Article 12 of Directive 92/32/EEC (7th amendment to Directive 67/548/EEC) makes provision for a family approach in hazard assessment (Annex VII D, paragraph B). In the particular case of a certain class of polyester, this family concept of grouping similar polymers is extended to grouping of similar monomers. The case refers to polyester copolymers incorporating a notified non-EINECS listed diol monomer R(OH)2 (where R is an alkyl group) in combination with EINECS listed alkyl diols, dicarboxylic acids and acid anhydrides. With restriction to this specific class of diol polyesters, the family approach is applicable on the basis of representative monomers. Monomers with similar essential chemical structure and toxicological profile are generically grouped, allowing copolymer production from representatives of several monomer groups, facilitating polymer notification and hazard assessment under the family approach.

This non-confidential MoD entry outlines the conceptual basis of a testing strategy for the diol polyesters in question. The strategy has been elaborated among polymer experts from competent authorities, in consultation with a stakeholder notifier from industry. Details of the test programme for hazard assessment, agreed among competent authorities from all member states, are stipulated as a confidential MoD protocol, available to regulators only.

Publication of a non-confidential conceptual summary respects transparency of administrative decisions and facilitates awareness of a case with potential for analogous development. However, the scheme does not set a general precedent applicable to any generic class of copolymer. The strategy indicates scope of flexibility feasible in the notification of copolymer families, aiming to promote innovative commerce within industry and alleviate administrative resources among regulatory authorities. The strategy is also consistent with the significance of the Directive respecting pragmatic and scientific account of cost/benefit and animal welfare, notwithstanding principles of public health protection and environment conservation.

85 42nd meeting of Competent Authorities, Lisbon, 5-6/5/92 - NOTIF/42/92 - rev. 1

86 42nd meeting of Competent Authorities, Lisbon, 5-6/5/1992 - NOTIF/42/92 - rev. 1

87 62nd meeting of Competent Authorities, Brussels, 9/11/2001 – NOTIF/54/2001

Notifiers considering analogous development, for notification of another copolymer family, should make inquiries with a competent authority.

Test strategy for the diol polyester family

The assumption of monomer grouping, in the diol polyester family, is that any resulting copolymers will have similar toxicological properties. Implicit in this approach is that polymer composition variation is negligible (i.e., fixed) when limited by monomer variation within the same group. For example, taking alkyldicarboxylic acids as a monomer group, it may be assumed that changing the carbon chain length of C6 (adipic acid) to C9 (sebacic acid) would not produce a significant difference in the toxicological properties of any resultant copolymers (inclusive of effects produced by residual monomers and oligomers). Toxicological data on representative monomers are available, in support of this diol polyester family approach.

With reference to the diol polyesters in question, and the known range of monomers which those copolymers comprise, five generic groups of monomers have been identified:

A. Alkyl alcohols.

B. Benzenedicarboxylic acids.

C. Alkyldicarboxylic acids

D. Maleic anhydride

E. Trimellitic anhydride

The relevant notifiable diol polyester copolymers are reaction products of an acid and an alcohol, which contain the new notified monomer, R(OH)2. Application of this family approach assumes that copolymers made by reaction of a representative acid or anhydride monomer from each group (B-E) with a representative alcohol from group A can be used to determine the toxicological profile of the polyester family. Care should be taken when introducing monomers equivalent to groups D and E, where reactive functional groups (e.g., double bonds) may be present. R(OH)2 would be representative of the several alcohol monomers which are in group A, provided that the various alcohol monomers have the same toxicological profile as R(OH)2.

Notification requires determination of the properties of diol polyesters made with R(OH)2 plus benzenedicarboxylic acids, R(OH)2 plus alkyldicarboxylic acids, R(OH)2 plus maleic anhydride, and R(OH)2 plus trimellitic anhydride, as core analogue notifications, complete with full base-set testing. The core analogue notifications serve to define the compositional/Mn limits of the diol polyester family and provide technical characterisation of the copolymer toxicological profile. In line with the approach of R(OH)2 as representative of group A monomers, a single acid or anhydride can be representative of the various monomers which fall into groups B, C, D and E. In practice, the full base set notification of the new monomer and four core analogue notifications are adequate to define the scope and properties of the particular diol polyester family.

Read-across from a single core analogue notification, as appropriate, would be sufficient to characterise and classify a related copolymer of the type, AB, AC, or AD. Classification of

related copolymers of the type ABC or ABD can be derived as a hybrid of two relevant core analogue notifications, respectively in this case, AB with AC, and AB with AD.

Toxicological deviation from core analogue properties may also be exhibited within the copolymer family due to alteration of process conditions adding monomer reactant, introduction of new functional groups, or residual increase of low molecular weight species. Accounting for these factors, additional testing may be warranted, at the discretion of a competent authority, to affirm similarity with core analogues.

5.7 APPLICABILITY OF THE DIRECTIVE TO INTERMEDIATES (REDUCED TEST PACKAGE)

The 28th Adaptation to Technical Progress of Directive 67/548/EEC[88] allows notifiers the possibility to submit a reduced test package (RTP) in support of the notification of a chemical intermediate that is solely manufactured for and consumed in a chemical reaction under strictly controlled conditions, as laid down in section 7.3 of Annex VII.A of the Directive. In particular it should be noted that application may only be made when the substance is restricted to a maximum number of 2 sites. Where notifiers intend to supply more than 2 users, they must submit a full test package, appropriate to the tonnage level, within the timeframe provided for by the Directive.

The technical dossier required for an RTP, as laid down in section 7.4. of Annex VII.A, represents a minimum data set designed to produce a preliminary risk assessment for the substance in question, relative to the quantities being placed on the market. The competent authority in the country of notification must accept the technical dossier as valid to support a RTP notification.

The competent authority will assess the information provided for completeness and in order to satisfy itself that the conditions for an RTP are met, as laid down in section 7.3. of Annex VII.A. This includes demonstration of rigorous containment by technical means during its whole life cycle in accordance with 7.3(d), (e) and (f). The degree of containment must be assessed by the notifier against the criteria down in section 7.5. of Annex VII.A.

The information prescribed for RTP substances placed on the market in quantities > 1 tonne per annum per manufacturer but less than 10 tonnes per annum is laid down in 7.4(g) of Annex VII.A. For quantities placed on the market in quantities > 10 tonnes per annum (or 50 tonnes total quantity) but less than 100 tonnes annum (or 50 tonnes total quantity), the information prescribed is that laid down in 7.4(g) plus the information required in Annex VIII, Level 1, paragraph 2. In the case of quantities placed on the market in quantities > 100 tonnes per annum (or 500 tonnes total quantity) but less than 1000 tonnes per annum, the information prescribed is that laid down in 7.4(g) plus the information required in Annex VIII, Level 1, paragraphs 2 and 3. If the authority authorises the notifier's application for an RTP it may still require additional studies, in accordance with Article 16(1) of the Directive, based on the outcome of the risk assessment.

88 Commission Directive 2001/59 of 6 August 2001, OJ L 225, 21.8.2001, p.1

5.7.1 Protocol for the acceptance of a reduced test package for intermediates

Although the submission and acceptance of a reduced test package for an intermediate is a matter primarily between the notifier and the competent authority in the country in which the notifier is located, it is necessary to recognise that other parties (e.g. intermediate users and competent authorities in other Member States where use, as opposed to manufacture, may take place) have a major stake in the process. This protocol is intended to set out a practical working arrangement to take into account the roles and responsibilities of these other parties.

Working arrangements between stakeholders

There are two basic cases, which need to be considered:

The notifier and the user(s) are in the same Member State,

the notifier and/or one or more of the user(s) are in different Member States.

1. Notifier and user in the same Member State

Before submitting an RTP dossier, the notifier must submit the request for the RTP to the competent authority in that Member State. After considering the request the competent authority will inform the notifier of its decision. If the request is granted the notification will be forwarded to the Commission's European Chemicals Bureau (ECB) in the usual way with a covering note to indicate the decision taken. ECB will copy the notification to other Member States.

2. Notifier and user in different Member States.

The submission and approval of an RTP should follow these stages:

The notifier works with all users to prepare a request for an RTP.

The request should be submitted to the notifier-CA and all users-CAs at the same time.

If a user-CA wishes to object to the request, then contact should be made with the notifier-CA within 30 days dated from the receipt of the request by the user-CA.

The notifier-CA must take full account of the views of the objecting user-CA when considering the request.

If the notifier-CA grants approval agreement, it is passed to all user-CAs, in addition to the usual submission to ECB.

Appeal and review

There will be no right of appeal by the notifier against the views of either the user or notifier competent authority. However the reasons for the decision must be clearly stated.

The Commission will prepare a report on the operation of the scheme after a period of 12 months and submit it to the meeting of competent authorities. If necessary the scheme will be modified in the light of the report.

5.8 COMPLEX POLYSACCHARIDE GUMS, ETC…, PRODUCED BY BIOTECHNOLOGY

The 42nd meeting of Competent Authorities discussed the question of complex polysaccharide gums produced by biotechnology.[89]

EINECS lists various products, such as certain gums (complex polysaccharides) derived by implication from natural sources. It is now possible to make what appears to be the same products by fermentation (i.e. biotechnology). However, it is difficult to prove that natural and biotechnology-derived gums are identical. The question is: can it be assumed that an EINECS entry covers both types?

It was agreed that prospective notifiers should provide analytical proof that their biotechnology product is identical to the natural product. This decision was confirmed at the 43rd meeting of Competent Authorities: in principle, substances used producing the new technologies should be notified if they are not on EINECS. If they are on EINECS, the notifier should prove that it is the same substance as the naturally occurring one in order to be exempted from notification.[90]

5.9 "MIXTURES" OF ISOMERS[91]

Notifications for a "mixture" of isomers (e.g. two isomers in about equal proportions) can be accepted. If, however, one of the components is later placed on the market in its own right, the substance must be renotified. The mixture does not cover each individual isomer in it (the same criterion as applied for EINECS). This also applies to optical isomers.

5.10 NOTIFICATION OF HYDRATED AND ANHYDROUS FORM OF THE SAME SUBSTANCE[92]

It was agreed that

- if the anhydrous form of a substance has been notified, all hydrated forms of the substance are covered by the notification and;
- if the hydrated form of a substance has been notified, anhydrous forms of the substance are not covered by the notification. It is however the responsibility of the individual CA to decide what additional test results are required for anhydrous forms and what can be "read across" from the notification of the hydrated form.

89 42nd meeting of Competent Authorities, Lisbon 5-6/5/1992 - NOTIF/42/92 - rev. 1
90 43rd meeting of Competent Authorities, London 14-16/12/1992 - NOTIF/5/93 - rev. 1
91 17th meeting of Competent Authorities, 4/2/1986 (doc. XI/176/86)
92 49th meeting of Competent Authorities, Brussels, 30-31/3/1995

5.11 DESIGNATION OF NOTIFIABLE SUBSTANCE[93]

The Competent Authorities have discussed the notification of impurities (new substances) in existing substances. At their 53rd meeting[94] Competent Authorities decided that a substance must consist of at least 80% of the (main) component in order to be covered by an EINECS entry. Thus in a system with one EINECS component > 80%, one other (new) substance is allowed without attracting a requirement to notify. See also Section 9.5 below.

5.12 APPLICABILITY OF THE DIRECTIVE TO MICRO-ORGANISMS (NOT GENETICALLY MODIFIED)[95 96 97]

Directive 67/548/EEC and its 7th Amendment (92/32/EEC) are the basis for the notification of "new" substances. Article 2 defines the meaning of "substance" and "preparation" respectively for the purpose of the Directive. "Substance" means chemical elements and their compounds in the natural state or obtained by any production process...; "preparations" mean mixture or solutions composed of two or more substances. However Article 1 declares that the Directive shall not apply to substances or preparations for which other notification or approval procedures exist, e.g. medicinal substances, foodstuffs or pesticides. Additionally, according to Article 13, substances which appear in the EINECS inventory ("old" or "existing" substances) shall be exempted from the obligation to notify. In principle, for the notification of new substances the same rules are used as for the reporting of substances for EINECS.

Taking into account that substances obtained by any production process have to be notified according to Directive 92/32/EEC, substances produced by micro-organisms (e.g. enzymes produced by biotechnology) have to be notified, if no exemptions are to be applied.

However it has to be checked whether micro-organisms themselves are "substances" within the definition of the Directive or not. Several cases can be distinguished:

1. Killed micro-organisms

For the EINECS inventory a protein hydolysate of micro-organisms was a "substance", see entry 309-204-7 ("Substance produced by acidic, alkaline or enzymatic hydrolysis of mixed micro-organisms..."). Therefore, protein hydrolysates obtained by other methods, e.g. heat, also have to be notified. Accordingly, different "substances" produced from killed micro-organisms also have to be notified. However, for instructions on how to describe these substances the chapter "How to report" in the guidance "Reporting for the EINECS Inventory" should be consulted.

2. Living micro-organisms as bacteria (prokaryota) and fungi (mycota, including yeasts)

Living organisms are obviously not covered by the definition of Directive 92/32/EEC and do not have to be notified. Other wise, the notification of animals and plants becomes an issue. Also, living organisms were not included in EINECS. Rule 19 of the EINECS criteria for reporting substances (Chapter II of "Reporting for the EINECS Inventory" (see Section 2.3)

93 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/8/95

94 53rd meeting of Competent Authorities, the Hague, 11-12/6/1997

95 3rd Technical & Scientific Meeting, Ispra, 23-24/9/1996

96 4th Technical & Scientific Meeting, Ispra, 4-5/3/1997

97 53rd meeting of Competent Authorities, the Hague, 11-12/6/1997

states that "Bacteria, fungi and yeasts themselves, being living material, should not be reported.

The use of Genetically Modified Organisms (GMOs) is covered by other existing Community Directives on biotechnology. The way to deal with pathogenic micro-organisms is also addressed. The use of special living micro-organisms, e.g. baker's yeast or lactic acid bacteria, has a long tradition in the food industry.

3. Viruses

Viruses are not able to reproduce themselves outside another living cell and are not therefore independent organisms. The chief constituents of viruses are amino acids and proteins. Their composition may change due to mutation. However, protein or amino acid hydrolysates of viruses have to be considered as "substances" and should therefore be notified.

5.13 RELEASE OF NEW SUBSTANCE IN USE

The notification requirements for a new substance released in use but not marketed as such was discussed. It was agreed that substances released in use need not be notified.[98,99]

5.14 NOTIFICATION REQUIREMENTS OF AN ACID/BASE 'SALT'

The question whether or not a solution of an acid/base "salt", should be notified was discussed in 1998. Whereas a majority of the Competent Authority concluded that "an aqueous mixture of an acid and a base both of which were reported for EINECS is notifiable if the salt is not listed in EINECS", the Dutch and the Belgian Competent Authority referred to a formal national decision made in the past. The Dutch Competent Authority had published in 1988 a code of practice on chemical substances including the non-notifiability of an aqueous mixture of an acid/base "salt". Harmonisation was needed and all Competent Authorities decided as follows:[100,101]

In particular the solution of 1,5 Diamino-2-methylpentane (EINECS No. 239-556-6) with either Isophthalic acid or Adipic acid was discussed.

Such substances were included in EINECS (see examples given below).

Examples:

Starting materials:

Isophthalic acid	EINECS No. 204-506-4
Adipic acid	EINECS No. 204-673-3
Dimethylamine, in aqueous solution	EINECS No. 204-697-4

98 7th Technical and Scientific Meeting, Ispra, 1-2/09/98, NOTIF/21/98-rev.1

99 56th Meeting of Competent Authorities, Vienna, 18-19/11/98, NOTIF/2/99

100 6th Technical and Scientific Meeting, Ispra, 10-11/03/98, NOTIF/5/98-rev.1 and 7thTechnical and Scientific Meeting, Ispra, 1-2/09/98, NOTIF/21/98-rev.1

101 56th Meeting of Competent Authorities, Vienna, 18-19/11/98, NOTIF/2/99

Produced substances:

Isophthalic acid, compound with dimethylamine (1:1) EINECS No. 275-226-8

Adipic acid, compound with hexane-1,6-diamine (1:1) EINECS No. 222-037-3

Therefore, it was agreed that an aqueous mixture of an acid and a base both of which were reported for EINECS is notifiable if the salt is not listed in EINECS.

CONCLUSION

Since there is no exemption to the general rule that substances obtained by any production process have to be notified, those killed micro-organisms which can be defined as substances (e.g. protein or amino acid hydrolysates) have to be notified. Living organisms, in contrast, do not have to be notified.

5.15 SUBSTANCES INCORPORATED INTO AGROCHEMICAL PRODUCTS

Article 1(2)(f) of Directive 92/32/EEC specifies that the Directive shall not apply to pesticides. [Active substances, inherent of biocides or plant protection products, are regulated under Directives 98/8/EC and 91/414/EEC, respectively].

New substances (not listed in EINECS) which are placed on the market as inactive ingredients of agrochemical products (e.g., additives such as ‘adjuvants’ and ‘anti-transpirants’) require notification according to Directive 92/32/EEC. This applies equally to substances supplied, either separately for formulation, or previously incorporated, into agrochemical products.[102]

102 63rd meeting of Competent Authorities, 17/06/02, NOTIF/5/2002

6 ARTICLES: SUBSTANCES

6.1 SUBSTANCES AND PREPARATIONS MARKETED IN A SPECIFIC FORM OR WITHIN SPECIFIC CONTAINERS

The Competent Authorities have been asked on a number of occasions whether a new substance marketed in the form of an item/object, including a substance in a specific container, is subject to the notification requirements of the Directive. Such items/objects are often termed "articles". Thereafter in this guidance the term "object" will be used. More recently, the same question has arisen in relation to the labelling of both new and existing substances incorporated in such objects.

Neither Directive 67/548/EEC nor Directive 1999/45/EC contains a definition of "article". Nor is there any exemption related to the form of the substance or preparation. Articles were exempt, however, from the reporting requirements for EINECS (criterion 13).

The legal service of DG ENV was consulted on this issue. It was identified that one important aspect that should be taken into consideration was the potential for release of the substance during the use of an object. As discussed initially at the 31st meeting of the Competent Authorities[103], it was decided that the two questions, which must be addressed in order to decide whether or not notification should be required, are:

(i) Is there a release of the substance during use of the object? If the answer is no, then the Competent Authorities considered that notification is not required. If the answer is yes, then a second criterion should be considered:

(ii) Is there a barrier preventing exposure of the user or the environment? If the answer is yes then the Competent Authorities considered that notification is not required, if no a notification is required.

The Competent Authorities discussed this issue on a number of subsequent occasions with reference to examples of different objects containing new substances, and the decision above was reconfirmed at the 53rd meeting of the Competent Authorities.[104] It was decided that the final decision on the need to notify will be taken on a case by case basis by the Competent Authority based on the answers to these questions.

The labelling of a dangerous substance or preparation marketed in the form of an item/object, including those marketed in specific containers, was also considered by DG ENV's legal service. Their advice was that the criteria established above in relation to notification should also be applied in reaching a decision as to whether the object should be labelled. This advice was discussed at the 55th meeting of the Competent Authorities.[105] It was concluded that, dependent on the answers to these questions, such objects may be subject to the packaging and labelling requirements of Directive 92/32/EEC and Directive 1999/45/EC.

The Competent Authorities agreed that the form of labelling should also be considered on a "case by case" basis, and that the exemptions from labelling and packaging requirements provided for in the Directives could be applicable to some of the objects under consideration.

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103 31st meeting of Competent Authorities - 4-5/12/89 - NOTIF/28/89

104 53rd meeting of the Competent Authorities, the Hague, 11-12 June, 1997

105 55th meeting of Competent Authorities, 23-24/6/98

In addition, Annex VI of Directive 67/548/EEC provides some advice for specific products (e.g. LPG cylinders, metals in their massive forms, alloys) which do not present a danger when supplied. They do not therefore require to be labelled, although they are still classified as "dangerous", and Safety Data Sheets must be supplied when such products are placed on the market.

6.2 FLUID FOR INSTANT PHOTOGRAPHIC FILM (ARTICLE OR SUBSTANCE?)[106]

Is there any need to notify a new substance present in a fluid in a sealed container on the back of an instant photographic film?

In the particular case considered it was decided that notification must be given because:

- the container could break during normal use and members of the public could come in contact with the substance;
- the container can be regarded as a package and not as a manufactured product.

6.3 CHEMICALLY SURFACE-TREATED SUBSTANCES[107]

Must notification be given of substances which have undergone chemical surface treatment?

Any decisions taken on notification must be compatible with those taken for EINECS, and in particular with criterion 13 for reporting to EINECS, i.e.:

"Articles should not be reported. Articles which undergo chemical surface reactions to increase their stiffness, strength, flame resistance or to increase their ion-exchanging capacity, chromatographic behaviour, resilience, bacterial resistance, etc. while maintaining their bulk structure retain their status as articles. Fluids and particles are not considered articles regardless of shape or design, but rather mixtures or substances.

Examples of articles include batteries, brake linings, chips, fabrics, fibres, filaments, films, flares, glass wool, leather, paper, pencils, rock wool, chromatographic supports, and yarns.

Components of articles and substances used in the finishing process of an article (e.g. dyes and fire retardants) can be reported if they have a separate commercial identity from that of the article."

6.4 ARTICLE-PLASTER BANDAGES USED IN RESETTING BROKEN[108]

Is there a need to notify (a) new substance(s) included in immobilisation bandages which are currently replacing plaster bandages used in re-setting broken bones?

Before use these bandages are enclosed in an airtight bag. They are impregnated with a preparation containing a pre-polymer and various products, i.e. a catalyst which is a new

106 7th meeting of Competent Authorities, 9-10/6/83 (doc. XI/383/83)
107 14th meeting of Competent Authorities, 14/3/1985 (doc. XI/325/85)
108 34th meeting of Competent Authorities, 3-4/7/1990, NOTIF/30/90

substance. To apply these bandages, the airtight bag should be opened and the bandages plunged into water. They will harden up.

Following the guidelines established by the authorities during their 31st meeting, the substance(s) in question should be notified, given that there exists a significant exposure for patients and in particular for doctors and nurses.

6.5 DYES FOR COLOUR PRINTERS

Various similar cases of products for colour printers sold as colour ribbon, "slitted roll", "jumbo roll", "transfer ink ribbon" or cassette, containing dyes which may be new substances and therefore notifiable, have been considered by the Competent Authorities.[109] [110] [111] [112]

On the basis of available documentation and the data supplied by the manufacturers, only the product commercialised in the form of a sealed cassette unit is considered as an article and therefore any new substance contained in it should not need to be notified. On the other hand, if there is the potential for release of any new substances contained in products, notification will be required if they are placed on the Community market (see also 6.1 above).

This issue was discussed again at the 3rd Technical & Scientific Meeting[113] in relation to new substances contained in printer ink cartridges. Although the cartridges themselves could be considered articles, it was agreed that there was the possibility of exposure to the chemicals contained therein. It was agreed therefore that the new substance in the ink cartridge has to be notified, in accordance with the principles laid out in 6.1 above. This decision was confirmed at the 53rd CA Meeting.[114]

6.6 POLYESTER FILM WITH NEW CHEMICALS

Is there a need to notify polyester films coated with new chemical substances?

This film is coated with up to 7 new chemical substances (dyestuffs) and will be placed into film cassettes. According to the information available, the cassette containing the film will be used in a thermoprinter where the substances coated on the film react to temperature. They sublime and are stored in the polyester of the image sheet.

The new dyestuffs do not react with the polyester film nor with the image sheet, but adhere by the use of resins on the film. From there they directly sublime to the image sheet.

This question was discussed at the 42nd meeting of Competent Authorities.[115] It was agreed that this case was similar to one previously discussed[116] and that the new substances involved should be notified since they are first placed on the market on a roll, with a risk of exposure during normal use, and not in a sealed unit.

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109 26th meeting of Competent Authorities, 5/10/1988 (doc. XI/811/88
110 27th meeting of Competent Authorities, 6-7/12/1988, NOTIF/1/89
111 36th meeting of Competent Authorities, 27-28/11/1990, NOTIF/1/91 rev.1
112 37th meeting of Competent Authorities, 25-26/2/1991, NOTIF/15/91
113 3rd Technical & Scientific Meeting, Ispra, 23-24 /9/1996
114 53rd meeting of Competent Authorities, the Hague, 11-12/6/1997
115 42nd meeting of Competent Authorities, 5-6/5/1992, NOTIF/42/92 rev. 1
116 37th meeting of Competent Authorities, 25-26/2/1991, NOTIF/15/91

7 NOTIFIER

7.1 DEFINITION OF NOTIFIER[117]

Article 2(1)(d) of Directive 79/831/EEC defined the "notifier" as "the manufacturer or any other person established in the Community who places a substance on the market and who "presents the requisite information to the competent authority of a Member State".

Article 6(1) stipulated that notification of substances manufactured in the EEC must be given by the manufacturer in the Member State in which the substance was manufactured.

In the case of substances imported into the EC, Member States may not require that the notifier must be established on its national territory. It is sufficient for this person to be established anywhere in the Community.

Within the 7th Amendment, for substances manufactured within the Community the notification is submitted by the manufacturer who places the substance on the market, either on its own or in a preparation; for substances manufactured outside the Community the notification is submitted by any person established within the Community who is responsible for placing the substance on the Community market, either on its own or in a preparation, or alternatively by the person established within the Community who is for the purposes of submitting a notification for a given substance placed on the Community market, either on its own or in a preparation, designated by the manufacturer as his sole representative (Article 2.(1)).

In any case, irrespective of the Member State in which the notifier is established, the Member States are not allowed to practice discrimination in the phase preceding placing on the market, nor to impose conditions not provided for in the Directive. Once the substance has been placed on the market, the competent authorities may request further details (e.g. the name of the consignee) for monitoring and control purposes.

The question of possible actions brought by the Member States against non-residents is covered by the Convention of 27 September 1968 on jurisdiction and the enforcement of judgements in civil and commercial matters[118].

7.2 WHO IS THE NOTIFIER? RESPONSIBILITY OF A THIRD PARTY SUBMITTING A NOTIFICATION[119]

The 39th meeting of Competent Authorities considered two questions raised in relation to the notification procedure:

- who is responsible when the notification is submitted by a third person on behalf of the importer?
- to what extent should the notifier be aware of the properties of the substance put on the market?

117 13th meeting of Competent Authorities, 6/12/1984 - doc. XI/31/85
118 OJ C 97, 11.4.1983, p.1
119 39th meeting of Competent Authorities, 19-20/9/1991, NOTIF/57/91

It was concluded that according to the 6th Amendment the legal responsibility always stays with the importer himself, but that a third company (eg. a testing house) can provide some information directly to the Competent Authorities. Nevertheless, it must also be ensured by the Competent Authorities that the legal notifier (the importer) has access to the information he needs in order to fulfil his legal obligations. This minimum information does not necessarily include the identity of the substance.

Under the 7th Amendment the person submitting the notification may be the sole representative. The importer should still have access to the information he needs in order to fulfil his legal obligations.

7.3 DIRECT TRANSMISSION TO THE COMPETENT AUTHORITIES OF CONFIDENTIAL INFORMATION BY NOTIFIERS FROM THE UNITED STATES OF AMERICA[120]

The United States of America asked the Commission to authorise foreign notifiers to transmit confidential information direct to the Competent Authority, and not via their importer. The latter would nevertheless remain the person legally responsible.

It should be borne in mind that during the TSCA negotiations the United States had agreed to Community notifiers acting in this way.

It transpired that there were no difficulties and that a mutual arrangement could apply provided there was a person responsible in the Community, i.e. the importer.

7.4 TOLL MANUFACTURING (SPECIAL PROCESSING) [121]

7.4.1 Who is the notifier?

Who must notify, the firm which asks for the products to be specially processed or the firm which processes them?

The definition of "placing on the market" suggests that the firm which carries out the special processing is responsible for notification of the resultant substance and not the firm which commissioned it.

7.4.2 Requirements of the 7th Amendment

In reply to a question raised at the 45th meeting of Competent Authorities[122] it was confirmed that, as under the 6th, also under the 7th Amendment notification is required in the case of toll manufacturing.

120 7th meeting of Competent Authorities, 9-10/6/1983 doc. XI/383/83

121 14th meeting of Competent Authorities, 14/3/1985 - doc. XI/325/85. This decision was confirmed at the 40th meeting of Competent Authorities, 17-18/2/1991, NOTIF/9/92 rev. 1

122 45th meeting of Competent Authorities, 15-16/12/1993, NOTIF/2/94

7.5 TWO SUBSIDIARIES IN THE EC, ONE MANUFACTURES, THE OTHER MARKETS THE SUBSTANCE

A company located in one Member State intended to import small quantities of a new substance, produced by its subsidiary in another Member State, with the intention of testing its suitability for further processing.

The issue was who should notify, the importing company or the manufacturer? Following legal advice, it was agreed[123] that the company would be required to notify in the country where they manufacture.

7.6 SOLE REPRESENTATIVE

A guidance document setting out the procedures for and responsibilities of the sole representative under the 7th Amendment has been adopted by the Competent Authorities at their 52nd meeting[124] and amended at their 61st meeting[125]. It is laid out in Section 7.6.1.

7.6.1 The Sole Representative facility (NOTIF/13/95, as amended by NOTIF 26/2001)

This facility was introduced with the implementation of the 7th Amendment Directive (92/32/EEC) so as to reduce the bureaucracy associated with the notification requirements for the case of a non-EU manufacturer wishing to export to a series of EU importers. Until that time each of those importers was required to make an individual notification, which sometimes meant 50 or more separate "repeat" notifications, individually for relatively small quantities, just for that one substance. Under the facility the sole representative acts as the notifier for either all or some of those importers.

The sole representative facility is applicable to all levels of notification. It should be noted that this procedure may also be used in any other countries within the European Economic Area (EEA) which exchange notification summaries.

The sole representative procedure means that unnecessary repeat notifications are avoided. The resultant reduction in the administration costs for both the authorities and industry is accompanied by a reduction in the fees (where applicable) which are received.

The facility was originally restricted for use by non-EU manufacturers in accordance with Article 2(d), 2nd indent of Directive 92/32/EEC. The facility was typically envisaged as being used by a single non-EU manufacturer wishing to export to a series of EU importers, as indicated in paragraph 1. Competent Authorities considered, however, that under the facility it is also possible to designate a sole representative if the same substance is manufactured by several non-EU manufacturers who then export to the EU.

The facility is available only to the original non-EU manufacturer(s) of a new substance, not to a formulator or any other person or organisation. This restriction helps ensure accurate tracking of quantities of a particular notified substance being placed on the EU market.

123 42nd meeting of Competent Authorities, 5-6/5/1992, NOTIF/42/92 rev.1
124 52nd meeting of Competent Authorities, Dublin, 8/10/1996
125 61st meeting of Competent Authorities, Stockholm, 27/06/2001

A separate arrangement must be made by each non-EU manufacturer wishing to use the sole representative facility. However, a non-EU manufacturer may appoint the same sole representative for each of its various products.

For the sake of completeness, it should be noted that the Competent Authorities also considered[126] the status of substances manufactured in the EU, subsequently exported without being placed on the EU market and then re-imported, e.g. in preparations, and the possibility of utilising the sole representative facility for such substances. Further details on this possibility are provided in Section 7.7.2.

Although this procedure represents a major convenience to both industry and the authorities, there are both limitations to its use and certain responsibilities a sole representative must accept, in writing, before the procedure can be used. It therefore seemed appropriate to set these out to help both Competent Authorities and industry and to ensure a consistent approach across the EU. It should be noted that this document is intended solely as guidance and it does not replace the legal requirements set out in the Directive.

1. Procedures and responsibilities

This section sets out the procedures that Competent Authorities require sole representatives to carry out in order to take advantage of the sole representative arrangements. The requirements given below apply to the cases whereby

- a single non-EU manufacturer exports a new substance to the EU;
- several non-EU manufacturers export the same new substance to the EU

via one or several EU importers. The substance may be imported as such or as a component of a preparation.

The sole representative, which can be a particular individual or an organisation, must:

1. enclose with the usual notification documentation a copy of the letter(s) from the non-EU manufacturer(s) officially assigning the sole representative status to it;

2. be established within the EU and have an EU contact address.

The sole representative does not necessarily need to be one of the actual importers. A non-EU manufacturer may, for confidentiality reasons, prefer to have an independent entity as sole representative who can provide a confidentiality break amongst the various parties - the details are plainly for those concerned to arrange; and

3. provide to the Competent Authority -

3.1 with the notification documents, a letter stating that they have arranged that all importers covered by the arrangement have been informed of the sole representative's identity and requirements (e.g. that quantity information will need to be provided);

3.2 without any delay, copies of those importers' individual agreements to the use of the sole representative procedure;

126 48th meeting of Competent Authorities. Brussels 17-18 January 1995 and subsequent meetings

3.3 within the initial notification documentation, the list of EU importers covered by this arrangement at that time, with approximate predicted initial per annum individual quantities and EU total.

The Competent Authority must also be informed of any new importers added to the group later, quoting the original notification number(s) and enclosing a copy of the agreement, before supply from that importer commences. It remains the responsibility of the sole representative to maintain a collated, up-to-date list of all importers (and manufacturers) at all times. The sole representative should tell the non-EU manufacturer(s) to inform its (their) non-EU customers, if any, that the substance is 'new' and that if it is sent into the EU in any form (substance as such or in a preparation) the sole representative must be told.

It should be noted that, in contrast to multiple repeat notifications, there is no 60-day delay for each new importer.

2. Taking over current notifications

If a sole representative takes over a series of individual import notifications, the sole representative must send to the competent authority documentation equivalent to that above and also:

a) A statement from each of those importers agreeing to the cancellation, by the lead competent authority, of those individual notifications, which then go into abeyance with zero t.p.a. (but remaining on the database and in ELINCS, and with the possibility for revival later as independent import notifications).

b) If the notifications are only to 6th Amendment level, they must simultaneously be upgraded to a single 7th Amendment notification within a time limit set by the competent authority.

3. The mixed situation

It is also possible to have a mixed situation where some imports are covered by a single sole representative 7th Amendment notification but the rest remain as individual 6th (or 7th) Amendment repeat notifications.

4. Practicalities

a) The notification shall be made to the sole representative's national competent authority whatever the distribution of importers - none of whom needs to be in that Member State.

b) The sole representative should inform the Competent Authority with whom they are in contact:

(i) Of the total quantity being placed on the EU market each year by the group of importers/ manufacturers the sole representative arrangement covers (by the following March); and

(ii) When that aggregate exceeds 10 t.p.a. (or 50t cumulative) etc., as for any other notification.

The Competent Authority will, along with the other information provided by the sole representative. (e.g. as under para 3 above), pass this information on to the other competent authorities under an agreed system.

c) The sole representative will have all the other usual responsibilities associated with notification such as reporting tonnages (as under (b)), arranging for Level 1/2 or other EU-agreed' tests to be done, and to an agreed timescale. The sole representative must also inform the competent authority of any new information normally expected of a notifier (e.g. new uses etc.). In the situation of multiple imports from a non-EU manufacturer, once the sole representative receives a copy of the official notification summary they must inform the individual importers, or ensure that the individual importers have been informed by the manufacturer, of the agreed classification and labelling. Further, when the import is of a dangerous substance or preparation, the sole representative should ensure that each is provided, by the sole representative or the manufacturer, with a copy of the Material Safety Data Sheet (MSDS).

5. Change of sole representative

There are various situations in which a change of sole representative becomes necessary or desirable. The following procedures address identified scenarios for sole representative arrangements involving multiple imports from a non-EU manufacturer.

a) The sole representative decides to withdraw from the arrangement, goes out of business, or otherwise does not fulfil their duties under the Directive in which case the substance in question will no longer be treated as having been notified. In this event either:

   (i) The manufacturer can appoint (either in the same or another Member State) a new sole representative to take over the duties. To do so, and to ensure no interruption of the notification, the manufacturer must inform, in advance, the competent authority holding the notification, obtain the agreement of the current sole representative to transfer the notification to the new sole representative and ensure the above responsibilities are made clear to the new sole representative. The current sole representative must inform the competent authority of his agreement to transfer the notification to the new sole representative and this new sole representative must write to the competent authority confirming that they are willing to take on the necessary duties, will do so from a stated date, has informed all current importers of the changeover, and has been provided with all relevant data so that they can maintain the cumulative tonnages and other records. Providing continuity is maintained, the notification number and the competent authority will remain unchanged, the competent authority informing other Member States by an immediate update. If the current sole representative does not agree to transfer the notification then the new sole representative will need to pursue a new notification. If the new sole representative is in a different Member State to the current sole representative then a new notification number will be required; or

   ii) No such arrangements are made for' a new sole representative, in which case those importers who wish to continue importing the substance would need to make formal repeat notifications, with the appropriate pre-supply delays depending on the level of notification (but with the normal possibilities for "data-share"). Until then the substance would be treated as not being notified.

b) The manufacturer withdraws from the arrangements and wishes to revert to sending the substance into the EU through one or more individual importers. This would require repeat notifications for each importer, with the same constraints, as under 5(a)(ii) above.

c) The manufacturer withdraws from the arrangements as part of ceasing to trade in the EU market. The sole representative must inform the competent authority holding the notification of the manufacturer's action. In these circumstances the notification will be in abeyance.

(d) The current sole representative or manufacturer voluntarily transfers the duties to a new sole representative, in which event the same conditions as under (a) above apply, with the addition that a further letter from the current sole representative confirming acceptance of the change must be sent to the competent authority.

Queries

Any queries, including change of sole representative scenarios not covered above (notably for sole representatives involving several non-EU manufacturers exporting to a single importer), should be addressed to the local competent authority.

7.6.2 Interpretation of "any person established"

The meaning of "any person established" (Article 2(1)(d), 2nd indent of Directive 92/32/EEC) has been discussed[127]. After a thorough exchange of views the general orientation of the meeting was that only a legal "registered" entity could be designated as sole representative.

7.6.3 Sole representative/importers

Three possibilities could be envisaged for substances manufactured outside the European Union[128]:

- a sole representative,
- a series of independent importers,
- a mixed situation (one sole representative + a series of independent notifiers).

The Directive did not foresee the possibility of designating several sole representatives by one manufacturer.

7.6.4 Non-EU contract manufacturer[129]

It was agreed that in the case of a non-EU manufacturer, under Directive 92/32/EEC, the contract manufacturer should designate the sole representative.

7.7 EXPORT AND RE-IMPORTS OF EU-MANUFACTURED

127 46th meeting of Competent Authorities, Brussels, 22-23/2/1994
128 47th meeting of Competent Authorities, Athens, 1-3/6/1994
129 49th meeting of Competent Authorities, Brussels, 30-31/3/1995

SUBSTANCES

7.7.1 Notified substances:

The question concerned a new substance manufactured in one Member State and notified there. This substance had then been bought by a non-EU company and introduced back into a 2nd Member State within preparations.

At the 43rd meeting of Competent Authorities[130], where the matter was briefly discussed, it was agreed that the substance should be notified again in the 2nd Member State. During their 47th meeting[131] the Competent Authorities reached the same conclusion.

In reply to a question concerning how to handle notified EU-manufactured substances exported and then re-imported into the European Union, it was agreed that such substances should be notified again when re-entering the EU and quantities in the first instance accumulated for the purpose of deciding subsequent test packages.

At their 48th meeting[132] the Competent Authorities considered that in the case of an EU manufacturer who places some of the substance on the EU market and some of the substance is exported and subsequently re-imported:

- the EU manufacturer is responsible for notifying the quantity they place on the EU market, the re-importer(s) (or sole representative) and the manufacturer are jointly responsible for the overall quantity placed on the markets (i.e. directly on the EU market and via import). The re-importer(s) (or sole representative) is (are) responsible for a notification of the quantity re-imported (normally a repeat).

Competent Authorities agreed to take all reasonable steps to avoid any double counting of quantities placed on the EU market, and the Competent Authorities and the European Commission agreed to persuade industry to accept this practical interpretation of the Directive.

7.7.2 Non-notified substances:

At the 48th meeting of Competent Authorities[133], the Commission stated that, in accordance with Article 5 (1) first indent of Directive 67/548/EEC, all new substances placed on the EU market must be notified. Article 2 (1) (d) states that it is the EU manufacturer (first indent) or the importer into the EU of a substance manufactured outside the EU who is responsible for notification, unless a sole representative is appointed (second indent). The Competent Authorities recognised, however, that in the case of re-importation into the EU of an EU-manufactured new substance, where the manufacturer may not know of the re-importation, the procedure in Article 2 (1) (d) first indent is not practicable.

Following a discussion of practical solutions to the problem, aimed at ensuring all new substances placed on the EU market were adequately notified, the Competent Authorities

130 43rd meeting of Competent Authorities, London, 14-16 December 1992 - NOTIF/5/93 rev.1
131 47th meeting of Competent Authorities, Athens 1-3 June 1994
132 48th meeting of Competent Authorities, Brussels 17-18 January 1995
133 48th meeting of Competent Authorities, Brussels 17-18 January 1995

considered that in this case the practical interpretation of the Directive should, in the following two cases, be as follows:

1· Export of the total EU production of one manufacturer and the subsequent re-importation of some or all of that production by one re-importer:
   - the re-importer is solely responsible for the notification and the quantity.

2. As (1) above but more than one re-importer:
   - each re-importer is responsible for notification and they are jointly responsible for the quantity. If a sole representative is nominated the responsibilities are with the sole representative.

Competent Authorities agreed to take all reasonable steps to avoid informing the EU manufacturer of details of the re-import, when requested by a re-importer. It is recognised, however, that in certain circumstances this may be difficult because of data sharing requirements and joint responsibility for notification quantities.

The Competent Authorities considered[134] the status of substances manufactured in the EU, subsequently exported without being placed on the EU market and then re-imported e.g. in preparations and the possibility of utilising the sole representative facility described in section 7.6.1 for such substances. In developing the guidance document on the Sole Representative facility[135] (see section 7.6.1), the Competent Authorities concluded that the facility could also be utilised for such substances, brought back into the EU by a series of importers.

7.7.3 Designation of sole representative:

At the 60th meeting of Competent Authorities[136] it was considered that a sole representative may be designated as follows:

(1) in the case of export and re-import, by the EU manufacturer (who may assume this duty himself), or,

(2) in the case where EU-manufactured substances which have been exported outside the EU (e.g., for formulation), then brought back into the EU by a series of importers, but the EU manufacturer may not be aware of the re-importation, the sole representative may be designated by those importers. Thus, where the EU manufacturer may not be aware of the re-importation by a series of importers, responsibility for notification and for monitoring quantities placed on the market may be assumed by a sole representative designated by those importers. In this case the sole representative will also act as the notifier for the series of importers in question.

134 48th meeting of Competent Authorities, Brussels 17-18 January 1995
135 52nd meeting of Competent Authorities, Dublin, 8th October, 1996
136 60th meeting of Competent Authorities, Paris, 12-13 February, 2001

8 PLACING ON THE MARKET

8.1 DEFINITION OF THE TERM “PLACING ON THE MARKET”

The definition of this term[137] in Article 2(1)(e) of the Directive is “the making available to third parties”. “Third parties” should be viewed as other legal persons; thus a transfer between two companies, even if they belong to the same group, is included, while transfer between two factories operated by the same company is not. Transfers between employees of the same company are not included where the employees act on behalf of the employer, not independently.

In the view of the Commission’s Services this definition covers all transfers of control, not only those which are accompanied by transfer of ownership. Transfer to a processor, for instance, is therefore covered by the definition. This view is supported, in particular, by the use of the phrase “making available” as an alternative to “supplying”, which implies an intent to cover transactions which do not involve a transfer of ownership.

Holding in stock by the manufacturer should not be considered to constitute a “placing on the market”. Otherwise, notification would have to take place in some case before the substance was even manufactured, due to the 60 day or 30 day period. In addition, the exemptions in the case of export and in the cases referred to in Article 13 would be severely limited, since the destination or eventual use of the substance would not generally be known at the time of stocking.

8.1.1 Company division as two commercial entities[138]:

A query was raised concerning definition of marketing applicable to manufacture among two commercial entities partitioned from an original single company. A chemical intermediate in question, previously transferred between two factories in one company, had become liable to transfer between two companies. Notification under toll manufacture would normally apply.

The case details are as follows: Company A (the synthesiser) intends to lease all licence to Company B (the purchaser) the plant required for manufacture of the intermediate. The plant would be supervised by Company B staff. Manufacture would be by Company A staff contracted to Company B for this aspect of their employment. There would be a mechanism to ensure that the staff in Company A would be paid by Company B for the work carried out by Company B. Company B would be in control of the manufacturing process at all times. Consequently, it is argued that Company B would be the manufacturer for the purposes of Directive 67/548/EEC, with exemption from notification.

It was agreed that "placing on the market", defined in the Directive as "making available to third parties", covered all transfers of control and not only those accompanied by transfer of ownership. Transfer to a processor is therefore covered by the definition where a notification would be required.

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137 Extract from doc. XI/790/82 of 16 /02/1983: "Working document of the Commission's Services on the interpretation of Directive 79/831/EEC". The opinion of the Commission's Services is in no way final, since only the Court of Justice is qualified to interpret legislation.

138 Technical and scientific meeting, Ispra, 14-15/3/2000, NOTIF 3/2000; 61st CA meeting, Stockholm 27 June 2001, NOTIF 45/2001

8.2 EXPORT AND TRANSPORT OF SUBSTANCES HAVING REGARD TO THEIR PLACING ON THE MARKET[139]

The Directive is designed to control substances, which are placed on the market "in the Member States". Where the transfer of a substance takes place before export from a Member State, this constitutes a placing on the market within the Community.

Where the manufacturer exports directly or where the transfer of control takes place while the goods are already undergoing a custom transit procedure, there is no "placing on the market" within the Community. This interpretation is based in part on Article 1(2):

"This Directive shall not apply to substances in transit which are under customs supervision, provided they do not undergo any treatment or processing".

Where simple transport by a third party carrier is concerned, Article 1(2) provides that:

"This Directive shall not apply to the carriage of dangerous substances by rail, road, inland waterway, sea or air".

It may be concluded from this that physical transfer to a carrier is not of itself to be regarded as "placing on the market". It may become necessary to define more clearly the limits of these exceptions in the case of export and of transport.

8.2.1 Import to EU customs territory[140]

Article 2(e) (Definitions) of Directive 92/32/EEC specifies ‘Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Directive’. Import territory is defined by EU rather than member state borders, including customs warehouses.

With reference to a specific case, a substance manufactured outside the EU may be legitimately marketed in the EU, with importer based in one MS (e.g., Germany), port of entry located in a second MS (e.g., Belgium), sole representative designated in a third MS (e.g., United Kingdom), and customers unspecified in any MS.

8.3 PRE-MANUFACTURING NOTIFICATION[141]

When it is apparent to a competent authority that a substance will not be placed on the market, then a notification under the Directive is not required.

139 Extract from doc. XI/790/82 of 16 /02/1983: "Working document of the Commission's Services on the interpretation of Directive 79/831/EEC". The opinion of the Commission's Services is in no way final, since only the Court of Justice is qualified to interpret legislation.

140 63rd meeting of Competent Authorities, June 2002, NOTIF/5/2002

141 36th meeting of Competent Authorities, 27-28/11/1990 - NOTIF/1/91 rev. 1

9 PROCEDURES FOR PROVISION AND EXCHANGE OF INFORMATION

9.1 SUMMARY OF THE NOTIFICATION DOSSIER

Article 17 of Directive 92/32/EEC provides that the Competent Authorities shall send the Commission a copy of the notification dossier or a summary thereof. The Commission has prepared a standardised form, which has been redesigned and improved along the years. The latest version was approved by Member States in February 1990[142,143]. In view of the computerisation of the exchange procedure, a Summary Notification Interchange Format (SNIF) has been developed[144].

9.2 GUIDANCE DOCUMENTS TO NOTIFIERS UNDER THE 7TH AMENDMENT

Guidance documents for notifiers on the preparation of base set and level 1 and 2 notifications have been prepared by the Competent Authorities, replacing the "Guidance Notes to those completing a summary notification dossier" drawn up under the 6th Amendment. These guidance documents have been published by the European Commission[145.]

9.3 SHARING OF DATA (ARTICLE 15 OF DIRECTIVE 92/32/EEC)

9.3.1 Data sharing - Article 15

At the 50th CA meeting[146] the question was raised as to whether the data-sharing provision in Article 15 of the 7th Amendment applies to notifications made under the 6th Amendment.

9.3.2 Legal Position

1. Article 15.1 specifically refers to notifications made under Articles 7.1 and 8.1 (i.e. 7th Amendment notifications) being able to be referred to by a subsequent notifier, there is no mention of referring to 6th Amendment notifications.
2. Article 15.2 could be interpreted as being a new requirement under the 7th Amendment and therefore would not place a duty on the Competent Authorities to respond to data sharing requests involving 6th Amendment notifications.
3. If 6th Amendment notifications are referred to, the subsequent notifier must provide the data required under the 7th Amendment and not included in the 6th Amendment.

142 Doc XI/85/90 final

143 32nd meeting of Competent Authorities, 27-28/2/1990 - NOTIF/9/90

144 NOTIF/27/89 rev. 3

145 Notification of New Chemical Substances in Accordance with Directive 67/548/EEC on the Classification, Packaging and Labelling of Dangerous Substances Technical Guidance for the Completion of a Summary Notification Dossier for a New Chemical Substance Utilising the Structures Notification Interchange Format (SNIF), Base-Set and Levels 1 and 2. Office for Official Publications of the European Communities, 1997, Luxembourg. ISBN 92-828-0195-0

146 50th meeting of Competent Authorities, Madrid, 22-23/11/1995 - NOTIF/3/96 rev.1

9.3.3 Commission Proposal

1. A purely legalist approach to the issue of data sharing would not be in line with one of the stated objectives of the 7th Amendment, i.e. avoiding unnecessary testing on animals. What is important as far as the system for the notification of new substances is concerned is the information available; an artificial distinction between 6th and 7th Amendment information would not be helpful.
2. The Commission therefore proposes that all Competent Authorities agree to

(i) apply Article 15 to all notifications, whether made under the 6th and 7th Amendments;

(ii) encourage and promote the sharing of data for all notifications made under the 6th and 7th Amendments; and

(iii) in cases where a "new" notifier has been given permission to refer to a 6th Amendment notification, request the "new" notifier to provide the information required under the 7th Amendment but not included in the 6th Amendment.

9.3.4 Data sharing enquiries

During the 46th meeting of the Competent Authorities[147], it was agreed to adopt a common policy in response to enquiries from (prospective) notifiers who are enquiring, as is generally to be encouraged, as to whether "their" substance has already been notified. This would help screen out frivolous enquiries from firms wanting to know what other competitors are doing. The information to be provided by the prospective notifiers is listed as:

1. IUPAC name (or description, if a UVCB substance);
2. Structure and molecular formula;
3. Nature and percentage of impurities;
4. Competent Authorities number;
5. Analytical and spectroscopic data (as required for 1.3.5 and 1.4);
6. Intended use and quantity to be placed on the EC market;
7. EEC number for substance, if believed to be in ELINCS;
8. Stereochemistry for optical/geometric isomers;
9. Client's identity (if the enquiry is from a test house on behalf of a client).

147 46th meeting of Competent Authorities, Brussels, 22-23/2/1994 - NOTIF/5/94

9.3.5 Procedures[148]

As to the attitude to adopt when several Competent Authorities were approached by the same prospective notifier, it was decided that he/she should be encouraged to contact the authority in the country in which he intended to notify.

It was agreed that when a notification was required from a manufacturer in a country "new" to the system (i.e. SWE, NOR, AUS), for a substance previously notified all possible steps should be taken to avoid repeat animal testing.

It was agreed that for all levels and types of notification Competent Authorities should take all possible steps to avoid unnecessary animal testing; the data sharing procedure should be observed before a substance is sent for testing prior to notification.

Substances placed on the market for the purposes of process-orientated research and developments (R & D) do not have to be notified, therefore there is no need to carry out tests on animals as part of a notification. Any information required by a CA should take animal welfare considerations into account. Once the exemption period is over (e.g after one year), and a notification is required, the data sharing provisions in Directive 92/32/EEC come into force [149].

9.4 10 YEAR RULE

At the 51st meeting of the Competent Authorities[150], the Commission reported that the view of the DG XI legal service on the applicability of Article 9 of Directive 92/32/EEC was as follows “In the absence of any specific transitional provisions, Directive 92/32/EEC is to be fully applied since 31 October, 1993. Therefore, notifiers should provide the information required under the 7th Amendment not supplied under the 6th Amendment.”

According to Article 9 of the 7th Amendment of the Directive, a new notifier need not to submit test data, if the data were originally submitted at least 10 years previously.

The 10-year rule is not applicable for limited announcements under the 6th amendment, because limited announcement are exemptions from the notification requirements and fulfil only national requirements. Updates would require new tests where existing data had been submitted within 10 years.[151],[152]

The rule is applicable 10 years after original acceptance of data, when summary results should be made available (not full test reports).[153],[154]

148 47th meeting of Competent Authorities, Athens, 1-3/6/1994 - NOTIF/11/94
149 49th meeting of Competent Authorities, Brussels, 30-31/3/1995 - NOTIF/16/95
150 51st meeting of Competent Authorities, Rome, 5-7/6/1996
151 7th Technical and Scientific Meeting, Ispra, 1-2/09/98, NOTIF/21/98-rev.1
152 56th Meeting of Competent Authorities, Vienna, 18-19/11/98, NOTIF/2/99
153 58th Meeting of Competent Authorities, Helsinki, 22/11/99
154 9th Technical and Scientific Meeting, Ispra, 7-8/9/99, NOTIF/99 rev.3

9.5 LISTING OF COMPONENTS AND IMPURITIES AND THE DEGREE OF DETAIL NORMALLY NEEDED

In order to describe the identity of a notified substance, both the components and the major impurities have to be listed. The Competent Authorities discussed on a number of occasions the degree of detail normally expected, and agreed on the following at their 53rd meeting[155]:

1. A substance must consist of at least 80% of the (main) component to be covered by an EINECS entry.
2. The same rule applies for entries in ELINCS.
3. Notifications: Substances consisting of different main components, the highest of which is < 80%, are mixtures.
4. Constituents present at levels of 10% or more in a mixture are components and are inserted in the SNIF-field 1.3.10. If there is no indication to the contrary, constituents lower than 10% are impurities and are inserted in the SNIF-field 1.3.20 along with residual starting materials, residual solvents, non-intended reaction products and inorganic salts at whatever %.
5. All the components have to be identified and measured. Impurities have to be identified and measured if they are 1% or more. Impurities which are thought to be labelled with T, or T+ or R50 (including R50-53) have to be measured and listed if the content is 0.1% or higher.
6. Impurities below 1.0% or 0.1% are listed only if the notifier provides the information on a voluntary basis. Grouping of similar substances is preferred.

155 53rd meeting of Competent Authorities, the Hague, 11-12/6/1997

10 MULTIPLE (REPEAT) NOTIFICATION

10.1 REPEATED NOTIFICATION OF THE SAME SUBSTANCE[156]

10.1.1 The relevant provisions of Directive 67/548/EEC

Article 6(1) of Directive 79/831/EEC or Articles 7(1) and 8(1) of Directive 92/32/EEC provide that any manufacturer or importer of the same new chemical substance is subject to the same obligations. Notification must be given by any person placing on the market a new substance compared with what existed on the Community market on 18 September 1981 and compared with what he himself has marketed previously.

However for a given substance placed on the market and manufactured outside the Community, the manufacturer may designate his sole representative for the purpose of submitting a notification (Article 2(1)(d) of Directive 92/32/EEC).

Article 6(2) of Directive 79/831/EEC or Article 15(1) of Directive 92/32/EEC, however, lays down that in the case of a substance which has already been notified the Competent Authority may agree that the notifier may, for the purposes of the technical dossier, refer to the results of the studies carried out by one or more previous notifiers (See data sharing, Section 9.3), provided that the latter have given their agreement in writing. This possibility is limited explicitly to the technical dossier only. The other three parts of the notification dossier must be completed by each notifier:

- a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged;
- the proposed classification and labelling of the substance in accordance with the Directive;
- proposals for any recommended precautions relating to the safe use of the substance.

The interpretation of the term "placing on the market" confirms that the notification is effectively due from each different legal person, and hence, for example, from different companies even if they are part of one and the same group.

10.1.2 Aim and usefulness of repeated notifications

The entire procedure of repeated notifications reflects a basic concept that the Member States wished to see enshrined in the Directive: that all the notifiers of the same substance are on equal terms. Accordingly, the cost of notification (technical dossier) does not lie solely with the first notifier (generally the innovator) since market forces may also play their part.

There is another very important advantage of repeated notifications. They trace how a substance develops on the market: origin, quantifies, uses, distribution, new information on the properties of the substance. However, the development of this substance may also be traced by the sole representative system. The whole idea of a sole representative was to deter importers from submitting multiple/repeat notifications.

156 10th meeting of Competent Authorities, 8/3/1984 (XI/330/84)
11th meeting of Competent Authorities, 7/6/1984 (XI/489/84)

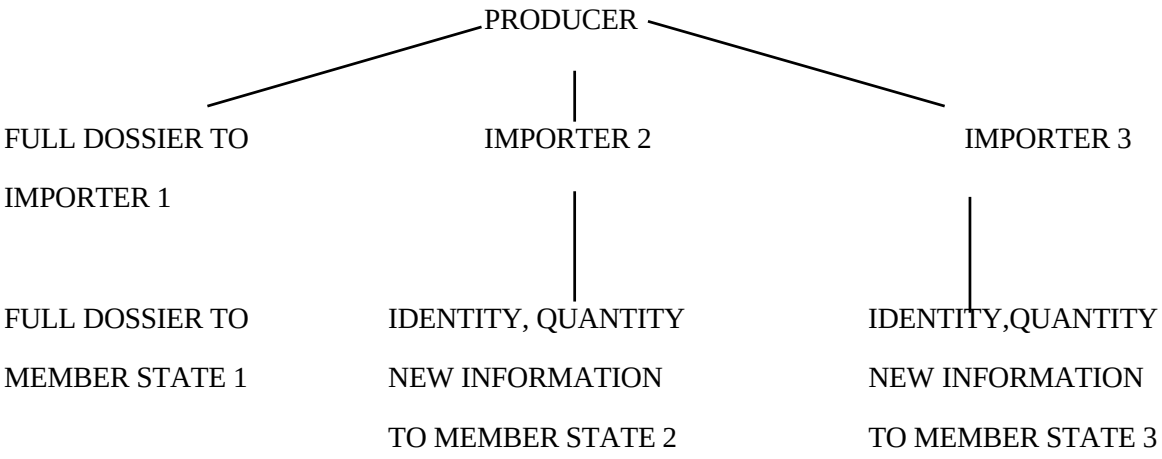
10.1.3 Description of situations which may arise

Basically, there are two possible cases:

1. the substance is produced by two entirely independent companies: being manufactured under different conditions, the type of impurities and the percentage of impurities as well as the degree of purity of the substance will no doubt be different. Conceivably, the substance could be tested by each manufacturer and notified independently. Where an identical process is involved, resulting in what appears to the Competent Authority concerned to be an essential identical substance (within the expected commercial composition range), by comparison of spectroscopic data on the two substances, Article 15(1) of Directive 92/32/EEC can be applied for the technical dossier on the basis of an arrangement between the interested parties. None the less, a firm must be aware that the substance in question is being marketed by someone else;

2. the substance is produced by a single non-Community parent company and imported directly into several Member States by, for example, subsidiaries of the producer. This is then definitely the same substance and the same notification dossier is involved, and Article 15.1 is clearly applicable for the technical dossier.

The routine adopted for the provision of information in this latter case is as follows:



10.2 AGREEMENT OF THE FIRST NOTIFIER FOR USE OF HIS DATA FOR THE TECHNICAL DOSSIER[157]

When a Competent Authority receives a summarised dossier for a substance already notified elsewhere it must ask for the written agreement of the first notifier. When a full dossier is submitted for a re_notification the written agreement of the first notifier is not needed.

157 18th meeting of Competent Authorities, 18/6/1986 doc. XI/462/86

10.3 THE LEAD COMPETENT AUTHORITY AND MULTIPLE NOTIFICATIONS

1. In the case of multiple notifications, the obligations resulting from the Directive, particularly supplementary testing requirements, are addressed to each notifier and not on a "per substance" basis[158]

2. The lead competent authority is the authority to whom the substance is first notified. Therefore, even in those cases where a subsequent notifier does not refer to the original notification under Article 15 (1) of Directive 92/32/EEC, the lead Competent Authority will remain the authority that received the original notification[159]

3. In the case of multiple imports of the same substance, made by the same manufacturer, the authority first receiving a notification dossier is designated as the lead Competent Authority, responsible for developing future testing programmes and for correspondence, through the first notifier, to the manufacturer[160]

4. Where there are several manufacturers of the same substance located inside or outside the Community, the authority receiving the first notification is designated as the file leader, responsible for co-ordinating the Community response while recognising that problems such as impurities may make complete harmonisation, concerning classification and labelling for example, impracticable.

DEFINITIONS

1. File leader notification

The oldest notification (dossier) received for a particular substance, whatever the manufacturer: the Competent authority receiving is the file leader. The notifier is called file leader notifier.

2. First notification

The oldest notification (dossier) received for a particular substance, produced by a particular manufacturer. The Competent Authority receiving such as dossier is the lead Competent Authority. The notifier is called the first notifier.

3. Other first notification

The oldest notification (dossier) received for the same substance, produced by different manufacturers. Each Competent Authority receiving the oldest dossier from one manufacturer is lead Competent Authority for all dossiers relating to that particular manufacturer. Each notifier providing the oldest dossier form one manufacturer is the first notifier for that particular manufacturer. The Competent Authority receiving the oldest dossier (irrespective of manufacturer) is the file leader.

Other first notifications are subdivided into two types:

158 28th meeting of Competent Authorities, 15-16/3/1989, NOTIF/10/89

159 28th meeting of Competent Authorities, 15-16/3/1989, NOTIF/10/89

160 32nd meeting of Competent Authorities, 27-28/2/1990, NOTIF/9/90

(a) Repeat notification

Other first notification with subsequent manufacturer in collaboration with the first one.

(b) Second notification

Other first notification without collaboration between manufacturers (full dossier).

4. <u>Multiple notifications</u>

Notification related to a substance already notified and produced by the same manufacturer (reduced or full dossier). This situation is now usually covered by a sole representative arrangement.

10.4 FILE LEADER

10.4.1 Identification of the file leader if two notifications are made of the same substance in different Member States on the same day

It was agreed[161] that if two notifications of a substance are made on the same day in different Member States the file leader should be established by the following procedure:

1. Commission informs the two Competent Authorities of the situation;
2. the two Competent Authorities should, bilaterally, try and reach agreement on which will be the file leader (e.g. on basis on tonnages) and inform the Commission; and
3. if agreement is not reached the file leader will be based on the first notification received by Commission.

10.4.2 Change of a file leader (I) when a substance is no longer being manufactured in that country[162]

1. With regard to the question of repeated notifications, the principle of a Competent Authority as file leader has been accepted. The file leader is generally the first Competent Authority to have received the notification.
2. There are now several cases where a substance having first been manufactured or imported in one Member State (and notified there), is no longer being manufactured or imported there. The role of the lead Competent Authority becomes difficult, because the notifier on its territory is no longer interested in the substance and will most likely not have the updated information. It is also not possible to ask a firm to carry out the work (contacts with the Competent Authority, updating of quantities, further testing, etc.) for a substance it no longer places on the market.
3. When the lead Competent Authority is aware that a substance is no longer manufactured or imported on its territory by the first notifier, it informs the Commission thereof. Automatically (unless quantity criteria should prevail) the Competent Authority who

161 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/16/95
162 24th meeting of Competent Authorities, 7-8/3/1988 - Doc. XI/179/88

received the second notification becomes lead Authority. However, for this Competent Authority to be able to carry out its task, it must be handed over the full dossier (or a copy thereof).

If production or importation is resumed by the original (first) notifier, it has been agreed[163] that the rule of continuity would apply (i.e.a Competent Authority designated as LCA even as a result of a transfer should remain LCA as long as possible).

The decision for the transfer of competence back to the original LCA should be based on the same criteria as those applied for a first transfer.

10.4.3 Change of a file leader (ii) for substances notified before 1 January 1995 in a Member State and manufactured in Sweden, Austria and Norway[164]

It was agreed that when a substance was notified before 1 January 1995 in a Member State but was manufactured in Sweden, Austria or Norway the file leader should, in principle, change to the country of manufacture. Competent Authorities should resolve such cases bilaterally and inform ECB when the file leader has changed so that the database can be updated; the transfer of "file leadership" should not happen until the "new" CA is in a position to accept responsibility for such notifications. If work is currently being carried out on the notification (e.g. a risk assessment) the concerned Competent Authorities should co-operate to complete the work and transfer 'file leadership once it is completed.

10.5 IMPORTATION/SEVERAL MANUFACTURERS, SAME SUBSTANCE

Should an imported substance, manufactured by several different manufacturers outside the Community, be notified once or several times?[165]

According to the advice of DG XI's legal service, within the framework of the 6th Amendment the Competent Authority could not request of the notifier the submission of several different dossiers (1 per manufacturer) for the same substance (provided the substance is the same).

On the other hand, under the 7th Amendment, for substances manufactured outside the Community, the notification should be submitted by a person designated by the manufacturer as his representative. Unless the importer is the representative person designated by all the manufacturers, several different notifications are necessary.

163 40th meeting of Competent Authorities, 17-18/12/1991, NOTIF/9/92 rev. 1

164 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/16/95

165 30th meeting of Competent Authorities, 4-5/10/1989, NOTIF/23/89

10.6 THE NEW SUMMARY NOTIFICATION DOSSIER (IN ACCORDANCE WITH THE 7TH AMENDMENT) AND MULTIPLE NOTIFICATIONS[166]

When a repeat notification is made by a second notifier, the latter will be required to submit the additional information foreseen in the new summary dossier format required under the 7th Amendment but which is missing from the original (6th Amendment) dossier that has been submitted. However, if necessary, the lead Competent Authority will take responsibility to obtain the missing information from the first notifier if the second notifier is unable to provide the information.

166 37th meeting of Competent Authorities, 25-26/2/1991, NOTIF/15/91

11 CLASSIFICATION AND LABELLING

11.1 CLASSIFICATION AND LABELLING OF NEW SUBSTANCES: PROCEDURE FOR ADOPTION IN ANNEX I[167]

New substance structured notification interchange format (SNIF) files, submitted to the Commission (European Chemicals Bureau, ECB) for distribution to other member states (MSs) include classification and labelling (C&L) proposals from file leader competent authorities (CAs) according to Annex VI of Directive 67/548/EEC.

A six-month deadline is set, from the date of original despatch from ECB, for MSs to comment on a lead CA proposal. Within a further three-month period, lead CAs should submit a final C&L proposal to ECB, indicating documented amendment or variance of opinion.

In practice, a separate C&L file containing the lead CA proposal would accompany the SNIF file when distributed to all MSs. On expiry of the 6-month period for comment, ECB would issue a reminder to all MSs, listing notifications eligible for final C&L proposal.

In absence of comment within the deadline (and to simplify administration) the lead CA would take no further action. Effectively, original C&L proposals, without observations attached, would be considered as final. ECB would then indicate C&L status, viz.: 'no comments'.

In cases where C&L is revised during the 6-month comment period, an updated C&L file would be distributed. The lead CA should confirm final C&L proposal within the further 3-month period, submitted to ECB as a separate C&L file created in SNIF format for updating the database file at ECB. C&L files containing revised final proposals should indicate C&L status, viz.: 'comments taken into account' or 'comments require discussion'.

Substance lists, sorted according to final C&L proposal status and differentiating health from environment, would be forwarded to a committee of C&L experts for approval and/or review. Subsequently, final proposals would be forwarded to a technical progress committee (TPC) for vote in adaptation to technical progress (ATP). Substances with C&L resolved are then incorporated into Annex I of Directive 67/548/EEC. Revision of C&L is admissible at any stage (e.g., on basis of new data availability) validated by the committee of C&L experts. Amendment of Annex I entries requires updated ATP vote.

For information, substances with C&L concluded among experts, pending formal vote of adoption into Annex I of Directive 67/548/EEC by ATP, are included in a published list, available at ECB internet address: http://ecb.jrc.it/new-chemicals/.

167 63rd meeting of Competent Authorities, June 2002, NOTIF/5/2002

11.2 CONFIDENTIALITY ISSUES IN RESPECT OF CLASSIFICATION AND LABELLING OF NEW CHEMICAL SUBSTANCES[168]

A problem of confidentiality will arise when classification and labelling proposals for new substances are examined and confirmed since the content of notification dossiers must be handled confidentially. While working on the list of notified substances it was decided that the identity of a new dangerous substance could not be disclosed until the substance was listed in Annex I to the Directive, i.e. until all the classification and labelling work was completed.

Where appropriate, new substances will be classified and labelled on the basis of the data contained in the notification dossier, and only security-cleared persons have access to these dossiers. The aim, therefore, in classifying and labelling new substances is to develop a procedure that gives every guarantee of confidentiality while ensuring consistency with the procedure for existing substances.

The solution to the problem of confidentiality is to treat new substances separately from existing substances at separate meetings.

11.3 LABELLING OF A SUBSTANCE ON THE BASIS OF THE PROPERTIES OF A SIMILAR SUBSTANCE[169]

For effects for which there is no test method, but which present a possible danger (estimated on the basis of the properties of similar substances or practical experience), it is in the spirit of the Directive to label accordingly. In any event, labelling must always be ratified by the Committee for Adaptation to Technical Progress.

11.4 DIFFERENT LABELLING FOR THE SAME NEW SUBSTANCE[170]

Where a new substance is the subject of more than one notification, it may be that the proposed labelling will not be identical for each dossier. In this case it is better to adopt the labelling presented in the first notification (chronologically speaking) while waiting for a final labelling to be established by the procedure laid down in Article 29 of Directive 92/32/EEC. It is also possible that where the purity/impurity profile of nominally the same substance made by different manufactures and/or routes differ significantly, the labelling may remain different.

11.5 THE USE OF S-PHRASES TO LABEL NON-CLASSIFIED SUBSTANCES[171]

If manufacturers wish to draw attention to a "danger" presented by a non-classified substance, they may voluntarily use S-phrases (e.g. "S22 - do not breathe dust", where a dyestuff structure suggests the possibility of respiratory sensitisation). In fact:

168 11th meeting of Competent Authorities, 7/6/1984 doc XI/489/84
12th meeting of Competent Authorities, 9/10/1984 doc XI/748/84
169 13th meeting of Competent Authorities, 6/12/1984 doc. XI/31/85
170 15th meeting of Competent Authorities, 20/6/1985 doc. XI/496/85
171 20th meeting of Competent Authorities, 10-11/3/1987 doc. XI/278/87

- if a substance is not dangerous according to the terms of the Directive, but the notifier or the Competent Authority nevertheless want to draw attention to certain properties, S-phrases can be used but not R-phrases, which are too closely related to the symbols;

In these cases the placing of the S-phrases on the label can in no event be mandatory, it must be done on a voluntary basis after discussion between the notifier and the Competent Authority. A second notifier cannot automatically be compelled to do the same.

11.6 USE OF THE COLOUR INDEX NOMENCLATURE[172]

The Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry (ETAD) asked Competent Authorities to consider the use of the Colour Index Nomenclature for the labelling of colouring materials classified as dangerous.

It was concluded that this nomenclature could not at present be considered an internationally-recognised nomenclature.

For substances which are not yet in Annex I, but which provisionally should be labelled, the Colour Index Nomenclature cannot therefore be used as it does not comply with the criterion in Article 23(2)(a) of Directive 92/32/EEC ("internationally recognised..."). The substance in Annex I may be listed with an abbreviated nomenclature, but always in addition to the IUPAC name, on the condition that this abbreviated name is unambiguous and the criteria for assigning the name are clearly known and definitive. This does not at present appear to be the case for the Colour Index Nomenclature.

11.7 CLASSIFICATION AND LABELLING OF SUBSTANCES AS SENSITISERS (R43 OR R42)

11.7.1 Skin sensitisers[173]

Common point of concern occurred in several dossiers related to the use of the results of testing on humans in the classification and labelling of substances as skin sensitisers (R43).

It was agreed that positive test results on animals should take precedence. The only case where the test on humans should influence the decision on classification is where human test results are positive and the animal test results negative. In general it is, however, accepted that tests on humans should be discouraged (see Chapter 3.2.6 of Annex VI).

11.7.2 Respiratory sensitisers[174]

An "in vitro" test method for sensitisation by inhalation is being developed by the European Centre for the Validation of Alternative Methods (ECVAM). Until this test method is ready, the R42 risk phrase and the safety phrases S22 or S23 should be used if there was evidence that a substance may be a respiratory sensitiser (see also 11.5 above).

172 16th meeting of Competent Authorities, 16/10/1985 doc. XI/745/85

173 31st meeting of Competent Authorities, 4-5/12/1989, NOTIF/28/89

174 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/16/95

11.8 LABELLING AND TESTING OF NOTIFIED SUBSTANCES IN RELATION TO THE PRESENCE OF IMPURITIES[175]

The following conclusions were agreed upon:

1. for the classification and labelling of substances containing dangerous impurities, the rules of the "Preparations" Directive (88/379/EEC) will apply;
2. all the base set tests will be carried out on the substance with impurities;
3. at levels 1 and 2 it was accepted that the same strategy should apply as for other substances. That means that although additional testing may not be necessary for the purpose of classification and labelling it is nevertheless necessary to carry out such tests to cover other objectives of the Directive (e.g. improved knowledge of substance and risk assessment);
4. it was accepted that in the case where the composition of the substance was altered with respect to the level of impurities, then an update should be made to the dossier including new tests, if such changes in composition were likely to change the classification. In the case where two substances, with and without impurities, continued to be commercialised two entries should be foreseen for Annex I.

11.9 FLEXIBILITY IN LABELLING ANNEX I SUBSTANCES[176]

At their 44th meeting, Competent Authorities briefly considered this question. The meeting noted that, according to the Directive, it was not permissible to allow some flexibility to notifiers to modify the official labelling position published in Annex I.

11.10 CLASSIFICATION AND LABELLING OF SUBSTANCES AS EYE IRRITANT

11.10.1 Irreversibility of effects as a criterion for R41[177]

It was agreed that, for the time being, the guidance as outlined below should be used if the test method (B5) had not been fully carried out. This was necessary because sometimes the 21 day period of the test was reduced to avoid further suffering to test animals.

11.10.2 Reversibility of the effects of the eye irritation test

The eye irritation tests have to be conducted according to the Annex V method, i.e. the reversibility of the effects have to be established at the end of the period of observation.

However, certain eye irritation tests were carried out before the irreversibility of the effects were taken into account for R41 classification. These tests were sometimes stopped after 72 h without checking whether the effects would be reversed.

175 34th meeting of Competent Authorities, 3-4/7/1990, NOTIF/30/90
176 44th meeting of Competent Authorities, 5-7/5/1993, NOTIF/18/93
177 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/16/95

In this case, to avoid repeating a test the following criteria should be followed: the R41 risk phrase is allotted if the irritation indexes observed at 72 h are, on at least one animal:

- corneal opacity: equal or higher than one, or
- lesion of the iris: equal to or higher than one, or
- conjunctive redness or oedema: equal or higher than 2

This means that if the irritation indexes observed after 72 h are 0 for corneal opacity, 0 for the lesion of the iris and one for conjunctive redness or oedema and if the criteria for the R36 risk phrase are not filled, the substance should not be classified as an eye irritant.

11.10.3 Persistent coloration as a criterion for R41[178]

It was agreed that there is no need currently to revise testing methods and classification criteria in order to accommodate this effec[t.]

178 Technical Scientific Meeting of Competent Authorities, Ispra, 11-12 /9/1995

12 SUBSTANCE TO BE TESTED

12.1 PURITY OF THE SUBSTANCE TESTED

12.1.1 Under the 6th Amendment[179]

Article 2(1)(a) stated that the word "substances" means "chemical elements and their compounds as they occur in the natural state or as produced by industry, including any additives required for the purpose of placing them on the market".

The preambles to Annexes VII and VIII lay down that tests shall be carried out on the substance to be marketed. This provision (in parallel with Article 2(1)(a)) indicates that the tests should be conducted using the substance marketed[180].

Annex VII sets out the information to be provided in a notification about the identity of the substance. This includes the degree of purity and the nature and percentage of impurities. The notification is therefore given for a substance with the degree of purity indicated in the dossier.

But to what extent should tests be carried out on the substance marketed when the effective percentage of the new substance is low compared with the total quantity of the product? This state of affairs is often due to the presence of auxiliary agents such as solvents or precipitating salts, the elimination of which is not necessary for the intended use, or which are even added for reasons of commercial convenience. This does not relate to impurities, which must not be equated with additives or by-products.

It has been decided to divide auxiliary agents into two categories:

1. essential agents, which are the additives required for placing on the market, e.g. additives needed to isolate the substance during the industrial process or to conserve its properties;
2. agents which are not present for any other reason and which are therefore non essential.

To prevent a situation from arising whereby the test results give information on the auxiliary agents rather than on the new substance, notifiers will be encouraged to eliminate (or not to add) non_essential agents when they test the substance.

This division into "essential/non-essential" categories is compatible with the definition of "substances" given in Article 2(1)(a) of the Directive, which refers to the additives required for marketing, meaning essential additives.

In any case it must not be forgotten that Article 6(4) of the Directive requires any notifier of a substance already notified to inform the Competent Authority of any changes in the properties resulting from a modification in the purity.

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179 11th meeting of Competent Authorities, 7/6/1984 (X1/489/84)

180 It has been agreed, however, (32nd meeting of C.A.) that "gross amounts of water, mineral oil or other solvents, etc. should be removed before the substance is tested even if it is marketed with these solvents present (see doc. NOTIF/15/89 "Guidance Notes to those completing a Summary Notification Dossier", General Points, item 1 and Detailed Comments, item 1.3).

12.1.2 Under the 7th Amendment

Article 2(1)(a) now states that the word "substances" means "chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

This definition rendered pointless the discussions and decisions described under point (i) above. Any solvent which may be separated from the substance without affecting the stability of the substance or changing its composition has to be removed from the substance sample to be tested.

12.2 NOTIFICATION OF A BASE AND ITS SALT[181]

In the case of the notification of a base and its salt should tests be carried out on both substances?

The Competent Authorities concluded that:

- tests should be carried out unless it is absolutely demonstrated that they are not necessary;
- a notification dossier should not be accepted if further information is requested;
- a dossier is incomplete if a Competent Authority considers it still needs reassurance on certain points.

12.3 DEGRADATION PRODUCTS[182]

According to the advice received from DG XI's legal service it is deemed acceptable for Competent Authorities to request notifiers to carry out further testing on degradation products if this is thought necessary for evaluating the risk of a substance notified under this Directive.

This opinion is based on the powers given to the authorities in Article 16 of Directive 92/32/EEC and applies even if the degradation products are "existing chemicals" i.e. in EINECS.

12.4 NOTIFICATION OF SUBSTANCES (ENZYMES) PRODUCED AND PROCESSED IN DIFFERENT MEMBER STATES[183]

Article 2(e) (Definitions) of Directive 92/32/EEC specifies ‘placing on the market’ as ‘making available to third parties’. Manual of Decisions entry 8.1 considers ‘this definition covers all transfers of control, not only those which are accompanied by transfer of ownership. Transfer to a processor, for instance, is therefore covered by the definition’. Notification procedure regarding a substance produced and processed in different member states, is provided by a model case decision.

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181 21st meeting of Competent Authorities, 15-16/6/1987 doc. XI/67/87

182 29th meeting of Competent Authorities, 16-17/5/1989, NOTIF/16/89 rev.1

183 63rd meeting of Competent Authorities, June 2002, NOTIF/5/2002

An enzyme is generated in one member state in a fermentation process using a GMO. The resulting culture “broth” is purified in another member state for use as a disposable catalyst. The final concentrate comprises only 4% enzyme (dry weight) prepared for use as a dilute solution, 10% total dry matter in water.

Notification in either member state, respectively as a UVCB or pure substance, might be warranted. Moreover, to notify either the culture broth or the solution may trigger unrealistic tonnage thresholds, where essentially water would be the assayed material.

It was agreed that the country of notification should be the one where production (broth fermentation) originates, and where testing of the dry matter (i.e., increasing dose level by 10-fold, to correct for the 90% dilution) would be appropriate.

13 TESTING METHODS

13.1 INTRODUCTION

The Competent Authorities have made a number of decisions related to testing methods. A number of these related to the parallel between OECD and EC methods and, prior to the updating of Annex V (Directive 92/69/EEC), to clarification of technical aspects of the test methods. A number of decisions also related to appropriate testing strategies for notified substances. The majority of the principles contained in these latter decisions have now been incorporated in the Technical Guidance Documents for Risk Assessment (see Section 16). Those decisions which have not been included in the TGD are outlined below.

The currently relevant texts of EC test methods (Annex V, base set) are to be found in Directives 92/69/EEC, 93/21/EEC and, from 31 May, 1998, Directive 96/54/EEC. Annex VIII (level 1 and 2 tests) are to be found in Directive 88/302/EEC. Details of these Directives are to be found in Section 1. Test methods for polymers (Annex VIID) are currently being finalised. The relevant texts of the Directives relating to Good Laboratory Practice (GLP) also apply.

13.2 EXPLOSIVE AND OXIDISING PROPERTIES

13.2.1 Guidelines for the determination of oxidising properties (Supplement to A17 method) [184]

Applicability

Before performing test A 17 for the determination of oxidising properties, it is important to check that this test is applicable to the substance.

Test A 17 is not applicable to liquids, explosive or highly flammable substances, it is therefore useful to perform tests A1, A 10 and A 14 before performing A 17.

Test A 17 cannot be applied to organic peroxides: these substances are classified as oxidising on the basis of their structure.

Test A 17 need not be carried out when examination of the structural formula establishes beyond reasonable doubt that the substance has no oxidising properties.

Compounds which have no highly electronegative atom - oxygen, fluorine, chlorine, bromine - are not likely to possess oxidising properties. Similarly, where these elements are present but the atoms are only bonded to carbon and/or hydrogen, then oxidising properties are unlikely.

A substance may have oxidising properties when:

- the electronegative atoms which are present constitute a high proportion of the molecule and are bound to elements in a high oxidation state;
- the electronegative atoms are bonded to each other or to other electronegative elements such as iodine, nitrogen, sulphur or phosphorus.

184 46th meeting of Competent Authorities, 22-23/2/1994, NOTIF/55/92 rev. 5

As the ability to predict the reactivity of chemical compounds from their structure is still limited, the best approach is by analogy with existing compounds. If the substance meets one of the above criteria, the lack of any reactive group named in Annex I may not be sufficient to justify not performing the A 17 test.

For organic substances only, the oxygen balance (OB) calculation may be useful as a criterion combined with an examination of the chemical structure as a means of predicting oxidising properties.

13.2.2 Annex V A17 Testing Method (false positives)

At the 39th meeting of Competent Authorities[185] a particular case was discussed where a substance gave a positive result in test A17 (oxidising properties) was not classified as oxidising by the Competent Authority concerned on the basis of the structure of the substance (i.e. the test result was a false positive according to that Competent Authority).

A discussion took place on the necessity of requiring a complementary test to reject the first positive result or whether expert advice could suffice. In general it was concluded that if a test had given a positive result, only a new negative test could lead to a change in the classification of the substance. However, more recently it has been concluded that if it is considered on the basis of expert opinion that the chemical structure indicates that the substance cannot possess oxidising properties, then this may be sufficient reason not to classify and label the substance as oxidising. Alternatively a test for false positives, using Kieselguhr, is outlined in Annex V. Current Guidance is available from Competent Authorities.

13.2.3 Explosive properties. Annex VII, point 3.11 – Applicability of the method

The method is appropriate for determining whether a substance or preparation will present a danger of explosion (thermal and mechanical sensitivity) in the particular conditions specified in the Directive.

The text of method A14: Explosive Properties (Directive 84/449/EEC) indicates under point 1.1 Introduction, 4th par.: "The tests are irrelevant when available thermodynamic information (heat of formation, heat of decomposition, absence of certain reactive groups in the formula) establishes beyond reasonable doubt that the substance or preparation is incapable of decomposing, forming gases and releasing heat very rapidly (i.e. the material does not present any risk of explosion)".

Examples of thermodynamic information:

- Heat of formation and heat of decomposition.
- Most chemical reactions are exothermic, but in the few endothermic reactions heat is absorbed into the reaction product(s) which are known as endothermic (or energy-rich) compounds. Such compounds are thermodynamically unstable because heat would be

185 39th meeting of Competent Authorities, 19-20/9/1991, NOTIF/37/92

released on decomposition to their elements. The majority of endothermic compounds possesses a tendency towards instability and possibly explosive decomposition under various circumstances of initiation.

- Many, but not all, endothermic compounds have been involved in violent decompositions, reaction, or explosions and, in general, compounds with significantly positive values of standard heat of formation may be considered suspect on stability grounds.
- Values of thermodynamic constants for elements and compounds can be found in specialised literature, but it should also be noted that endothermicity may change to exothermicity with increase in temperature.

Examples of compounds containing endothermic groups:

Acetylenic compounds

Alkyl metals

Azides

Boranes

Cyano compounds

Dienes

Halogen oxides

Metal acetylides

Metal fulminates

Oxides of nitrogen

Presence of certain reactive groups:

Various structural factors are known to confer explosivity to the substance or to enhance explosibility properties. Their presence in a molecule indicates a potential hazard related to explosive properties. The following are some of the most common reactive groups - acetylenic, metal acetylenic, diazirine, diazo, nitroso, nitro, acyl or alkyl nitrite or nitrate, epoxide, triazene, peroxide, azide, chlorate, perchlorate. In contrast a structure with a very low Oxygen Balance (less than minus 100) indicates a low tendency for explosivity.

13.3 USE OF STRUCTURE ACTIVITY RELATIONSHIP TO DETERMINE WHICH TESTS ARE TO BE CARRIED OUT[186]

Structure activity relationship cannot be used to reduce the number of tests provided for in Annex VII, but can lead to further information being requested.

186 12th meeting of Competent Authorities, 9/10/1984 doc. XI/748/84

13.4 GUIDANCE FOR THE COMPLETION OF A SUMMARY NOTIFICATION DOSSIER[187]

13.4.1 Hydrolysis test

A corrigendum to the Commission guidance on completion of SNIF (booklet dated February 1997) has been agreed, respective of section 5.2.21, which should read as follows:[188, 189]

13.4.1.1 Hydrolysis as a function of pH

General:

This test need not be carried out if the substance is readily biodegradable or if the notifier can demonstrate, for example on the basis of chemical structure, that hydrolysis cannot be expected to play a significant role in the degradation of the substance in the environment. For poorly soluble substances (<1 mg/l), consideration may be given to omission of the test if it is not practical, i.e. the limit of detection of the analytical method does not allow quantification.

13.4.2 Adsorption/Desorption Assay

A strategy for implementation of adsorption/desorption assay, integral to notification, intended for updating of Commission guidance on completion of SNIF (booklet dated February 1997) has been agreed. Section 5.3.10 (page 62) [where absence of guidance had been awaiting availability of an agreed procedure] should read as follows:[190]

13.4.2.1 Adsorption/Desorption Screening Test

For base set notification (Annex VII A) determination of K_{oc} by HPLC analysis (Annex V test method C19) would normally be applicable. At upper tier notification (Annex VIII, levels 1 and 2) or in case of hazard concern, determination of adsorption/desorption on soils, including K_{oc}, using the batch equilibrium method (Annex V test method C18) would be applicable.

Where determination of K_{oc} at base set (method C19) is either technically not feasible or scientifically invalid, estimation of K_{oc} using QSAR prediction would be acceptable. QSAR calculations derive log K_{oc} from linear extrapolation of log K_{ow}. Either HPLC or batch equilibrium methods are valid for determination of K_{ow}. For many chemicals, HPLC analysis and QSAR estimation of K_{oc} would yield similar results.

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187 Notification for new chemical substances in accordance with Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances - Technical Guidance for the completion of a summary notification dossier for a new chemical substance utilising the structured notification interchange format (SNIF), Base set and Level 1 and 2. ISBN 92-828-0195-0

188 7th Technical and Scientific Meeting, Ispra, 1-2/09/98, NOTIF/21/98-rev.1

189 56th Meeting of Competent Authorities, Vienna, 18-19/11/98, NOTIF/2/99

190 63rd meeting of Competent Authorities, June 2002, NOTIF/5/2002

K_{oc} values obtained from QSAR prediction are influenced according to alternative model equations, which should be applied as appropriate. Acceptable QSAR estimations also require conformity to validity criteria (e.g., non-polarised molecules, single functional group structures, etc.). In practice, the scope of QSAR prediction is limited to experienced case by case evaluation.

Further information is available from Commission technical guidance on risk assessment, respective of new (Directive 93/67/EEC) existing (Regulation 1488/94) and biocide (Directive 98/8/EC) substances (http://ecb.jrc.it/).

14 TESTING STRATEGIES

The Competent Authorities made a number of decisions in the past related to testing strategies, including testing strategies for inhalation, mutagenicity and biodegradation testing, choice of route of administration in the 28 day test, and replacement of the 28 day test by a 90 day test. The principles contained in these decisions have now been incorporated in the Technical Guidance Documents for Risk Assessment (see Section 16).

15 LEVEL 1 AND LEVEL 2 TESTING

15.1 ROUTINE PROCEDURE TO ESTABLISH A TESTING PROGRAMME[191]

The quantities of a substance placed on the market are reaching higher levels and Annex VIII testing will be required more and more. Therefore, it was considered useful that a routine procedure be developed for Annex VIII testing.

Annex VIII testing is dependent on actual quantities placed on the market, and not on predicted tonnages. However, if the notifier does not correct his predictions with the real figures and inform the Competent Authority thereof, the Competent Authority can only base its actions on the predictions in the dossier.

Within level 1 of Annex VIII, the Directive establishes two sub-levels:

- 10 t per year or a total of 50 t
- 100 t per year or a total of 500 t

At 10 t/year (or 50 t total), the Competent Authority may require additional studies; at 100 t/year (or 500 t total) the Competent Authority shall normally require the tests to be carried out.

When the lead Competent Authority draws up the list of tests it wants carried out in the framework of Annex VIII, the other Member States may also introduce requirements. But to do so, they must be informed and have the opportunity to see the requirements of the lead Competent Authority and to comment on them.

In view of the above, the following procedure is agreed upon:

1. when the threshold is reached, the lead Competent Authority informs the Commission and suggests the tests it would require;
2. the Commission circulates this information to the other Competent Authorities;
3. the Competent Authorities send their comments (and reasons why) as soon as possible, not later than six weeks afterwards[192,] to the Commission, for onward transmission to the lead Competent Authority.

When establishing a test programme the lead Authority is taking a decision on behalf of all the other Member States and it should take into account all the situations which may arise throughout the 15 Member States[193.]

Testing strategy for level 1 and level 2

The Competent Authorities agreed at their 51st meeting[194] that at present the testing requirements at level 1 and level 2 should be decoupled from the (results of the) risk assessment.

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191 24th meeting of Competent Authorities, 7-8/3/1988 - doc. XI/178/88

192 Experience will tell whether this time period is appropriate and anyway it can be extended on formal request of a Competent Authority who wishes to submit additional proposals.

193 Under the 7th Amendment, art. 7.2 deals with the additional tests and studies for levels 1 and 2 as detailed in Annex VIII.

194 51st meeting of the Competent Authorities, Rome, 5-7/6/1996

15.2 QUANTITIES TRIGGERING ANNEX VIII IN THE CASE OF A SUBSTANCE IMPORTED BY SEVERAL LEGAL PERSONS[195]

If the same substance is imported by several different legal persons (e.g. by several importers) the substance must be notified the same number of times. This can be concluded both from the terms of the Directive and from the interpretation of the phrase "placing on the market".

Annex VIII states that: "any person who has notified a substance to a Competent Authority in accordance with the requirements of Article 6 of this Directive shall provide at the request of the Authority further information and carry out additional tests as provided for in this Annex".

Reference is also made throughout Annex VIII to the obligations of the notifier. It is clear from Articles 2(1)(d), 7 and 8 of Directive 92/32/EEC that the notifier is either the manufacturer of the substance established in the Community or a person established in the Community who imports the substance into the Community, or the Sole Representative (see 7.6).

Community manufacturers should not, however, be penalised, for if the levers triggering Annex VIII refer to individual importers and not to foreign manufacturers these dossiers could pass through the hands of several importers, thus limiting the quantifies attributable to each of them and avoiding application of Annex VIII. It should therefore be possible to calculate the total quantities of a substance from one and the same foreign manufacturer when this substance has been notified several times by importers. The name of the foreign manufacturer must therefore be part of the information exchanged.

Article 7(1) of Directive 79/831/EEC and Article 16 of Directive 92/32/EEC allow for the possibility of asking for further information. To prevent explicit requests for the name of the foreign manufacturer each time and given that it is an element needed to evaluate risks, it was decided under the 6th Amendment to add this item of information as of right in the exchange of information. The name of the foreign manufacturer was therefore mentioned in the summary of the notification dossier as part of a voluntary arrangement between Competent Authorities.

These provisions have changed under the 7th Amendment since Directive 92/32/EEC requires very clearly that only the manufacturer, not the supplier/formulator, of the substance could designate its sole representative (Article 2(1)(d). The whole idea of the sole representative was to deter importers from submitting multiple/repeat notifications[196].

15.3 METHOD OF CALCULATING QUANTITIES TRIGGERING ANNEX VIII[197]

15.3.1 Basic Principles

- Annex VII requires that the quantities of substances be indicated for the first twelve months (t/year) and thereafter (t/year).

195 Fifth meeting of Competent Authorities, 16-17/12/1982 (XI/2/83)
Sixth meeting of Competent Authorities, 10-11/3/1983 (X1/200/83)
196 46th meeting of Competent Authorities, Brussels, 22-23/2/1994
197 18th meeting of Competent Authorities, 18/6/1986 (XI/362/66 and XI/462/86)

- Experience has shown that notifiers generally indicate their forecasts for the first twelve months starting from the date of first placing on the market and then switch to the calendar year thereafter.
- It has also been seen from experience that the forecasts made by the companies are not very accurate and often overestimated. The Competent Authorities can therefore at best only make a rough calculation of the quantities placed on the market from the data contained in the notification dossiers. It is not a question of developing a highly specific calculation method but rather of having a simple tool which will allow the Competent Authorities to monitor notifiers and remind them of their obligations.
- In the case of multiple notifications for the same substance the quantities can only be added when all the figures relate to the same period.

15.3.2 Yearly tonnage limit

Annual production/import tonnage limits, defined according to notification level test requirements in Articles 7 and 8 of Directive 92/32/EEC (7th Amendment to Directive 67/548/EEC) refer to calendar year.

In the year of notification, supply tonnage equivalent to the full calendar year limit is valid, irrespective of calendar year fraction remaining following date of notification.

❖ 57th Meeting of Competent Authorities, Berlin, 17/06/99, NOTIF/?/99

❖ 8th Technical and Scientific Meeting, Ispra, 9-10/03/99, NOTIF/4/99-rev.1

15.4 REQUEST FOR EXEMPTION FROM ANNEX VIII

15.4.1 In the case of temporary import[198]

A firm from outside the Community applied for an exemption from Annex VIII in order to import a substance into the Community temporarily for special processing. The firm agreed to give notification in the form of the base-set, but the quantities were going to top 100 tonnes a year immediately.

Two arguments led to this request being refused:

1. Article 1(2) of Directive 92/32/EEC stipulates that the Directive does not apply to the provisions relating to "substances in transit which are under customs supervision, provided they do not undergo any treatment or processing";
2. application of Annex VIII is a scientific question; it is not possible to prejudge which level 1 or level 2 tests will or will not be necessary, without having the results of the base-set.

15.4.2 In the case of intermediates placed on the market for a short time[199]

It was agreed that a pragmatic, case by case, approach should be taken but that care should be taken not to introduce an unwelcome precedent. In the particular case discussed it was agreed

198 Fifteenth meeting of Competent Authorities, 20/6/1985, doc. XI/496/85

199 50th meeting of Competent Authorities, Madrid, 22-23/11/1995 (NOTIF/24/95)

that the substance, on the basis of the information given, was notifiable. A level 1 and 2 test package would not be sought unless the substance was placed on the market for a second time; another CA had however received an enquiry from the manufacturers of the same substance. An entry would be put in the SNIF stating that if the substance was placed on the market a second time a level 1 and 2 test package must be completed. In similar cases in the future Competent Authorities were recommended to identify level I and 2 test package with the notifier at the time of the base-set notification.

15.5 NEED TO PERFORM THE FERTILITY TEST REFERRED TO IN ANNEX VIII[200]

Must a fertility test always be requested when the 100t/year level is reached?

Under the terms of the Directive, it is the notifier who has to justify the non-performance of the test and not the Competent Authority which has to justify testing. Also, the intended uses of a substance cannot be a condition for the performance of a test or otherwise, as the notifier does not have control over all possible uses of his substance.

This question has been discussed as part of the exchange of information on test programmes for Annex VIII. The strategy for reproductive toxicity testing is also addressed in the Technical Guidance Documents for risk assessment (see Section 16).

15.6 LEVEL 1 TESTING – SUBCHRONIC/CHRONIC/MUTAGENESIS/CARCINOGENICITY SCREENING[201]

The majority view concerning the interpretation of the requirements for level 1 at the 100 tonnes per annum level elaborated at the 27th meeting of the Competent Authorities was as follows:

- a subchronic and/or chronic toxicity study should be carried out if the results of the base-set testing suggest it is appropriate to do so;
- with respect to additional mutagenesis studies (including screening for carcinogenesis), testing should include both aspects, this interpretation being without prejudice to the preamble for Annex VIII which allows that tests are not carried out if it is not technically possible or if it does not appear necessary.

The strategy for subchronic/chronic toxicity, mutagenicity and carcinogenicity testing is also addressed in the Technical Guidance Documents for risk assessment (see Section 16).

15.7 LEVEL 1 TESTING – NEED TO PERFORM A SPECIFIC TERATOGENICITY TEST

It was agreed[202], [203] that unequivocal teratogenicity effects observed during fertility study would be sufficient for Classification & Labelling (classification with R61) and would, in

200 16th meeting of Competent Authorities, 16/10/1985, doc. XI/745/85

201 27th meeting of Competent Authorities, 6-7/12/1988 (draft Summary Record dated 22/12/88)

202 8th Technical and Scientific Meeting, Ispra, 9-10/03/99, NOTIF/4/99-rev.1

general, exempt further testing. However, further testing may be required to define a No-Effect-Level (NOEL) including the nature of dose-response. Equivocal effects observed during fertility study would warrant specific teratogenicity testing.

203 57th Meeting of Competent Authorities, Berlin, 17/06/99, NOTIF/?/99

16 RISK ASSESSMENT

16.1 INTRODUCTION

Risk assessment of notified substances was discussed on many occasions within the framework of the 6th Amendment, and a number of meetings of the Competent Authorities were specifically devoted to this aspect. Article 3(2) of the 7th Amendment required "the real or potential risk to man and the environment shall be assessed on the basis of the principles adopted.....". These principles were established in Directive 93/67/EEC[204] of 20 July, 1993, and detailed technical guidance on carrying out risk assessment of both new and existing substances has been subsequently been developed by the European Commission in consultation with the Member States.[205]

The European Commission has organised two Workshops on Risk Assessment, to identify problems encountered by the Competent Authorities and to ensure as far as possible a common approach. These Workshops were held at the JRC, Ispra, in 1996 and in Copenhagen in 1997, and the Proceedings of the Ispra Workshop has been published[206]. The Proceedings of the Copenhagen Workshop will be published in the future.

16.2 USE CATEGORIES

In the framework of Risk Assessment, it had been decided[207] that use categories should be entered in the summary notification dossiers by using the definitions included in doc. NOTIF/23/90, from 1st January 1992. This document has been revised several times since then and finally discussed at a Risk Assessment meeting on 1-2 April 1993 where it was finally adopted. At their 44th meeting[208] Competent Authorities confirmed this decision·

In the Technical Guidance Documents, Part III, three types of categories are distinguished, i.e. main category, industrial category and use category. The main category was created originally to supply default values for release fractions where adequate information is lacking. The four sub-categories of this category type are related to different stages of the life cycle, and are as follows:

I Use in closed systems

- non-isolated intermediates
- isolated intermediates stored on-site
- isolated intermediates with controlled transport

II Use resulting in inclusion into or onto a matrix

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204 OJ No. L 227, 8.9.93, p. 9.

205 Technical Guidance Documents in support of Commission Directive 93/67/EEC on risk assessment of new notified substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances. Office for Official Publications of the European Communities, Luxembourg, 1996. ISBN 92-827-8011-2

206 Risk Assessment, Theory and Practice, Ed. Vollmer, G., Giannoni. L. Sokull-Klüttgen and Karcher, W. Office for Official Publications of the European Communities, Luxembourg, 1996, ISBN 92-827-7311-6

207 40th meeting of Competent Authorities, Den Haag, 17-18/12/1991, NOTIF/9/92 rev.1

208 44th meeting of Competent Authorities, Copenhagen, 5- 7/5/1993, NOTIF/18/93

III Non_dispersive use

IV Wide dispersive use

"Use in closed systems " as such refers to the processing stage when a substance is used in a transformer or a circulation circuit of refrigerator; on the other hand it may refer to the stage of production where a substance like an intermediate is manufactured in closed apparatus.

"Use resulting in inclusion into or onto a matrix" may refer to the stage of formulation, e.g. when a substance is included in the emulsion layer of a photographic film. It also may refer to the stage of processing, e. g. when a substance applied as a UV_stabiliser in pain$_t$s ends up in the finished coating layer.

"Non dispersive use" and "wide dispersive use" are related to the number (and size) of the emission sources.

16.3 RISK ASSESSMENT FOR COSMETIC SUBSTANCES[209]

For new substances which are cosmetic active ingredients and which are placed on the market individually a risk assessment should be executed. When relevant, the result can be communicated to the Cosmetics Directive group which will then decide what actions to take.

The Commission stated that a risk assessment should be carried out on cosmetic ingredients which are placed on the market separately from the cosmetic product. The Commission would investigate how the results of risk assessments on cosmetic ingredients could be fed into the system for the evaluation of cosmetic products under Directive 76/768/EEC, there could be a problem of confidentiality of data.

16.4 PERFORMANCE OF RISK ASSESSMENT

The necessity of carrying out a risk assessment for non-classified substances has been discussed. Whereas some Competent Authorities conduct risk assessment only on classified substances, other Competent Authorities prefer to conduct a risk assessment in all cases, i. e. also for non-classified substances for which adverse effects are observed which do not lead to classification but which nevertheless require in-depth consideration. It was recommended not to distinguish between classified and unclassified substances for the risk assessment.[210]

Specifically for high production volume new substances (notifications according Annex VIII of Directive 67/548/EEC: level 2 tonnage) risk assessments should be done, even for 6th Amendment notifications, unless justifiably exempt. Risk assessments should be submitted as updated notifications (SNIF files).[211][212]

209 Technical Scientific Meeting of Competent Authorities, Ispra, 11-12/9/1995 -{NOTIF/15/95)
210 Technical Scientific Meeting of Competent Authorities, Ispra, 11-12/9/1995 - (NOTIF/27/95)
211 58th Meeting of Competent Authorities, Helsinki, 22/11/99
212 9th Technical and Scientific Meeting, Ispra, 7-8/9/99, NOTIF/99 rev.3

16.5 RISK ASSESSMENT WITH CONCLUSIONS (IV) – INTRODUCTION OF SUB-CATEGORIES

Experience with risk assessment in accordance with Directive 93/67/EEC showed that conclusion (iv) led in practice to quite a huge range of different recommendations for risk reduction. Therefore, it was agreed[213,214] to indicate subcategories a, b, c and d resp. (i), ii), (iii) and (iv) for the risk assessment conclusion (iv), as indicated in Article 2 (2) (e) of Directive 93/67/EEC.

16.6 RESPONSIBILITY FOR THE RISK ASSESSMENT

With reference to substances already notified under the 6th Amendment, and therefore not subject to risk assessment, it was agreed[215, 216] that the Competent Authority receiving the first notification under the 7th Amendment would be responsible for the risk assessment.

16.7 SITE SPECIFIC OR GENERIC SCENARIO?

For new substances a generic assessment would normally be conducted. However, there may be circumstances where occupational or environmental exposure for some life-cycle stages is limited to specific sites (e.g. production of chemicals, processing of intermediates etc). It may therefore be adequate to carry out a site specific risk assessment only, if the CA is satisfied that such specific information will enable a full evaluation of the risks. In such cases, it is the responsibility of the notifier to provide site specific data and to show that the available information is valid for the sites being assessed. The risk assessment should make clear that a site specific assessment has been conducted. In these cases, the notifier is obliged to confirm in writing that they will inform the CA of any relevant changes which may affect the risk assessment conducted. The CA should confirm details of the assessment not later than two years after completion of the risk assessment, and at any subsequent tonnage trigger, or as deemed necessary. The CA should distribute relevant information appropriately"[217, 218]

213 5th Technical and Scientific Meeting, Ispra, 23-24/09/97, NOTIF/19/97-rev.1
214 54th Meeting of Competent Authorities, Brussels, 15/12/97, NOTIF/2/98-rev.1
215 6th Technical and Scientific Meeting, Ispra, 10-11/03/98, NOTIF/5/98-rev.1
216 55th Meeting of Competent Authorities, Edinburgh, 23-24/06/98, NOTIF/16/98-rev.1
217 6th Technical and Scientific Meeting, Ispra, 10-11/03/98, NOTIF/5/98-rev.1
218 55th Meeting of Competent Authorities, Edinburgh, 23-24/06/98, NOTIF/16/98-rev.1

17 RESEARCH AND DEVELOPMENT

17.1 GUIDANCE ON RESEARCH AND DEVELOPMENT

A guidance document, NOTIF/10/96, laying down common principles on the interpretation of exemptions for research and development was adopted at the 52nd Meeting of Competent Authorities[219], as follows.

219 52nd meeting of Competent Authorities, Dublin, 8/10/1996

GUIDANCE FOR THE INTERPRETATION OF THE RESEARCH AND DEVELOPMENT EXEMPTIONS IN DIRECTIVE 92/32/EEC

INTRODUCTION

Under Directive 92/32/EEC the interpretation of exemptions for research and development are left, in the framework of subsidiarity, to individual Member States (MS). The Competent Authorities for the implementation of Directive 67/548/EEC (CAs) and industry have, however, identified this as an area where there are significant working differences between the interpretations of the CAs and that this may introduce different levels of protection for people and the environment and possibly barriers to trade. A sub-group of the CAs considered this issue and put forward proposals to all the CAs; following lengthy discussions this paper was agreed as the position of the CAs. It is of necessity in many areas a compromise between the different views of the CAs.

Whilst all the CAs will as far as possible follow this guidance they reserve the right to consider each application on a case by case basis and make decisions outside that given in this guidance if they deem it to be necessary. As a result of national legislation some CAs have more flexibility than others and some CAs will require specific or additional information. All prospective notifiers and those seeking to make use of the research and development exemptions in Directive 92/32/EEC are advised to contact the relevant CA at as early a stage as possible; CAs can often give advice that will save industry time and money in following the requirements in the Directive. This guidance cannot answer, nor does it try to, every possible question on research and development exemptions; questions not addressed should be put to the relevant CA.

This Guidance does not override the legal requirements in the Directive. The requirements of the Directive are paramount.

RESEARCH AND DEVELOPMENT EXEMPTIONS

General

Research and development exemptions cannot be used to establish the commercial viability of a substance (either on its own or in a preparation or in an article).

SCIENTIFIC RESEARCH AND DEVELOPMENT (SRD)

Directive 92/32/EEC

Article 2 - "scientific research and development" means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development.

Article 13 - a SRD exemption can be applied to up to 100 kg per manufacturer per year for substances placed on the market intended solely for SRD carried out under controlled conditions. The manufacturer or importer making use of this exemption must maintain written records containing the identity of the substance, labelling data, quantities and a list of customers.

Interpretation

SRD activities are solely limited to scientific experimentation, research or analysis, under controlled conditions, to investigate the route for chemical synthesis and to collect information on intrinsic properties. SRD activities include:

- synthesis of new chemical substances with as yet uncertain applications;
- analysis, experimentation or research;
- physical/chemical properties testing;
- health and environmental effects testing;
- examining the efficacy of the substance (e.g. screening tests for potential new uses);
- does the substance, in combination with others, act as intended (e.g. UV stabilisers in polymers, stability of preparations).

The phrase "under controlled conditions", is considered to mean persons using the substance must be professional researchers engaged within a research site in collecting information about and monitoring tests of the substances being studied or developed. It may be acceptable to carry out appraisal work on the research site using a group of volunteers from the workforce but distribution off the research site and/or to the general public is not.

PROCESS-ORIENTATED RESEARCH AND DEVELOPMENT (PORD)

Directive 92/32/EEC

Article 2 - "process-orientated research and development" means the further development of a substance in the course of which pilot plant or production trials are used to test the fields of application of the substance.

Article 13 - PORD can only be with a limited number of registered customers in quantities which are limited to the purpose of PORD. The exemption period is one year, after which the substance is normally subject to notification. The manufacturer or importer of the substance must provide the relevant CA with details of the substance's identity, labelling data, quantity, justification for the quantity and a list of customers and the research and development programme.

The above information must be submitted to the CA in each Member State (MS) in which the manufacture, importation or PORD takes place. CAs may also impose other conditions which must be adhered to. These conditions may include information provided for in Article 8 (i.e. up to an Annex VII B notification). An assurance will also be given to the relevant CAs that the substance (or preparation) will be handled only by customer's staff in controlled conditions and will not be made available to the general public at any time either on its own or in a preparation. This restriction may be extended to products containing the new substance which were produced during the PORD if the CA considers that there may be an unacceptable risk to people or the environment.

The exemption period may in exceptional circumstances be extended for a further year if justified to the satisfaction of the relevant CA.

Interpretation

A PORD exemption must be sought in each MS where manufacture, importation or PORD takes place. PORD exemptions will only be granted when a CA is convinced that the activities to be undertaken are compatible with the definition of PORD. A PORD exemption

can only be justified if it is not known whether the substance can be used in the particular circumstances to achieve the desired effects and/or results in a particular production process.

Annex 1 lists the points that, where applicable, should be addressed by a manufacturer or importer to enable the CA to decide whether a PORD exemption is applicable. CAs may require additional information in some cases.

PORD activities can take place outside a research site (i.e. by customers). PORD exemptions may be applicable for a company which has manufactured a substance and makes it available to others to test and when a company receives a substance from another company to test itself.

PORD exemptions can be granted for any stage in a development process. The development process could ultimately lead to the production of an existing substance but if the process being evaluated is new and involves new substances a PORD exemption may be applicable. PORD exemptions may be applicable to any stage in the evaluation of a new process to develop any new product. **Once the PORD activity has been completed and it is planned to place the substance on the market a notification must be made in accordance with the Directive.**

The following is a non-exhaustive list of situations in which a PORD exemption may be granted:

the testing of a new single or multiple-step process;

tests or demonstrations of equipment or production processes, which typically take place in pilot facilities, but may also involve production in full-scale commercial runs (e.g. testing to ascertain whether commercial scale equipment produces the desired result, testing a new or modified process or an existing process at a new site or a scaled-up process to determine process capabilities such as yield, purity, consistency, uniformity);

efficacy and performance tests (e.g. testing of colour or fastness of a dye, efficiency or lifetime of a catalyst) using a new (i.e. not used previously) solvent in an industrial process to see how its performance compares with that currently in use;

making available to another entity to carry out a step in the production process as part of the evaluation of the whole process (e.g. drying by another entity to see if the result enables the next step in the process to be undertaken);

intermediates in the development, by new processes, of new pharmaceutical or pesticidal products prior to authorisation.

Quantities

PORD exemptions should only be granted for the quantity of substance required for the PORD activity. The justification for the quantity must cover the number of activities (e.g. batches, test runs), the quantities used in total and each activity and the quantity to each customer. When the PORD activity is stopped, any remaining new substance must not be placed on the market on its own or in a preparation without notification except for waste disposal but may be incorporated into an article for sale as long .as there is no release of the substance.

Further Information Requested from PORD Applicant if an Exemption is Granted

Currently the approach varies in the Member States in accordance with the flexibility written into the Directive. The test data required ranges from none to that required under Annex VIIB and is assessed by CAs on a case by case basis.

Information Exchange Between CAs

In many cases R & D activity will take place in several MS. To help ensure a consistent approach between CAs:

- for a substance manufactured in the EU, the CA in the country of manufacture will check that other relevant CAs know about the possible use in their country and whether or not they think an exemption should be given.
- for a substance imported into the EU, CAs approached by the applicant will contact, if necessary, other CAs with an involvement in the request. CAs may complete the fiche at Annex 2 and copy it directly to the CAs concerned or to ECB who will copy it to the CAs. The use of the fiche will be evaluated in the future.

Start of R & D Period

The R & D period will start, following the granting of an exemption, when the applicant so wishes; the start date must be confirmed by the applicant.

Extension of PORD Exemption to a Second Year

An extension will only be granted if the applicant can justify why the PORD programme has not been finished and why they want an extension. The application for an extension must be made before the end of the first year of exemption. All testing required must be completed before an extension can be given.

ANNEX 1

INFORMATION REQUIRED FOR A REQUEST FOR A PROCESS-ORIENTATED RESEARCH AND DEVELOPMENT EXEMPTION

The following points should be addressed by the applicant, where applicable:

1a) What is the chemical identity of the substance i.e. structure, IUPAC name, CAS number, impurities, essential additives, spectral data etc.?

1b) What is the envisaged use of the substance?

1c) What R & D work has already been carried out either by yourself or, if appropriate, by the customers involved in the R & D programme (e.g. internally or under the <100 kg per annum scientific R & D exemption)?

2a) What is your justification for wanting to use this exemption (including an assurance that you do not currently know whether you can achieve the desired effect and that you need to carry out research and development to do so)?

2b) What additional information will be gained through the proposed R & D programme? What other methods have been considered for obtaining this information?

2c) Please give a summary of the R & D plan, including the process to be investigated, the timetable and a proposed start date;

2d) Which parameters will be investigated?

2e) What is the justification for the quantity involved in the proposed R & D programme (including justification for the number of batches and quantity per batch etc.)?

3a) What is the name and address of the manufacturer of the substance (if not the applicant)?

3b) Which customers will receive the substance and why and how much will each customer receive (please provide names, addresses and contact names)?

4a) Have you made an application to any other Member States? If so please provide details including the status of these applications.

Either at the time you write requesting an exemption or once we are satisfied with your justification and grant an exemption please provide:

5a) confirmation that the substance, or any preparation containing it, will only be handled by the customers staff under controlled conditions and will not be made available to the general public;

6a) information on how customer(s) ensure protection of people and the environment (e.g. by the provision of an adequate label - including the phrase "Caution - substance not yet fully tested" - disposal procedures etc.);

7a) any test data that is already available on the substance (final results only);

7b) details of any tests you intend to carry out;

8a) estimated date of the corresponding notification; and

9a) information on whether you intend to use the substance to produce articles and whether these would be made .available to the general public.

17.2 DEFINITION OF THE TERM "REGISTERED CUSTOMER"

A registered customer is a person to whom the manufacturer or importer has provided merchandise and who must be on a list transmitted to the Competent Authority upon request. This list must serve to show that the number of customers is limited.

17.3 SUBSTANCE ALREADY NOTIFIED

It was agreed that it was possible to receive a research and development exemption after a substance has already been notified as long as the conditions in Directive 92/32/EEC were met.[220]

220 50th meeting of Competent Authorities, Madrid, 22 -23/11/1995

18 CONTROL MEASURES

18.1 GUIDANCE MANUAL

The Competent Authorities have co-operated in a successful control action programme which has investigated compliance with the requirements of the Directive, in particular the notification of new substances requirements on a European-wide basis. Common principles of enforcement have been agreed and a Guidance Manual for the enforcing authorities has been developed and approved.[221]

This document is the result of the mandate given to a subgroup of Competent Authorities at their 37th meeting[222]. One of the purposes of the manual is to establish a common approach to controlling the compliance with the Directive in relation to the notification of new substances throughout the Community. At the 37th meeting it was agreed that the manual should be used by Member States control authorities for on-site inspections and that reports should be submitted to the Commission, by March 1993, on their experience in applying the recommendations of the manual together with their suggested modifications.

A new revised version of the Manual was briefly considered at the 45th meeting of the Competent Authorities.[223] Before further expanding or updating the document it was decided to request an interim report by the national inspectors at the end of 1994.

In the meantime, several co-ordinated control actions at Community-wide level have already taken place concerning full notifications and 6th Amendment Limited Announcements with the objective of checking quantities actually put on the Community market.

221 42nd meeting of Competent Authorities, Lisbon, 5-6/5/1992, NOTIF/42/92 rev.1
222 37th meeting of Competent Authorities, 25-26/2/1991, NOTIF/15/91
223 45th meeting of Competent Authorities, Brussels, 15-16/12/1993, NOTIF/2/94

19 TRANSITION FROM THE 6TH TO THE 7TH AMENDMENT

19.1 ANSWERS TO QUESTIONS CONCERNING THE IMPLEMENTATION OF THE 7TH AMENDMENT TO DIRECTIVE 67/548/EEC

Prior to the entry into force of the 7th Amendment, the Ca discussed various issues related to the implementation of the new Directive and/or any transitional measures. A policy document, NOTIF/11/93, was agreed, the text of which is reproduced below.

Suggested Answers to Questions concerning the implementation

of the 7th Amendment to Directive 67/548/EEC

Full Notifications: Article 7 of the 7th Amendment

Question 1: Need to up-grade

The information to be provided by notifiers of substances to be placed on the market in quantities above 1 tonne per annum has changed considerably under the 7th Amendment as compared to the 6th. Does this mean that notifiers who have submitted full notifications under the 6th will be requested to "up-date" their notifications to bring them in line with the requirements of the 7th?

Answer

No. Notifiers will not be required to systematically upgrade the notifications they have submitted under the 6th. However, notifiers will continue to be obliged to inform the authorities of any new follow-up information relating to previous notifications and as required under Article 14 of the 7th Amendment.

Question 2: Supplementary Testing Requirements

If a notifier has submitted a notification under the regime of the 6th Amendment and subsequently, once the 7th Amendment comes into force, reaches a marketing level triggering a supplementary testing programme, will that supplementary testing programme be drawn up in conformity with the rules of the 6th Amendment or the 7th Amendment?

Answer

The supplementary testing requirements will be drawn up according to the rules of the 7th Amendment. It will be at the discretion of the Competent Authority responsible whether to ask for the "missing" base set data as part of the supplementary testing programme.

Substances manufactured outside the Community and previously subject to one or more notifications under the 6th Amendment (Article 11 of the 7th Amendment, also Article 7 and the definitions given under Article 2.1)

Statement

Under the 6th Amendment full notifications were submitted by each person responsible for placing a substance on the EC market. This meant that for some substances produced by one manufacturer outside the EC but marketed by many persons inside the EC, we have received many, sometimes up to 50, notifications. Furthermore, the 6th Amendment calculated the tonnages placed on the EC market in relation to each full notification, not in relation to each manufacturer of a given substance. In order to try and avoid the repeated notification of the same substance, the 7th Amendment allows (but does not oblige) manufacturers to nominate for each substance a legal representative who will be responsible for submitting the notification. The dossier will contain details of all separate imports which will be made of the substance. Furthermore, the 7th Amendment states that tonnages placed on the EC market will be calculated per substance per manufacturer and that if there is more than one notifier, all notifiers will be collectively responsible for supplementary testing programmes.

Question 3:

If a substance, produced by one manufacturer outside the EC, has been the subject of multiple/repeated notifications under the 6th Amendment, what will happen when the 7th Amendment comes into force? Will the authorities be required under Article 11 of the 7th Amendment to calculate total tonnages per manufacturer and will supplementary testing requirements be imposed collectively on all notifiers even those who have submitted notifications under the 6th Amendment?

Answer

The Competent Authorities/the Commission will (under Article 11 of the 7th Amendment) calculate the total amounts of the substance (produced by an outside-the-EC manufacturer) placed on the EC market as from the date of entry into force of the 7th Amendment. This means that amounts of the substance placed on the market after the entry into force of the 7th Amendment but related to notifications submitted under the 6th Amendment will be taken into account in these tonnage calculations. However, amounts placed on the market before the entry into force of the 7th Amendment will be not be taken into account in making these calculations.

Question 4:

What is the situation for a new notifier of a substance manufactured by one manufacturer outside the EC, for which numerous notifications have been submitted under the 6th Amendment and for which the new notifier wishes to submit a notification under the 7th Amendment?

Answer

The new notifier will be required to submit a notification according to the 7th Amendment rules.

Question 5:

The same as 4 above but in this case the manufacturer wishes to nominate the new notifier as his sole legal representative and the latter includes with his notification a list of importers covered by the notification, which list includes the names of some or all of the previous notifiers.

Answer

In this case the new notifier should submit statements from those previous notifiers which are covered under the new notification, to the effect that they cancel their previous notifications which should now become void. If this does not happen, previous notifiers would be able to market the substance both under the previous notification and under the new notification submitted by the sole representative. This would make sensible calculations of marketed tonnages totally impossible. Obviously the necessity to include a statement would not apply to new importers i.e. those not covered by previous notifications.

It is of course entirely possible to have a "mixed situation" where a substance manufactured outside the Community is marketed both under one or more notifications submitted under the 6th Amendment and under a new notification submitted in accordance with the 7th Amendment and for which a sole representative has been designated.

NB: A variant of question 5 concerns the case where the manufacturer chooses to name one of the previous notifiers as his sole representative. In this case the notifier would be required to upgrade his earlier notification to the standard required under the 7th Amendment. Where the upgraded notification indicated that it also covered one or more of the importers who had previously submitted notifications under the 6th Amendment, the approach described under question 5 and answer would apply.

Reduced Notification Requirements (Article 8 of 7th Amendment) and Limited Announcements (Article 8 of the 6th Amendment)

Statement

Under the 6th Amendment, substances marketed in quantities of less than one tonne per annum per manufacturer across the EC could be marketed without submission of a full notification (but were nevertheless considered as being notified) on condition that a limited announcement was submitted by the manufacturer to the authorities in each Member State where the substance was marketed and that the manufacturer complied with any conditions imposed by those authorities. Under the 7th Amendment, the concept of limited announcements no longer exists and analogous notification procedures will be applied to substances marketed in quantities less than one tonne per annum as are applied to substances marketed in quantities above one tonne per annum (the data requirements for substances marketed in quantities less than one tonne are, however, reduced as compared to those prescribed for substances marketed in quantities greater than one tonne).

Question 6:

What will be the status of substances, which have been subject to limited announcements under the 6th Amendment? Can they continue to be marketed under the 7th?

Answer

A substance (manufactured by a given manufacturer) subject to one or more limited announcement (s), and therefore considered as being notified under the 6th Amendment, can continue to be marketed under the 7th Amendment without the submission of a notification according to the 7th Amendment on condition that:

a) it is only marketed in the Member State(s) where limited announcement(s) have been submitted under the 6th Amendment;
b) the manufacturer continues to respect the conditions imposed by the authorities in each Member State where a limited announcement has been submitted;
c) the total tonnage placed on the EC market remains less than one tonne per annum (5 tonnes cumulative) for that manufacturer;
d) a notification (for the same substance manufactured by the same manufacturer) in conformity with the 7th Amendment, is not subsequently submitted.

In transposing the 7th Amendment into national law, each Member State should stipulate that for new substances marketed in quantities of less than one tonne across the EC, only those which have been subject to the notification requirements under the 7th Amendment or those which have been the subject of a limited announcement in that country under the regime of the 6th Amendment (provided that the manufacturer is the same) will be allowed access to their national market.

Where Member States have imposed conditions upon manufacturers submitting limited announcements under the 6th Amendment, it is suggested that where manufacturers wish these conditions to be modified that this should act as a trigger for requiring the submission of a reduced notification according to the 7th Amendment.

Where a substance manufactured by one manufacturer and subject to a limited announcement under the 6th Amendment reaches a marketing level of 1 tonne per annum per manufacturer then this should also provide a trigger for the submission of a full notification according to Article 7 of the 7th Amendment. The previous limited announcements will then become void.

Similarly, where a substance (manufactured by a given manufacturer) subject to one or more limited announcements under the 6th Amendment, is subsequently notified according to the provisions of the 7th Amendment, all previous limited announcements should become void.

When a substance (manufactured by a given manufacturer) subject to one or more limited announcements under the 6th Amendment is then notified under the 7th Amendment, the notifier should submit a listing of all previous limited announcements linked to that substance and that manufacturer.

Question 7:

Will substances which have been the subject of limited announcements under the 6th Amendment be incorporated into ELINCS (European List of New Notified Chemical Substances)?

Answer

No. Only substances which have been subject to the harmonised notification procedure under the Directive are included in ELINCS.

Substances manufactured outside the Community and previously the subject of one or more Limited Announcements under the 6th Amendment.

Question 8:

When the 7th Amendment comes into force what will be the status of limited announcements relating to substances manufactured outside the EC: will there be any difference in approach for these substances as compared to substances manufactured inside the EC?

Answer

The status of limited announcements for substances manufactured outside the EC will be the same as for substances manufactured inside the EC and therefore the policy outlined under questions 6 and 7 will apply. In particular the submission of a notification according to the 7th Amendment for the same substance produced by the same manufacturer will render all previous limited announcements void.

The 10 year rule - (Article 9, 7th Amendment; Article 6.3, 6th Amendment)

Statement

The 7th Amendment allows that new notifiers of a particular substance need not provide the information required under Articles 7 and 8 for the technical dossiers in Annexes VII A, VII B, VII C and VII D, with the exception of items 1 and 2 thereof, if the data were originally submitted at least 10 years previously. Similarly the 6th Amendment allowed notifiers not to

submit the data required for the technical dossier in Annex VII with the exception of points 1 and 2 thereof if the substance was originally notified at least 10 years previously.

It should be noted that the 6th Amendment only applied the 10 year rule to base set notification, not to limited announcements.

Question 9:

If data were submitted in support of notifications submitted under the 6th Amendment, does the 10 year rule laid down in the 7th Amendment also apply to these data?

Answer

Yes. The 10 year period is calculated from the date of submission of the data, irrespective of whether this was under the regime of the 6th or 7th Amendments.

Question 10:

What is the status of data submitted in support of limited announcements: does the 10 year rule apply to these data?

Answer

The data submitted under the 6th Amendment in support of a limited announcement were not covered by the 10 year rule. If these data are subsequently used to upgrade a limited announcement to a notification in conformity with the 7th Amendment (see question 11) the 10 year rule will only apply to these data as from the date of acceptance of the upgraded notification.

Re-notification of the same substance and avoidance of duplicating testing on vertebrate animals (Article 15, 7th Amendment, Article 6, 6th Amendment).

Statement

Under the 6th Amendment Art. 6.2 allowed that subsequent notifiers of the same substance could refer to the results of the studies contained in the technical dossier submitted previously by another notifier as long as this earlier notifier gave his permission in writing. This possibility of cross reference is maintained in Art. 15.1 of the 7th Amendment, but problems now arise as to the status of data submitted previously under the 6th Amendment in support of limited announcements. The 7th Amendment also requires in Articles 15.2 and 15.3 that in order to avoid duplicative animal testing, national authorities are obliged to divulge to prospective notifiers the identity of previous notifiers and vice versa in order that they may come to some arrangement to share data and avoid duplicative animal testing.

Question 11:

If a notifier submits a notification relating to a substance which has previously been the subject of one or more limited announcements can he, with the permission of the submitter of the limited announcement(s), (the manufacturer) refer to the data previously submitted?

Answer

It is suggested that cross reference to data submitted in previous limited announcements should be allowed as long as these data were generated according to acceptable (Annex V) test methods and GLP. Note that the 10 year rule would only apply to those data once they

had been accepted as part of the new notification (see question 10). It is clear that the authorities accepting such a notification would be required to circulate summaries of any studies which were cross-referenced as described above.

Question 12:

Can notifiers and manufacturers who have submitted notifications or limited announcement under the 6th Amendment be subjected to the requirements of Articles 15.2 and 15.3 under the 7th Amendment?

Answer

It is suggested that for a period of 12 months following the entry into force of the 7th Amendment, on a case by case basis the first notifier (submitter of a limited announcement) be approached by the authority concerned and encouraged to give his permission for the release of his name/address to the new, potential notifier. After this 12 month period, the provisions of Articles 15.2 and 15.3 should apply equally to notifications submitted under the 6th Amendment and the. 7th Amendment.

Confidentiality (Article 19, 7th Amendment, Article 11, 6th Amendment)

Statement

The confidentiality provisions under the 6th Amendment were more restrictive i.e. more information was allowed to be treated as confidential, e.g. name of manufacturer and notifier, than under the 7th Amendment.

Question 13:

Will notifications submitted under the 6th Amendment now be treated according to the provisions of the 7th Amendment as far as confidentiality is concerned?

Answer

Yes. Council Directive 90/313/EEC on the access to information concerning the environment makes it clear that the authorities should allow greater access to environmentally relevant information. Therefore, if it is considered appropriate that data submitted under the 7th should not be regarded as confidential then it is difficult to argue that similar data on other substances should be considered as confidential because it was submitted under the 6th Amendment.

Exemptions (Article 13, 7th Amendment)

Statement

Some classes of substances exempted under the 6th Amendment (Article 8 para 1) are now covered under the 7th Amendment e.g. laboratory reagents.

Question 14:

What is the status of these substances; should they now be notified even though they were legitimately on the market under the 6th Amendment?

Answer

Yes. These substances should, unless they are covered by other exemptions under Article 13 of the 7th Amendment, be subject to notification. It would appear that substances used in medical diagnostic kits may fall into this category.

19.2 LABORATORY AGENTS

At the 45th and 46th meeting,[224,225] Competent Authorities discussed the status of the several thousands of laboratory agents on the market which were exempted from notification under the 6th amendment but should be notified under the 7th. The majority of participants supported the decision that laboratory agents placed on the market before 1 November 1993 should be exempted from notification.

The Commission legal service has confirmed that the position taken by the Competent Authorities is legally correct and this position should now replace the answer given to question 14 in the document "Suggested answers ... " in point 19.1[226].

Competent Authorities would be free to go back to industry to require further information; this would, normally be less than that required for an Annex VII B[227].

In individual inspections, control authorities could request proof that the substance was already on the market before that date[228] [229].

It was agreed that this exemption only applied up to one tonne per annum per manufacturer[230] [231].

19.3 CONFIDENTIALITY

Under the 6th Amendment, Article 6(2) allowed that subsequent notifiers of the same substance could refer to the results of the studies contained in the technical dossier submitted previously by another notifier as long as this earlier notifier gave his permission in writing. Under the 7th Amendment (Article 13(2) and 15(3)) national authorities are obliged to divulge to prospective notifiers the identity of previous notifiers and vice versa in order that they may come to some arrangement to share data and to avoid duplicative animal testing.

This question was briefly discussed at the 45th meeting of Competent Authorities[232] and it was agreed to grant notifiers a twelve month "period of grace" during which their name and address would not be given to new prospective notifiers against their will, although they would be strongly encouraged to allow this.

224 45th meeting of Competent Authorities, Brussels, 15- 6/12/1993, NOTIF/2/94
225 46th meeting of Competent Authorities, Brussels, 22-23 /2/1994, NOTIF/5/94
226 Addendum to the Summary record to the 49th meeting of Competent. Authorities, Brussels, 30-31/03/1995, NOTIF/16/95
227 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/16/95
228 45th meeting of Competent Authorities, Brussels, 15-16/12/1993, NOTIF/2/94
229 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/16/95
230 Addendum to the Summary record to the 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/16/95
231 49th meeting of Competent Authorities, Brussels, 30-31/3/1995, NOTIF/16/95
232 45th meeting of Competent Authorities, Brussels, 15-16/12/1993, NOTIF/2/94

20 MISCELLANEOUS

20.1 OPPORTUNIST QUESTIONS ASKED BY PROSPECTIVE NOTIFIERS

At their 40th meeting[233], Competent Authorities discussed what attitude they should take when a prospective notifier puts the same question to all Competent Authorities. It was decided[234] that in such cases a Competent Authority should answer and that the others should simply refer to the answer given by the first Competent Authority.

20.2 PUBLIC ACCESS TO DATA

Relationship between Directive 90/313/EEC on the freedom of access to information on the environment and Directive 67/548/EEC.

Directive 90/313/EEC provides that any environment-related information should be made available to the public except where Member States make provisions to limit this access in conformity with Article 19 of Directive 92/32/EEC (this Article lists cases where such limitation can occur, eg. when commercial and industrial secrecy is involved).

The question raised at the 40th meeting[235] of Competent Authorities on this subject were:

1. Does Directive 67/548/EEC on dangerous substances fall within the scope of Directive 90/313/EEC?

2. Do the provisions of Directive 90/313/EEC affect the decisions taken by a Competent Authority under Article 19?

The matter was discussed again at the 41st meeting[236] of Competent Authorities and it was decided that the operating guideline should be that the decision to release or not some data should be taken by the Competent Authority receiving the dossier. Where more than one notification exists for a substance then the view of the Lead Competent Authority should prevail, pending, if disagreements arise, resolution at a future meeting of the Competent Authorities·

At their 44th meeting[237], Competent Authorities considered an initial proposal on what and how information held by the Competent Authorities should be made available to the public in accordance with the Access to Environmental Information Directive.

233 40th meeting of Competent Authorities, Den Haag, 17-18/12/1991, NOTIF/9/92 rev.1
234 40th meeting of Competent Authorities, Den Haag, 17-18/12/1991, NOTIF/9/92 rev.1
235 40th meeting of Competent Authorities, Den Haag, 17-18/12/1991, NOTIF/9/92 rev.1
236 41st meeting of Competent Authorities, Brussels, 5-6/3/1992, NOTIF/24/92
237 44th meeting of Competent Authorities, Copenhagen, 5-7/5/1993, NOTIF/18/93

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