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FOOD MIGROSURE

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EU Project QLK1-CT2002-2390   “Foodmigrosure”

“Modelling migration from plastics into foodstuffs as a novel and cost efficient tool for estimation of consumer exposure from food contact materials”

F I N A L S Y N T H E T I C P R O J E C T R E P O R T

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1 Executive summary

Between March 2003 and September 2006 the FOODMIGROSURE project, contract number QLK-CT2002-2390, was carried out by 9 European project partners with the intention to develop an 'into-food' migration model tool which should enable prediction of mass transfer of constituents from plastics food contact materials into foodstuffs in support of calculations/estimations of the exposure of consumers towards food packaging constituents.

Chronologically, the first objective of the project was to conclude on an appropriate selection of plastics reference films acting as release matrices for model migrants as well as on the type and nature of the chemical migrants themselves. Finally, a total of 18 chemical substances was defined as model migrants covering a representative molecular weight range, chemical and physical nature, most importantly considering polarity and solubility properties.

In parallel, a selection of foods/food groups was carried out following the criteria:
(a) classification of foodstuffs/food groups with respect to those physico-chemical properties which can be expected to influence the behaviour of food as a sorption matrix for the uptake of migrants
(b) consideration of consumption data and market related classification.
Finally, as a synthesis of (a) and (b) and taking also other factors into account such as analytical difficulties or the expectable tendency for migration of a packed food, a list of 23 foodstuffs/food groups could be established as a solid basis for the experimental studies in this project. The selected foods were a priori categorised into three main foods groups: (i) aqueous and acidic foods, (ii) fatty foods and (iii) dry foods.

With the definitions and selections made as described above, the core work of the project was then conducted. The major objective of this work was to establish the physico-chemical parameters needed for 'into-food' migration modelling. These parameters are in the first place the diffusion coefficient in food, D_F, and the partitioning coefficient between food contact plastic and food, $K_{P/F}$. Experimentally these parameters were accessible in a complementary way by performing both, kinetic migration experiments where the time-dependent migration the model substances in foods was investigated and on the other hand by measuring concentration profiles of model migrants in foods after defined time-temperature migration conditions. The latter experiments provide essential information on the deepness a migrant penetrates into a food under given storage conditions. In total 240 kinetic migration curves were measured using test conditions in most cases according to conditions in real use and, concerning concentration profiles, more than 170 experimental set-ups were carried at different time-temperature conditions.

An important pre-work for these studies was the development of appropriate analytical methods for the quantitative determination of the model migrants in all foodstuffs. Indeed a comprehensive collection of analytical methods for all of the model migrants and principally working for all selected foods has been established. This method collection and further technical/analytical guidance to support migration testing was publicised with European Reports EUR 22232 EN and EUR 22552 EN.

Migration processes into and within foodstuffs strongly depend on their nature/composition and physico-chemical properties such as the fat content and solubility for a given migrant. Consequently, a further objective was to establish the specifications and parameters which are typical and representative for the foods used in the studies of this project. These food parameters were established either from the known specifications or by measurements and complied and listed for all of the foodstuffs used in the project.

From the experimental core work extensive data sets on the migration of model migrants in contact with foods have been elaborated. On the basis of these data sets an advanced migration model for the migration from plastics and other materials into foodstuffs was developed. This migration model is therefore considered to be an advanced model because it is based on the exisisting validated diffusion model [EU-project contract SMT-CT98-7513] that already exists for food simulants and was extended for the application to foodstuffs. The working principle of the advanced model can be substantiated as follows: In the 'old' bi-phasic system 'plastic in contact with a liquid medium (food simulant)', the time scale of the migration process is defined by the diffusion coefficient, D, of the migrant in the plastic only and the maximum amount in the contact medium at equilibrium is defined by the partition coefficient, K, of the migrant between plastic and contact medium. Accordingly the system may be denoted as a "D/K" system. On the other hand, foodstuffs can also contribute to the migration process by a food specific diffusion or a diffusion-like process which can be expressed as an effective diffusion coefficient in the food, D. Consequently, a "D/K/D" system was selected as an advanced diffusion model and applied for evaluation of the time dependent migration investigations and concentration profiles into foodstuffs. From this food specific partition coefficients and diffusion constants could be derived which can now be used in general for estimative 'into-food' migration modelling. However, further refinement and validation work will be necessary to improve the model.

To demonstrate the principal use of the into-food migration model for exposure estimations, the model was linked with exposure by drawing exposure scenarios and comparison with exposure case study results from food surveys. This was done by using 9 different migrants known to be present in plastics food contact articles. The requirement for this validation exercise was that migration levels estimated by into-food migration modelling should be higher than real migration into foods (and so be conservative) but should be less than the unrealistic 'worst-case' assumptions made for migration levels in safety evaluations performed currently by the EU conventions. The results from this comparison support the principle applicability of the advanced migration model for establishing concentrations of migrants in foods and thus for exposure estimations.

In parallel to the technical-scientific project activities described above, as a complementary consumer related scientific issue, the social acceptance by the consumer of migration modelling versus chemical measurements and its implications for exposure estimation was investigated. This was carried out by suitable involvement of consumers as well as consumer protection representatives and through communication with other scientific experts outside of the Foodmigrosure project. As an important result it turned out that under certain conditions the consumer will feel confident in migration modelling but not as a stand alone tool and rather in connection with a sufficient degree of experimental verification. From these project findings and experiences it was concluded that new science communication ties between the consumer and risk communication activities at European level can be created.

Already in the course of the project, it turned out that the Foodmigrosure results and findings would have a significant impact on the current EU food packaging safety legislation and on the analytical-technical aspects of food packaging compliance testing. The major reason for that was the insufficient migration simulation capability of the official EU food simulants according to EU Directive 85/572/EEC. This was finally confirmed at end of the project. Indeed, the EU Commission has already taken one important measure to meet the findings of this project: The food simulant water for milk and milk products was corrected by replacing simulant A with 50% ethanol. This correction was implemented in 2007 with EU Directive 2007/19/EC which, in fact, represents an amendment to 85/572/EEC. In the meantime, further regulatory changes are currently in the discussion between the Commission and the member states with regard to the appropriateness of the simulation of foods by the food simulants as laid down in 85/572/EEC.

2 Introduction to the project

Food contact materials like e.g. plastic packaging materials facilitate the preservation, protection and distribution of high quality foodstuffs. Since packaging materials intensively come in contact with foodstuffs it is well known that chemical substances release and migrate from the packaging material into the foodstuff while stored. One important aspect within the European Union's public health care is the exposure of consumers to undesirable chemicals in the diet. Food contact materials (FCM) are one potential contamination source and therefore of particular interest for food exposure assessments. On the other hand, scientific investigations concerning the migration potential and behaviour of food packaging materials have demonstrated that diffusion in and migration from FCM are foreseeable physical and, in principle, mathematically describable processes. To underpin EU public health-monitoring programmes, it is necessary to estimate dietary exposure to chemicals appropriately. For this purpose, reliable information about chemicals in food products and the consumption levels of these products by the European population is needed. Furthermore, to determine the influence of the sub-determinant 'FCM', additional statistical information about the nature, type, size and use frequency of packaging materials applied to these products is required.
The essential equation to calculate exposure from FCM can be formulated as follows:

$$Exposure = \frac{\sum C_i \cdot P_i \cdot M_i}{\sum C_n}$$

where: C_i = *consumption rate of a particular food i*
P_i = *relative packaging usage of a given FCM for a particular food i*
M_i = *migration rate from a given FCM into a particular food i*
n = *the number of foodstuffs considered for the exposure estimation*

Enormous scientific knowledge concerning the migration potential and migration behaviour of food packaging materials has been accumulated in the last 30 years. Most of these investigations and methodological developments have been carried in support of national and European food contact materials legislations or guidelines and recommendations. Consequently, the studies have been performed using officially authorised food simulating liquids. For reasons mainly of analytical difficulties, systematic studies of chemical migration into foodstuffs have only rarely been conducted. All these numerous scientific investigations have demonstrated that diffusion in and migration from food contact materials are foreseeable physical and, in principle, mathematically-describable processes. Mass transfer from a plastic material, for instance, into food simulants is predictable and obeys in most cases to Fick´s laws of diffusion.
As logical consequence of this situation the Foodmigrosure project was initiated within the 5th Framework Programme of the European Commission. The intention with the Foodmigrosure project was to extend currently existing migration models (so far applicable to food simulants) to foodstuffs themselves. The main objective of the project was to provide a novel and economic tool for estimation of consumer exposure to chemicals migrating from food contact materials under any actual contact conditions. Furthermore, the project aimed to increase the knowledge of the mechanisms of diffusion of organic compounds in foodstuffs and to provide data on the partitioning effects between FCM and real foodstuffs. This aspect is increasingly regarded as a fundamental influence parameter for migration into foods. It was expected that based on the project achievements a much better scientific basic would be available to allow scientifically appropriate amendments of the European FCM legislation, in particular to the contents of Directive 85/572/EEC as well as to support further developments with the so-called Plastics Directive 2002/72/EC.

3 Project aim and objectives

The overall project aim was to provide a novel and economic tool for estimation of consumer exposure to chemicals migrating from food contact plastic materials. The tool was established as a physico-chemical migration model that describes mathematically the migration processes from plastics into actual foodstuffs under any foreseeable contact conditions.

The model should be applicable for exposure estimations in different ways:

(I) As a stand alone tool to estimate exposure related migration within the conventional frame conditions of the EU food regulatory evaluation system (that is the consumer eats per day 1 kg food packed completely with the plastic) by applying a worst case exposure scenario.

(II) In conjunction with statistical data obtained from food consumption and food plastics packaging surveys to estimate realistic or worst-case consumer exposure for any situation of interest which is achievable through the flexibility of calculating the migration rate into any food from any plastic and under any contact conditions.

Detailed scientific, technological and social objectives were the following:

(i) To make use/take advantage of the specified or pre-certified character of the reference plastic materials from the EU project "Specific Migration" (contract no°G6RD-CTG2000-00411) which can serve as the most suitable test and reference materials which are currently available.

(ii) To define a list of foodstuffs representing approximately 15 – 20 food groups with respect to such physico-chemical properties which can be expected to influence the behaviour of food with respect to mobility of migrants and sorption properties for the uptake of migrants.

(iii) Harmonising the list from (ii) with the actual food consumptional market situation and consumer protection standpoint (which foodstuffs are most frequently consumed and deserve therefore consideration at higher priority).

(iv) To elaborate a comprehensive data set of migration values and other physico-chemical parameters (e.g. diffusion in food, D_F, partitioning plastic/food $K_{P/F}$, partitioning within food between different food compartments, $K_{F1/F2}$), obtained from migration, diffusion and partitioning experiments using reference plastics, model substances and foodstuffs mentioned above and from literature.

(v) To generate from the results of (iv) a better understanding of the mechanisms and physico-chemical food properties which influence mass transport processes of packaging constituents into and within foodstuffs.

(vi) To establish on the basis of the experimental data set from (iv) an advanced migration model for the contact of plastics and other materials with foodstuffs by expanding the scope of the existing diffusion model (validated within EU-project "Migration Models" (contract n°SMT4-CT98-7513) for the contact of plastics with food simulants.

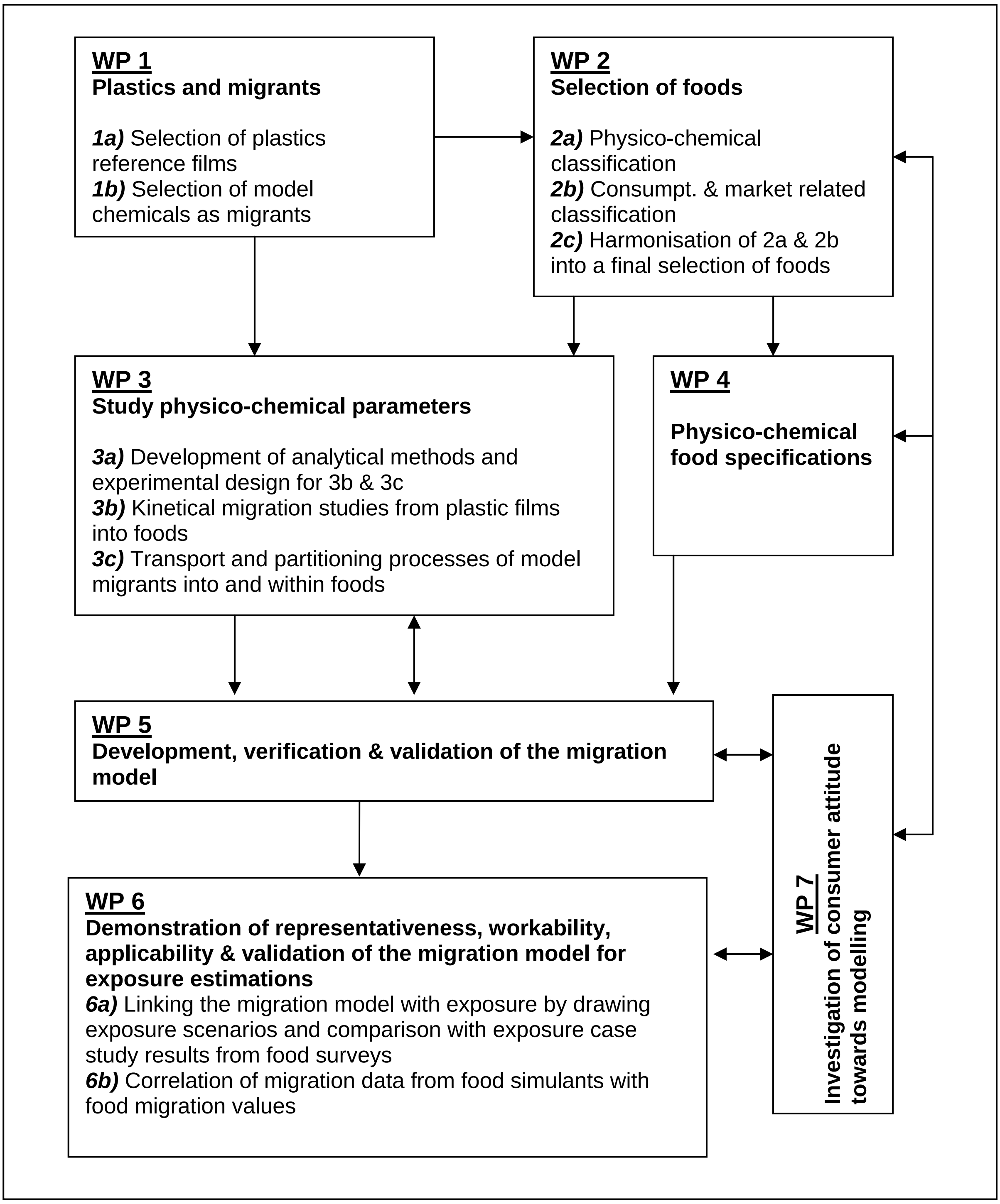
(vii) Correlation of food simulant linked migration data from EU project "Specific Migration" (contract n° G6RD-CTG2000-00411) and the foodstuff linked data from the proposed project and generating from that a translation tool for correlation of any food simulant migration data obtainable from various available migration data banks into food migration at any conditions of interest.

(viii) To link the outcome of this project with exposure research groups and make the migration model linkable with computer programs established in the Stochastic Modelling project (contract n°QLK1-1999-00155)

(ix) Investigating the social acceptance of migration modelling versus chemical measurements, and its implications for exposure estimation by carrying out a consumer questionnaire and involvement of consumer protection representatives.

4 Project work packages and deliverables

4.1 Overview project work packages (WP)



4.2 Overview project deliverables

No	Description
D1	Comprehensive dossier on the final definition and selection of plastic films, model migrants as well as foodstuffs/food groups (physico-chemical, scientific, industrial, social justification). In addition, at this moment, a project website will be installed in the internet where the outcome of WP's 1 and 2 are summarized . Also, the first leaflet in 'layman's' language will be made available at this time.
D2	Compilation of the analytical methods developed for the set of migrants in the individual foodstuffs including validation data and written in a harmonised format. This compilation will be placed on the internet for public access as an useful tool for analysts from industrial as well as public surveillance laboratories for compliance testing purposes.
D3	Review on WP3b presenting the applied experimental approach and a summary of physico-chemical parameters measured
D4	Review on WP3c presenting the experimental approach adopted and a summary of physico-chemical parameters measured
D5	Overview document giving the physico-chemical specifications of the investigated foodstuffs
D6	State-of-the-art report on current migration models for food simulants combined with a rational on how to proceed with actual foodstuffs (this is especially for presentation at consumer council and diffusion to consumer organisations)
D7	Dossier describing the establishment, working principle, representativeness, verification and validation of the migration model developed for foodstuffs. Guidance document with instructions and examples how to use the migration model.
D8	Compendium on exposure scenarios and case studies to demonstrate workability of the migration model for exposure assessment from packaging materials.
D9	Dossier on the correlatability of food simulant with food migration for the purpose of transferring existing food simulant data bank values into corresponding food migration rates for exposure assessment.
D10	Dossier on the investigation of the consumer attitude towards modeled versus measured migration & the final project leaflet in 'layman's' language will be made available.

Explanation: *All deliverables are by nature of Research (R) type and by dissemination level of public availability (PU) type.*

5 Project results

5.1 WP 1 'Selection / Definition of Plastics and Migrants'

The objective of this WP was to conclude on an appropriate selection of plastics reference films acting as release matrices for model migrants as well as on the type and nature of the chemical migrants themselves. These materials and substances will be used in the WP3 studies.

A total of 5 plastics films and 18 chemical substances was defined (see list below).The selected model migrants cover a molecular weight range from 104 up to 532 (above this diffusion is significantly slower). The selected model migrants also cover a range of chemical groupings and polarities, with polar water soluble substances such as caprolactam and triclosan and water insoluble substances such as di-isopropyl naphthalene (DIPN) and 1-octene. In addition, all of the model migrants, except one, can be found in packaging materials either as monomer residues or additives or contaminants. The exception is film no.2 which contains diphenyl butadiene (DPBD) which was chosen because of the availability of a test film from the EU project G6RD-CT 2000-0411 and due to the low detection limits possible in foodstuffs.

Final list of polymer test films and model migrants for WP3

Test film no.& Polymer type	No. and	chemical name of model migrant	MW [Da]	PM/REF no
1 **LDPE*)**	**1**	Benzenepropanoic acid-3,5-bis(1,1-dimethylethyl)-4-hydroxyoctadecyl ester (Irganox 1076)	532	68320
2 **LDPE**)**	**2**	Diphenylbutadiene (DPBD)	206	-
3 **HDPE***)**	**3** **4**	2-hydroxy-4-n-octyloxybenzophenone (Chimassorb 81) 2,5-bis(5-tert-butyl-2-benzoxazoyl)thiophene (Uvitex OB)	326 431	61600 38560
4 **PA Nylon****)**	**5**	Caprolactam	113	14200
5 **LDPE*****)**	**6** **7**	Benzophenone Diphenyl phthalate	182 318	38240 -
-	**8**	Bis(2-ethylhexyl)adipate (DEHA)	370	31920
-	**9**	Styrene	104	24610
-	**10**	2,2-Bis(4-hydroxyphenyl)propane (Bisphenol A)	228	13480
-	**11**	1-octene	112	22660
-	**12**	Limonene	136	63970
-	**13**	Diisopropyl naphthalene (DIPN)	212	
-	**14**	Laurolactam	197	19490
-	**15**	Triacetin (GTA)	218	57760
-	**16**	Tri-n-butylacetyl citrate (ATBC)	402	93760
-	**17**	2,6-di-tert-butyl-p-cresol (BHT)	220	46640
-	**18**	2,4,4' Trichloro-2'-hydroxydiphenyl ether (Triclosan)	290	93930

*) Material no. 1 from project G6RD-CT 2000-0411 **) Material no. 2 from project G6RD-CT 2000-0411
) Material no. 4 from project G6RD-CT 2000-0411 *) Material no. 15 from project G6RD-CT 2000-0411
*****) Material from a national project of partner 1

A comprehensive report on this work package is given by Deliverable D1.

5.2 WP 2 'Selection of foodstuffs'

The objective here was (a) to classify foodstuffs/food groups with respect to those physico-chemical properties which can be expected to influence the behaviour of food as a sorption matrix for the uptake of migrants and (b) to consider consumption data and market related classification of food groups. Consideration was also given to the impact of socioeconomic as well as cultural ethnical and religious factors as well as to the influence of changing demographics in Europe (dual career families, ageing populations, increasing ethnic diversity), concept of healthy eating, food scares or lack of codes of practice for animal welfare, influence of television, brand loyalty, food preference and behaviour arising from cultural/ethnical or ideology based factors. But also other facts such as analytical problems or the relevance of a packed food for its migration potential were taken into account.

As an overall result, a list of 23 foodstuffs/food groups could be established as a solid basis for the studies in WP3.

The selected foods were categorised into three main groups:

1. **Aqueous and acidic foods**
2. **Fatty foods**
3. **Dry foods**

List of foodstuffs/food groups selected for inclusion in the project and justification why

Foodstuff	Justification of foodstuff
Category 1	**Aqueous and acidic foods**
Orange juice, unsweetened with fresh pulp	Representing fruit juices as aqueous foods with low pH value (3,6), low viscosity (liquid with suspended pulp) and no fat content. To consider the possible influence of suspended fruit flesh a fresh orange juice with pulp was selected for the migration studies. Orange juice also appears to be a good choice considering its high consumption and availability on the markets within the EU
Apple sauce	Representing not only from the consumption point of view the very important group of processed fruit products. Having a lower water content and higher carbohydrate content than the unsweetened juices, yet still low pH value (3,7) due to which the product can be considered as fairly aggressive towards the packaging. The viscosity of this suspension is considerably higher than that of juices
Milk, UHT (min. 3,5% fat)	Representing the essential group of dairy products. Compared to the previous products in the list the milk has much higher pH value (6,7). The viscosity is low (emulsion - fat, suspension – casein micelles), and it contains some fat (3,5%). This is expected to be a fundamental parameter for the migration of the lipophilic migrants from packaging into the food. Therefore the milk can be considered an interesting choice as a first step from aqueous- to fatty foods

Tomato ketchup	Representing important group of processed vegetable products. Ketchup is a semi fluid food showing plastic behaviour (flow occurs after the yield stress has been exceeded), high viscosity (suspension), with lower water content, due to low pH value (3,65) highly aggressive , packaged in considerable amounts in plastic packaging. Used for various purposes, and as an ingredient in some cases also heated (as a single component of convenience foods tomato ketchup can be considered as a single representative for this more and more popular group of foods)
Carbonated beverage (cola drink)	Sweetened drinks (homogenous liquid) containing carbon dioxide. The pH value is very low (3,4). Carbonated beverages are widely spread on the market and are very popular, resulting in high consumption. They are preferably packaged in plastic bottles
Wine (beer)	Representing alcoholic drinks. Low viscosity (homogenous liquid). Chosen to analyze the influence of alcohol content on the migration of the substances from packaging. Preferred in the list compared with beer because of higher alcohol content. It was also agreed to analyse migration into **beer** as well to see, if there is any difference in behaviour considering migration. Both will be linked and compared with carbonated beverages

Foodstuff	Justification of foodstuff
Category 2	**Fatty foods**
Margarine (80% fat content)	Representing foodstuffs with very high fat content (water in oil W/O emulsion), semi fluid food showing plastic behaviour (flow occurs after the yield stress has been exceeded), higher pH value (4,85), low water content. Very good contact between the foodstuff and the packaging results in good migration potential. Will be linked with mayonnaise to see if they behave in a similar way
Mayonnaise (80% fat content)	Representing foodstuffs with very high fat content (a pasty O/W emulsion), semi fluid food showing plastic behaviour (flow occurs after the yield stress has been exceeded), due to the consistency good migration potential, low water content. The pH value (3,84) is lower than the pH of margarine while the fat content is similar. Therefore mayonnaise will be linked with margarine to compare their behaviour towards the migration
Cheese Philadelphia (~70 % fat in dry matter)	Soft and smooth fresh cheese, very extensive contact with the packaging material. Due to considerable amount of fat present in the matrix (yet lower than in the sauce type cheese) the migration of lipophilic substances can be expected
Cheese Gouda (45 % fat in dry matter)	Representing solid foodstuffs (composite material) with high fat content, also high in protein and still with considerable water content. Good migration potential
Cheese sauce (18,5% fat)	The combination of fat content, smooth consistency providing extensive contact between the food and packaging, and the possibility of heat treatment while still in the packaging makes this product very interesting from the migration potential point of view. Due to this specific application possibility, this product can be also considered as a representative for the more and more popular group of convenience foods

Cottage cheese (fresh cheese, ~10 % fat content in dry substance)	Representing dairy products with high water- and protein content. The considerable fat content increases the migration potential, while the microstructure is somewhat different from the previous types of cheese. Its not as smooth and the structure is porous. The fat content decreases in the following order: fresh cheese Philadelphia type → Cheese Gouda → Cheese sauce → cottage cheese. This should enable to determine the influence of different fat contents in one food category (cheese) on the amount of substances migrating from the packaging into the foodstuffs
Whipping cream, UHT (~30% fat)	After mayonnaise, whipping cream represents another fluid product with high fat content (yet considerably lower than in the mayonnaise) and low carbohydrate and protein content. The water content is much higher than that of mayonnaise. In the group mayonnaise, whipped cream, condensed milk, and yogurt drink the fat content decreases while all four foods having fluid character give a good media for migration processes
Condensed milk (10% fat)	High viscosity, but still fluid character ensures good contact with the packaging material. With a fat content at 10 % condensed milk represents a link between the whipping cream (30 % fat content) and yoghurt drink (3,5% fat content). The pH value of condensed milk is rather high (6,5)
Yoghurt drink, (min. 3,5 % fat)	Dairy product, rough chemical composition similar to milk, but with lower pH value and higher viscosity, good contact with the packaging material
Chocolate, dark, milk free, min. 40 % cocoa content (30% fat)	Representing solid foodstuffs (dispersion of solid particles in fat). Due to the possibility of ‘blooming’, formation of fat crystals on the surface, and overall high fat content, lipophilic substances are likely to migrate into the chocolate. The blooming phenomenon can increase the potential for migration of lipophilic substances since pure fat gets into direct contact with the packaging material
Chocolate spread (25% fat**)**	Representing a food similar to chocolate but with lower fat content and paste-like consistence
Meat, lean pork meat (minced, fat content ≤5)%)	Representing red meat, complex matrix with lower fat content, high water content. Lean meat was selected for the following reason: fresh meat can hardly be standardized (different animal individuals, physical condition etc.). Due to this fact it would be difficult to ensure even quality of meat for each partner of the project (even without the necessity of meats with different fat contents). Therefore lean pork meat was selected, with fat content of approximately ≤5 %. Separately, pork fat (75% fat) will be bought and mixed with the pork meat, resulting in meat with higher (and more exactly defined) fat content. This way, minced meat samples with fat contents between 5 – 50 % will be prepared and the influence of different fat contents will be determined. The assessed migration will be plotted against the fat content of the meat and the results will be compared with other types of meat (salmon, chicken breast etc.) to see, if the fat content can be considered as the most relevant parameter responsible for migration

Foodstuff	Justification of foodstuff
Category 3	**Dry foods**
Milk powder	Widely used in various foods, also for baby-food, making this product interesting for the migration studies. Very high surface area and fat content exceeding 25 % promotes the migration. Lactose, as the main carbohydrate of milk powder, is present in an amorphous form (glassy state)
Butter toast (4% fat)	Chosen as a representative for bakery products (bread). Their porous structure favours the migration of volatile substances from the packaging into the foodstuff
Wheat flour	Representing particulate dry foodstuffs [increased surface area, particle size >28µm (50%) and <28µm (50%)], high carbohydrate content, low water and fat content, rich in protein. Characteristic is the high surface area, just like by milk powder, but the fat content is much lower. This makes it possible to compare the influence of fat content on the migration into particulate foods with high surface area
Rice	Dry solid foodstuffs, high carbohydrate content, rich in proteins and low water content, particulate character increases surface area. Vacuum packed in plastic bags – tight contact between the rice and packaging material. Rice in plastic bags suitable for cooking as a whole (rice within a plastic bag) is also widely spread on the market, making this particular foodstuff convenient for migration studies. Catherine Simoneau recommended rice used for risotto (2 special varieties of rice are used for risotto called “Violone” and “Arborio”)
Honey	Representing semi fluid high quality natural product with very high carbohydrate content, lower water content, no fat, high viscosity (depending on variety and temperature), intermediate pH value (3,9)

A comprehensive report on this Work Package is given by Deliverable D1.

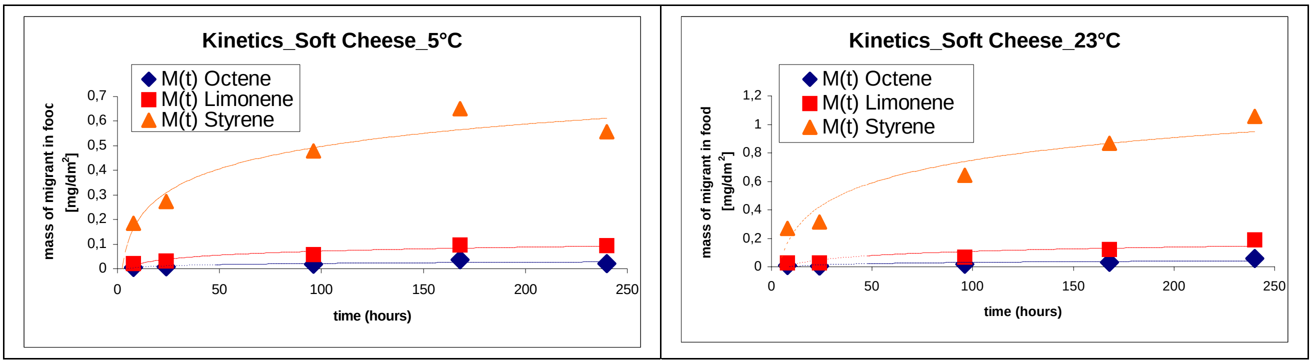
5.3 WP 3 'Study physico-chemical parameters'

The major objective of this work package was to establish the physico-chemical parameters needed for the migration model and which are in the first place the diffusion coefficient in food, D_F, and the partitioning coefficient plastic/food, $K_{P/F}$. Experimentally these parameters were accessible from kinetical migration experiments using the plastics reference films from WP1 and from other mass transport and partitioning processes such as measuring concentration profiles of model migrants (WP1) into foodstuffs as selected in WP2.

An important pre-work here was to develop the appropriate analytical methods for these studies. Indeed a comprehensive collection of analytical methods for all of the model migrants and principally working for all selected foods has been established. The method collection and further technical/analytical guidelines for assistance to migration testing has been laid down in Deliverable 2 as well as in 2 publicised European Reports EUR 22232 EN and EUR 22552 EN.

On the experimental side comprehensive kinetical migration studies from plastic films into foods were carried out. In total, by number, 240 kinetic curves were measured. The test conditions were being selected as being most appropriate for the conditions in use that the representative foodstuffs would normally be exposed to during storage. In many cases two or more temperatures were used. Where a foodstuff has a relatively long shelf storage time at ambient temperature, such as chocolate, the experiment was continued to 30 or 90 days as appropriate.

As an example the results of the kinetic migration experiments at 5°C and 23°C for the model migrants octene, limonene and styrene from a LDPE film (previously spiked with these migrants) in contact with soft cheese is depicted:



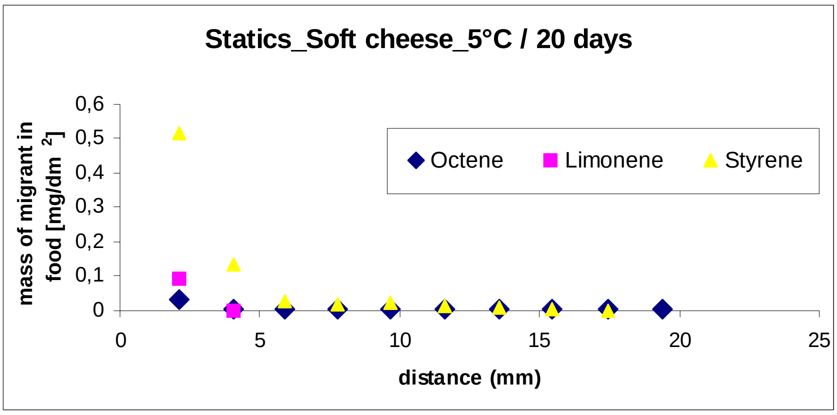
An overview of the kinetical migration tests and test conditions is given in the following table:

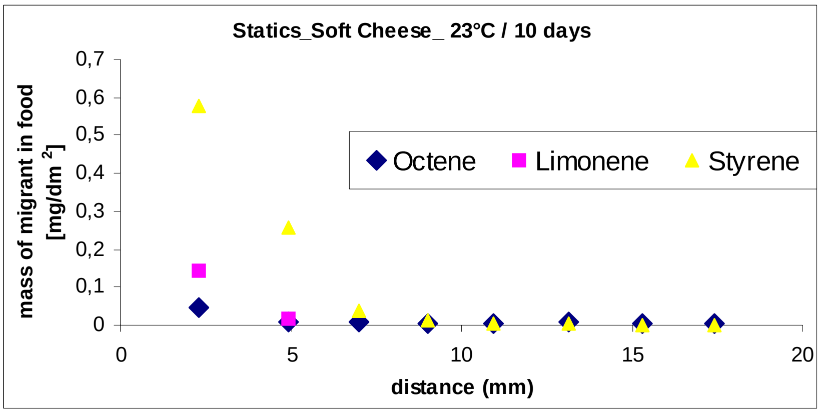
In Deliverable D3, an overview report on the kinetical migration experiments including the experimental approach is given.

Overview of test conditions and measured time points in kinetic migration experiments:

Foodstuffs	T[°C]	Time points (1) (LDPE)	Time points (2) (LDPE, HDPE, PA films)
Orange juice	5 23 40	2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d 1, 2, 4, 7, 10 d	2, 4, 10, 20, 30 d 2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d
Apple sauce	23	1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d
Milk (3.5% fat) UHT	5 23 40	2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d 1, 2, 4, 7, 10 d	2, 4, 10, 20, 30 d 2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d
Tomato Ketchup	23 70	1, 2, 4, 10, 20 d 2, 4, 8, 16, 24 h	2, 4, 10, 20, 30 d 8, 16, 24, 48, 96 h
Cola Drink Decarbonated	23 40	1, 2, 4, 10, 20 d 1, 2, 4, 7, 10 d	2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d
Beer decarbonated & wine (white, ~11%)	23	1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d
Margarine	5 23	2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d 2, 4, 10, 20, 30 d
Mayonnaise (80 % fat)	5 23	2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d 2, 4, 10, 20, 30 d
Cheese Gouda 45%	5 23	2, 4, 10, 30, 90 d 1, 2, 4, 10, 20 d	2, 4, 10, 30, 90 d 2, 4, 10, 20, 30 d
Soft cheese (68% in dry matter)	5 23	2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d
Cottage cheese ~10% fat	5 23	1, 2, 4, 10, 20 d 0.5, 1, 2, 4, 10 d	2, 4, 10, 20, 30 d 0.5, 1, 2, 4, 10 d
Cheese sauce ~18.5% fat	5 90	2, 4, 10, 20, 30 d 5, 10, 30, 60, 120 min	2, 4, 10, 20, 30 d 5, 10, 30, 60, 120 min
Yoghurt drink	5	2, 4, 10, 20, 30 d	2, 4, 10, 20, 30 d
Condensed milk	23	1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d
Whipping cream (~30% fat) UHT	5 23	2, 4, 10, 20, 30 d 1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d 2, 4, 10, 20, 30 d
Chocolate dark	23 40 70	2, 4, 10, 30, 90 d 1, 2, 4, 7, 10 d 30min., 1, 2, 4, 8h	2, 4, 10, 30, 90 d 1, 2, 4, 7, 10 d
Choc spread	25	1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d
Pork minced meat (plus 4 different fat conc.)	5 23	1, 2, 4, 10 d 8 h, 2 d	1, 2, 4, 10 d 8 h, 2 d
Pork neck (~15-20% fat) & Chicken breast (low fat)	5 23	1, 2, 4, 10 d (8 h, 2 d)	1, 2, 4, 10 d (8 h, 2, d) , 1, 2, 4, 10, 20d
Fish (salmon, high fat)	5	8 h, 1, 2, 5 d	8 h, 1, 2, 5 d
Milk powder	23 40	2, 4, 10, 20, (60,180 d) 1, 2, 4, 7, 10 d	2, 4, 10, 20, (60,180 d) 1, 2, 4, 10, 20 d
Butter toast	23	1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d
Wheat flour	23 40 70	2, 4, 10, 20, (60,180 d) 1, 2, 4, 7, 10 d (8, 24 h)	2, 4, 10, 20, (60,180 d) 1, 2, 4, 10, 20 d (8, 24 h)
Rice	23 40	2, 4, 10, 20, (60,180 d) 1, 2, 4, 7, 10 d	2, 4, 10, 20, (60,180 d) 1, 2, 4, 10, 20 d
Honey	23	1, 2, 4, 10, 20 d	2, 4, 10, 20, 30 d

In addition, the migration behaviour of model migrants into foods was investigated by static migration experiments where after a defined time-temperature contact of the particular food with a migrant release system the concentration profile of the model migrant within the food was determined. In total more than 170 concentration profiles were measured at different time-temperature conditions. From these data supplementary support was obtained concerning the derivation of and conclusions on physico-chemical parameters needed for modelling (WP5).
As an example the results of the static migration experiments at 5°C and 23°C for the model migrants octene, limonene and styrene from a LDPE film (previously spiked with these migrants) in contact with soft cheese is depicted:





These concentration profiles show that in migration takes place into the first 5 to 10 mm of the soft cheese only.

The table below gives an overview over the extend and combinations of static experiments carried out in this work package.

In Deliverable D4, an overview report on the static migration experiments including the experimental approach is given.

Type of food	Temp [°C]	time	Model migrants
Apple sauce	25	20 d	DIPN
Milk (3.5% fat) UHT	5	30 d	DIPN, Laurolactam
	25	20 d	DIPN, Laurolactam
	40	10 d	DIPN
Tomato Ketchup	25	20 d	DIPN, Laurolactam, DPBD, BHT, Triclosan
	70	1 d	Laurolactam, DPBD, BHT, Triclosan
Cola Drink Decarbonated	25	20 d	DIPN
	40	10 d	DIPN
Margarine	5	5d+10d	Styrene, Octene, Limonene, Laurolactam, C81
	25	5 d	Styrene, Octene, Limonene, ATBC, DIPN, Laurolactam
	40	5 d	Octene, Limonene
Mayonnaise (80% fat)	5	20 d	Laurolactam, C81
	25	20 d	Laurolactam, C81
Cheese Gouda 45%	5	10 d	Styrene, Octene, Limonene, ATBC, DIPN, Laurolactam, C81, DPBD, BHT, Triclosan
	25	5 d	Styrene, Octene, Limonene, ATBC, DIPN, Laurolactam, C81, DPBD, BHT, Triclosan
	40	5 d	Styrene, Octene, Limonene
Soft cheese (68% in dry matter)	5	20 d	Styrene, Octene, Limonene, DIPN, Laurolactam, C81, DPBD, Triclosan
	25	10 d	Styrene, Octene, Limonene, DIPN, Laurolactam, DPBD, Triclosan
Cottage cheese ~10% fat	5	20 d	Styrene, Octene, Limonene, DIPN
	25	10 d	Styrene, Octene, Limonene, DIPN
Cheese sauce ~ 18.5% fat	5	30 d	Styrene, Octene, Limonene
Yoghurt drink	5	30 d	Styrene, Octene, Limonene
Whipping cream ~30% fat UHT	5	30 d	DIPN
	25	20 d	Styrene, Octene, Limonene, DIPN
Choc spread	5	20 d	Styrene, Octene, Limonene, C81
	25	10 d	Styrene, Octene, Limonene, ATBC, DIPN, Laurolactam, C81, DPBD, BHT, Triclosan

Type of food	Temp [°C]	time	Model migrants
minced pork 2% fat	5	10 d	ATBC, Laurolactam
	25	5 d	Styrene, Octene, Limonene, ATBC, Laurolactam, DPBD, BHT, Triclosan
minced pork 10% fat	5	10 d	Laurolactam
	25	5 d	Styrene, Octene, Limonene, DIPN, Laurolactam, DPBD, BHT, Triclosan
minced pork 20% fat	5	5 d	Laurolactam
	25	5 d	Styrene, Octene, Limonene, DIPN, Laurolactam, DPBD, BHT, Triclosan
minced pork 30% fat	5	10 d	Laurolactam
	25	5 d	Styrene, Octene, Limonene, DIPN, Laurolactam, DPBD, BHT, Triclosan
minced pork 50% fat	5	10 d	Laurolactam
	25	5 d	Styrene, Octene, Limonene, DIPN, Laurolactam, DPBD, BHT, Triclosan
Salmon high fat	5	5 d	DIPN, C81
Milk powder	25	20 d	C81
	40	10 d	C81
Butter toast	25	20 d	Styrene, Octene, Limonene, ATBC, DIPN, Laurolactam
Wheat flour	25	20 d	DIPN, Laurolactam, DPBD, BHT, Triclosan
	40	10 d	DIPN, Laurolactam, C81, DPBD, BHT, Triclosan
	70	0.3 d	DPBD, BHT, Triclosan
Rice	25	20 d	Laurolactam, DPBD, BHT, Triclosan
	40	10 d	Laurolactam, DPBD, BHT, Triclosan
Honey	25	20 d	DPBD, BHT, Triclosan
Bacon	5	10 d	C81

5.4 WP 4 'Physico-chemical food specifications'

The objective here was to establish the specifications and parameters which are typical and representative for the foods used in the studies of this project. Based on these parameters a better understanding of the experimental results from work package 3 was expected. Moreover, the expectation was to enable correlation of food categories with the physico-chemical parameters obtained from work package 3.
The food parameters were established either from the known specifications or by measurements and listed for all of the foodstuffs from the final list in work package 2. The measurements were done in the majority of cases according to standard or state-of-the-art methods or were adopted from the labelling of the foodstuff.

The following picture which shows as an example the electron micrograph of milk illustrates the matrix complexity of foodstuffs which is then mechanistically involved in mass transport processes for migrants within the food itself.

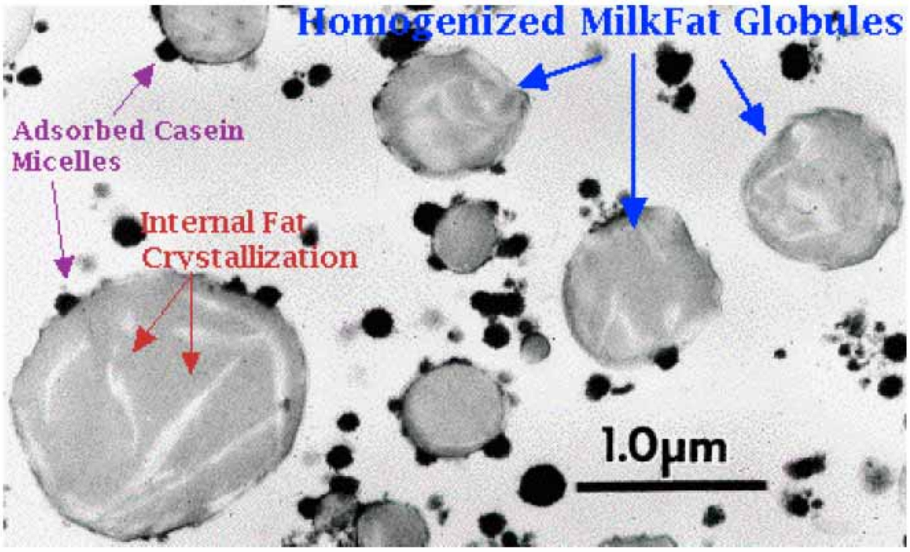


Figure 1 Electron micrograph of homogenized milkfat globules

Parameters essential for migration were the following:

- the chemical composition (water content, fat content, protein content, carbohydrate content)
- pH value
- density
- mass-to-volume ratio ("bulk density")
- particle size
- contact area

Deliverable D5 gives a full overview on this work package and includes all details on the established food specifications.

5.5 WP 5 ‘Development, verification and validation of the migration model’

Objective…
…of this work package was to develop on the basis of the experimental data set from work package 3 an advanced migration model for the migration from plastics and other materials into foodstuffs, by adapting the validated diffusion model [EU-project contract SMT-CT98-7513] that already exists for food simulants.

Starting point (migration model for food simulants)
A validated migration model for plastic materials in contact with food simulants ("well mixed liquid") exists. Plastics brought into contact with food or food simulants may transfer their constituents (migrants) to the contact medium. The validated migration model assumes that the rate determining step is the diffusion process of the migrant in the plastic and its migration process can be described by Fick's second law of diffusion (second order differential equation). The influence of the contact medium to the time scale of the migration process is neglected.
At the same time partitioning of the migrant between plastic and contact medium occurs until equilibrium. Under the above assumptions an analytical solution of the diffusion equation can be derived and for its solution the following input parameters are required:

Plastic:	initial concentration of migrant, thickness and density
Food:	volume and density
Contact conditions:	time and temperature
Mass transfer constants:	diffusion- and partition coefficient

In most cases the mass transfer constants are not available and estimated worst case values are used. According to the validated migration model, diffusion coefficients in the plastics are estimated according to a semi-empirical approach developed by partner 03 [compare EU-project contract SMT-CT98-7513]. For this the polymer specific constant of the plastic and the molecular weight of the migrant must be available. The partition coefficient is assumed to be K = 1 for migrants soluble in the contact medium (food simulant) and K = 1000 for migrants not soluble in the contact medium.
In the system plastic in contact with a liquid medium (food simulant) the time scale of the overall migration process is defined by the diffusion coefficient, D, of the migrant in the plastic and the maximum amount in the contact medium at equilibrium is defined by the partition coefficient, K, of the migrant between plastic and contact medium. Accordingly the system may be denoted as a D/K - system.

Migration model for real foods
Foodstuffs do generally not fulfil the condition of a “well mixed liquid”. The contribution of the contact medium to the overall time scale of the migration process must be considered. With other words: compared to the simple system ‘plastic in contact with a well mixed liquid’ denoted above as a “D/K” system, the diffusion process of the migrant in the foodstuff itself must be considered in addition. For the evaluation of the time dependent migration investigations and concentration profiles into foodstuffs the advanced diffusion model “D/K/D” was assumed. A diffusion - or diffusion like process of the migrant in the foodstuff was considered, contributing to the overall time scale of the migration process.

The experimental results from work package 3 show that for semi-solid and solid food stuffs concentration profiles of the migrants in the foods are observed. In the figure below (migration of Laurolactam from a spiked LDPE film into margarine and migration of 1-octene from a spiked LDPE film into chocolate spread) the experimental data points are represented as dots. With the advanced migration model D/K/D the concentration profile of the migrants in the food can be well described. The theoretical concentration profile of the migrant in the food estimated by the advanced migration model is represented as continuous line in the figure below.

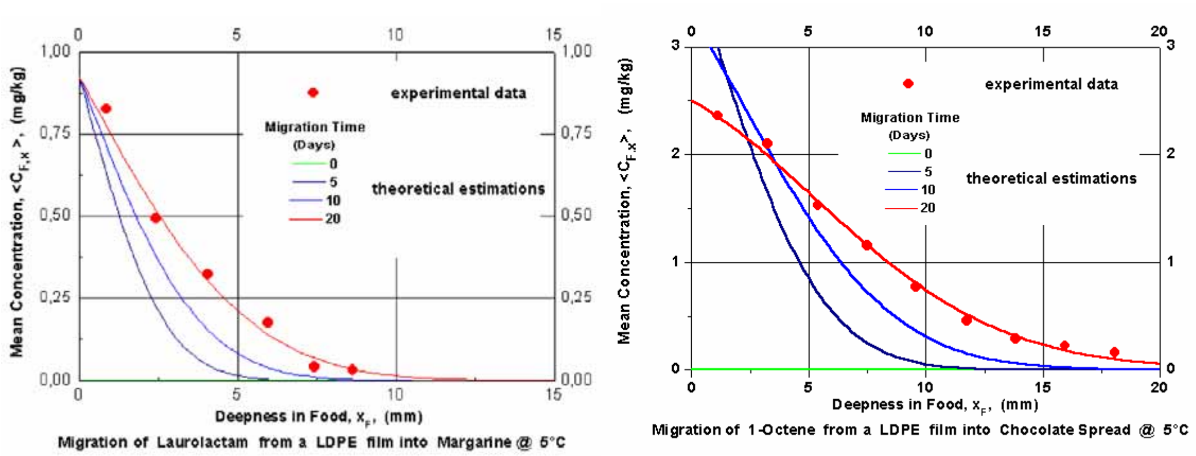


Figure: Concentration profiles obtrained from a static migration experiment for laurolactam in margarine (left) and 1-octene in chocolate spread (right)

For the advanced migration model D/K/D the same inputs are required as for the simple D/K model. In addition the diffusion coefficient of the migrant in the food is required.

Mass transfer constants

Partition coefficients

Mass transfer constants, i.e. partition coefficients of various migrants between plastics and foods and their diffusion coefficient in the foods were derived from experimental data in work package 3, i.e. from time dependent migration curves in foods as well as from concentration profiles in foods. The diffusion coefficients of the migrants in the plastics were assumed to be known based on the availability of polymer specific constants for the plastics investigated.
The partition coefficients of the migrants between plastics and foods derived from the various migration experiments performed were correlated in a log/log-plot with the polarity of the migrants expressed as octanol / water-partition coefficients. In the figure below the log/log-plot of partition coefficients between polyolefines and gouda cesses (left) respectively soft cheese (right) of various migrants against their octanol/water partition coefficient is shown.

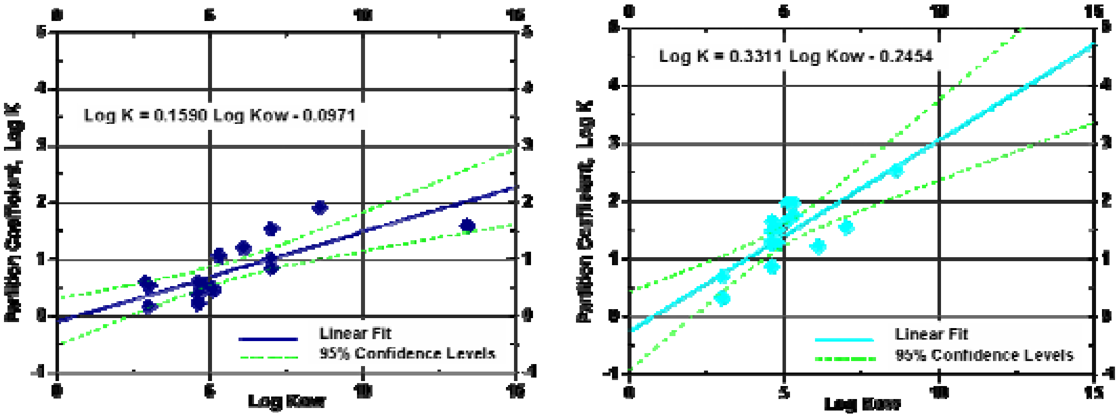


Figure: log/log-plot of partition coefficients between polyolefine and food against octanol/water partition coefficients of the migrants investigated (gouda cheese at the left and soft cheese at the right).

In the log/log-plots a linear relationship between plastic/food and octanol/water partition coefficients was postulated.

From these observations obtained from all investigated cheese types it appears that these cheese types may be grouped into one food group "cheese" which can be described by one graph as shown in the figure below.

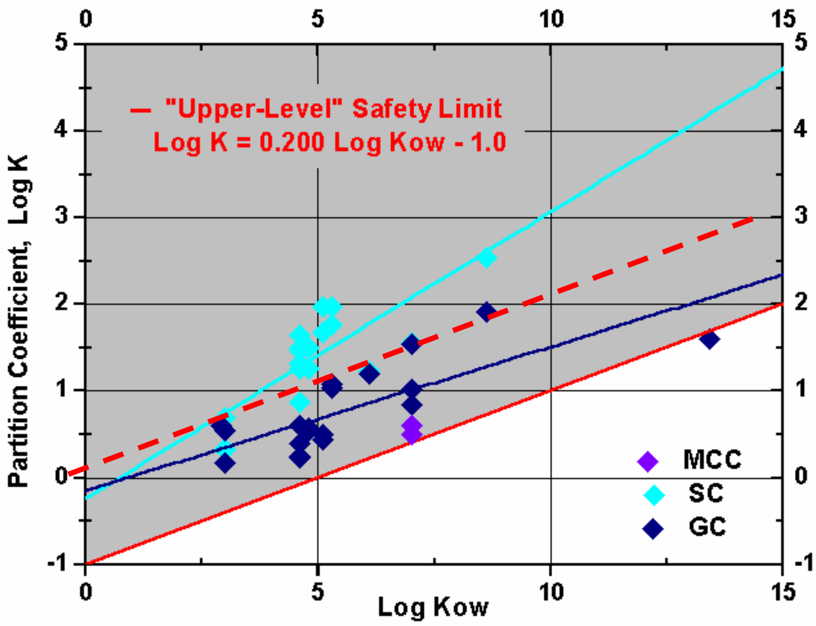


Figure: Food group "cheese": log/log-plot of partition coefficients between plastic and food against octanol/water partition coefficients of the migrants investigated.

From this figure the following can be concluded: for a food group (in this case “cheese”) two lines can be identified:
(a) the "mean" line, i.e. the best fit to the experimental data points with a linear function (dashed red line)
(b) the "lower level" line which includes a safety margin and which is a parallel line to the "mean" line shifted downwards below all experimental data points.

Using the "mean" line to identify the partition coefficient between plastic and food for a migrant based on its octanol/water partition coefficient gives a realistic estimate of the migrants migration from the plastic to food. Using the "lower level" safety line a worst case migration estimation for this food group would be obtained.

Diffusion coefficients
It was assumed that migration of plastic components in the foodstuffs follows a diffusion - or diffusion like process. Furthermore it was considered that the diffusion coefficient in foods can be described mathematically by an Arrhenius like equation.

$$D = D_0 \cdot e^{\frac{-E_A}{RT}}$$

D = diffusion coefficient [cm² s –1]
D_0 = pre-exponential factor [cm² s –1]
E_A = activation energy [kJ/mol]
R = gas constant [8,314 J/mol K]
T = temperature [K]

The activation energy of the apparent diffusion process in foods was determined by plotting the natural logarithm of the diffusions coefficients in food against 1/T (Arrhenius plot) as shown in the figures below.

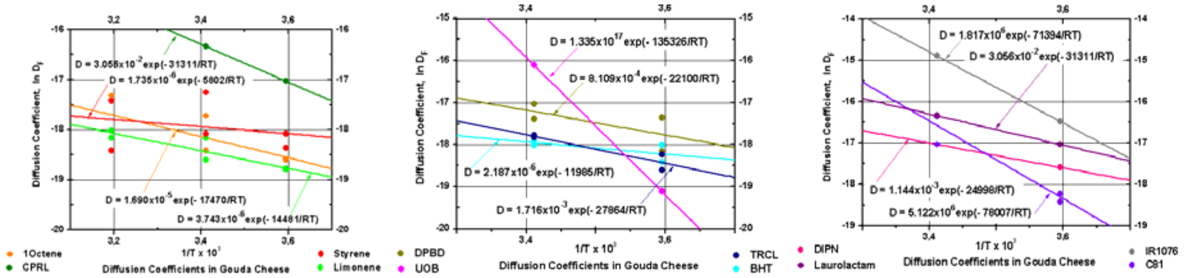


Figure: Arrhenius plot for all migrants investigated in gouda cheese
(CPRL = Caprolactam, DPBD = Diphenylbutadiene, UOB = 2,5-Bis(5-tert-butyl-2-benzoxazoyl)thiophene, TRCL = 2,4,4' Trichloro-2'-hydroxydiphenyl ether, BHT = 2,6-Di-tert-butyl-p-cresol, DIPN = Diisopropyl naphthalene, IR1076 = Benzenepropanoic acid-3,5-bis(1,1-dimethylethyl)-4-hydroxyoctadecyl ester, C81 = 2-Hydroxy-4-n-octyloxybenzophenone)

The average activation energy E_A for each food group was determined as the mean value of all migrants investigated. Because the activation energies derived from the Arrhenius plot scatter in a wide range, the highest and the smallest values were omitted. For the calculation of the food specific constants A_F the average E_A was used.

$$D = D_0 \cdot e^{\frac{-E_A}{RT}} \text{ where } D_0 = e^{A_F}$$

$$A_F = \ln D + \frac{E_A}{RT}$$

D = diffusion coefficient [cm² s –1]
D_0 = pre-exponential factor [cm² s –1]
E_A = activation enery [kJ/mol]
R = gas constant [8,314 J/mol K]
T = temperature [K]
A_F = food specific constant

Figure: Food specific constants (A_F-values) for cheese sauce CE, soft cheese SC, gouda cheese GC and matured cheddar cheese MCC.

From this figure the following can be concluded: for a given food group (in this case “cheese”) two A_F-values can be identified:

(a) the "mean" value (dashed red line)

(b) the “upper level” safety value for cheese products (red line)

The “upper level” safety limit-food specific constant A_F* for each food group was determined by the calculation of the 95% quantile of all individual A_F-values.

The “upper limit” diffusion coefficient D_F* for the food category, which describes the worst case migration, can be derived from the “Upper limit” A_F*.

Validation
Verification and validation of the migration model was achieved by carrying out additional migration tests on commercially available packaging samples in contact with appropriate foodstuffs and comparing those results with the calculated ones. Generally with an overestimation in at least 95% of the cases a sufficient safety margin for the calculation of migration into foodstuffs is guaranteed and the validity of a migration model is demonstrated.

For this purpose commercially available packed samples from the category 'milk products' were analysed by partners 01 and 04. Also migration results transmitted from the involved US-FDA laboratory were included.
The migration of styrene from polystyrene packaging materials into the milk products at the temperature of 5°C and 40°C analyzed by partner 01 und 04 was overestimated by the calculated migration curve in all cases except for one migration experiment with uncertainties regarding the initial concentration of the migrant in the polymer.
For the migration of Irganox 1010 measured by the FDA laboratory in some cases an underestimation by the modelled values in the range of 50% to 85% was observed. However Irganox 1010 with a molecular weigh of 1178 Dalton is not covered by the range of molecular weights from 112 to 532 Dalton of the migrants chosen in work package 1. Therefore the applicability of the migration model for Irganox 1010 is questionable.
Furthermore the "Upper limit"-migration curve of liquid foods (established up to temperatures of 40°C) appears to underestimate the migration values of Irganox 1076 and Irganox 1010 into water at higher temperatures (75 – 130°C) significantly. The reason appears to be the following: Solubility of migrants changes with temperature resulting in variation of the log Kow with temperature. Most of the migration experiments into foodstuffs were performed in the temperature range from 5°C to 40°C. For correlation of the migration results with the polarity of the migrant log Kow values at 25°C were available. For the migration experiments performed by FDA at high temperature (77°C to 130°C) no corresponding high temperature log Kow were available, hence the migration model for these testing conditions is not applicable.
Omitting the high temperature migration tests into water as well as the migration experiments with the high molecular weight substance Irganox 1010 overestimation in 96.4% of the calculations was observed. Especially with the measurements on commercially available packaging samples containing milk products and with moderate contact temperature conditions at 8°C and 40°C, the validity, workability and applicability of the migration model could be demonstrated.

Critical review
The following critical review on the workability and applicability of the basic migration model D/K/D developed for the estimation of the migration from polymers into foodstuffs should be considered.

Influence of temperature on diffusion coefficients
The migration model developed in this project accounts only for diffusion like mass transfer processes in the system polymer in contact with food. For the diffusion behaviour of the migrants in the foods no significant temperature dependence was found. The activation energies derived from the ln D_F – 1/T – Arrhenius plot scatter in a wide range. Nevertheless an Arrhenius-like dependence for the diffusion processes in the foodstuffs was assumed.

Influence of temperature on partition coefficients
The octanol/water partition coefficients are temperature dependent. No empirical relation ship or knowledge on the temperature dependence of octanol/water partition coefficients could be identified and hence this fact was not considered in the migration model. Therefore the results from the migration experiment into water at high temperature conditions (77°C to 130°C) measured by the FDA laboratory cannot be described with the migration model. Due to high migration rates of Irganox 1076 and Irganox 1010 from the polyolefines into water the migration curves generated on the basis of the migration model would underestimate the experimental data points. It is expected that for high temperatures much lower log Kow values would be valid and if so, an overestimation of migration would result. Within the project, the validity of the migration model for high temperature testing could not be proven.

Complex mass transfer processes
The mass transfer in the system packaging/food is very complex.
The most important difference between food simulants and real foodstuffs is the fact that food simulants are homogeneous liquids and the real foodstuffs in most cases not. The foods chosen in this project are heterogeneous on macroscopic and/or microscopic scale. For example pork minced meat with 30% lard added is visibly heterogeneous at the interface plastic/food (see figure below). These heterogeneities might lead to boundary resistance at the interface plastic/food.

Figure: Interface plastic/food: pork minced meat, 30% fat added (light coloured = fat, reddish = peaces of pork mince)

Likewise milk is an emulsion of butterfat globules within a water-based fluid. In this fluid casein protein micelles are the largest structures. The fat globules as well as the casein micelles which are large enough to deflect the light, contribute to the white colour of the milk. The following picture shows (again, see also work package 4) that milk is an example for a food with heterogeneities on microscopic scale.

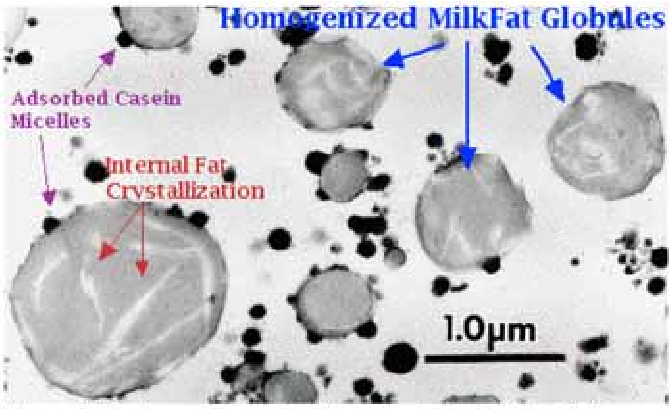


Figure 1 Electron micrograph of homogenized milkfat globules

Although these heterogeneities suggest complex mass transfer processes at the interface food/polymer as well as in the food itself, the migration model developed assumes that only diffusion like mass transfer processes in the food occur. Partitioning processes between the continuous phase and heterogeneities in the foodstuff, convection, boundary resistance etc. are not considered in the model.

Limitations

The migration model developed is applicable within the following limitations:

- estimation of migration from polyolefines into foods:
  Only a few data could be obtained in the project for polar test films like polyamide and these were limited to one single migrant (caprolactam). Therefore the partition coefficients for caprolactam between polyamide and foods were omitted for the correlation of the partition coefficients with log Kow:
- investigated temperature range from 5°C to 70°C
- investigated molecular weight range for potential migrants from 112 to 532 Dalton.
- foods investigated in this project, other foodstuffs have to be assigned to the given food categories.

How to use the model

According to the limitations summarized above <u>the advanced migration model is limited in the first place to applications where polyolefines or similar (polarity, diffusion) packaging materials are in contact with food</u> because only for these plastics category comprehensive ufficient data including validation were gathered in the project. In addition, the advanced migration model is applicable also to low diffusivity plastics like polyethylene terephthalate (PET) and polystyrene (PS) according to the worst case considerations made below (see under "Other plastics"). For polar plastics like polyamide (PA) the data basis gathered in the project was to low to include them in the advanced migration model after termination of the project. PA and other polar polymers need further systematic migration investigations to be included in the D/K/D model.

The advanced migration model assumes that the migration of components from plastics into food obeys the law of diffusion. At the same time partitioning of the migrant between plastic and food occurs until equilibrium. Accordingly the model is denoted D/K/D.

To estimate the migration of migrants from plastics to food the diffusion equation must be solved numerically (an analytical solution is no more available). The solution of the diffusion equation requires the following inputs:

- Plastics contact material:	initial concentration of migrant, thickness and density
- Foodstuff:	volume and density
- Contact conditions:	time and temperature
- Mass tansfer constants:	diffusion and partition coefficient D (in plastic and in food) and K

<u>Diffusion coefficients in plastics</u>

Diffusion coefficients of migrants in plastics typically are estimated by the semi-empirical relationship developed by partner 03 which requires the additional input of the polymer specific constant for the plastic (A_P-value) and the molecular weight of the migrant.

Table: Overview of A'_P-values ($A_P=A'_P-\tau/T$) for migration modelling from polyolefines under 'worst-case' conditions from Begley et al. [Food Additives and Contaminants, January 2005; 22(1): 73–90]

Polymer	A'_P	S	$A'_{P(max)}$	$A'_{P(min)}$	N	t	$A'_P{}^*$	τ
LDPE	10.0	1.0	11	7.0	27	1.7	11.7	0
HDPE	10.0	1.9	12.6	5.0	49	1.68	13.2	1577
PP	9.4	1.8	12.9	6.2	53	1.68	12.4	1577
PET	2.2	2.5	7.2	−4.3	58	1.67	6.35	1577
PEN	−0.34	2.4	3.8	−5.5	38	1.7	3.7	1577
PS	−2.8	1.25	0.0	−6.5	32	1.7	−0.7	0
HIPS	−2.7	1.67	0	−6.2	33	1.7	0.1	0
PA (6,6)	−1.54	2.0	2.3	−7.7	31	1.7	1.9	0

<u>Partition coefficients between plastics and foods</u>

Partition coefficients of migrants between polyolefines and food groups are estimated from their linear relationships with the octanol/water partition coefficient of the migrant in the log/log-plots characterizing the food groups as listed in the following table.

Table: Overview of linear relation ships between log $K_{P,F}$ and log $K_{O/W}$ for polyolefines in contact with food groups

Food group		log $K_{P,F}$ (at 5°C)	log $K_{P,F}$ (at 20-25°C)	log $K_{P,F}$ (at 40°C)	log $K_{P,F}$ (at 70°C)	log $K_{P,F}$ (at 90°C)
cheese products	"lower limit"	= 0,233·log $K_{O/W}$-1,0	= 0,2·log $K_{O/W}$-1,0	= 0,2·log $K_{O/W}$-1,0		= 0,2·log $K_{O/W}$-1,0
	"mean"	= 0,233·log $K_{O/W}$	= 0,2·log $K_{O/W}$	not applicable		= 0,2·log $K_{O/W}$+0,5
chocolate products	"lower limit"	= 0,133·log $K_{O/W}$-1,0	= 0,133·log $K_{O/W}$-1,0			
	"mean"	= 0,233·log $K_{O/W}$-0,2	= 0,233·log $K_{O/W}$			
fish	"lower limit"	= 0,233·log $K_{O/W}$-1,0				
	"mean"	not applicable				
margarine & mayonnaise	"lower limit"	= 0,2·log $K_{O/W}$-1,0	= 0,167·log $K_{O/W}$-1,0	= 0,167·log $K_{O/W}$-1,0		
	"mean"	= 0,2·log $K_{O/W}$+0,5	= 0,167·log $K_{O/W}$	not applicable		
meat products	"lower limit"	= 0,267·log $K_{O/W}$-1,0	= 0,233·log $K_{O/W}$-1,0	= 0,233·log $K_{O/W}$-1,0		
	"mean"	= 0,267·log $K_{O/W}$+1,0	= 0,233·log $K_{O/W}$+0,5	= 0,233·log $K_{O/W}$+0,5		
milk products	"lower limit"	= 0,267·log $K_{O/W}$-1,0	= 0,233·log $K_{O/W}$-1,0	= 0,233·log $K_{O/W}$-1,0		
	"mean"	= 0,267·log $K_{O/W}$+1,0	= 0,233·log $K_{O/W}$+0,5	= 0,233·log $K_{O/W}$		
orange juice	"lower limit"	= 0,267·log $K_{O/W}$-1,0	= 0,233·log $K_{O/W}$-1,0			
	"mean"	not applicable	not applicable			
fruits & vegetables	"lower limit"		= 0,35·log $K_{O/W}$-1,0		= 0,35·log $K_{O/W}$-1,0	
	"mean"		= 0,35·log $K_{O/W}$+1,0		= 0,35·log $K_{O/W}$+0,5	
liquid foods	"lower limit"	= 0,55·log $K_{O/W}$-1,0				
	"mean"	= 0,55·log $K_{O/W}$+0,5				

Diffusion coefficients in foods/food groups

Diffusion coefficients of migrants in food groups are estimated by an Arrhenius type relationship using as a food specific constant (and in analogy to A_P values) A_F values and the mean activation energy for that food group.

Table: Overview food specific constants, A_F values, and mean activation energies ($E_{A,mean}$) for all food groups

Food group	A_F-value		$E_{A,mean}$
	"upper limit"	"mean"	[kJ/mol]
cheese products	-1.8	-4.8	30
chocolate products	8.7	6.7	56
margarine & mayonnaise	8.3	6.3	53
meat products	16.6	13.6	69
milk products	3.8	-0.8	34
orange juice	-9.4	-12.4	3.5
fruits and vegetables	5.6	3.6	48
liquid foods	8.1	6.1	43

Other plastics

Polyolefines (LDPE, HDPE, PP, etc.)

Migration estimation from polyolefines (LDPE, HDPE, PP, etc.) in foods is possible with the migration model D/K/D developed in the project, based on the estimation procedures established for the mass transfer constants to be used.

Polar plastics, e.g. polyamide

Polyamide (PA) was another plastic investigated in the project. Unfortunately only migration experiments with one migrant (caprolactam) and a few foods could be performed. Furthermore swelling of polyamide with aqueous, acidic and alcoholic foods was observed, resulting in a change in its diffusion behaviour. Polyamide and other polar polymers need further systematic migration investigations to be included in the D/K/D model.

Low diffusivity plastics such as polyethylene terephthalate (PET) and polystyrene (PS).

Plastics which were not specifically considered and investigated in the project are the so-called low diffusivity plastics such as polyethylene terephthalate (PET) and polystyrene (PS). Also polycarbonate and rigid PVC or poly(methyl)methacrylates and other polymers would fall into this category.

Migration from these plastics into foods is in the first place and almost only controlled by the diffusion in the polymer itself (diffusion controlled migration). In these cases partitioning of migrants between plastic and food as well as diffusion of migrants in the food has no or nearly no influence on the migration process. With other words, as a general worst case assumption $K_{P,F} = 1$ can be applied for the partition coefficient of the migrants between all plastics and all foods and the diffusion process in all foods can be neglected by using as a general worst case diffusion coefficient of $D_F = 1{,}0$ e-4 cm²/s for all migrants in all foods.

Based on these worst case assumptions made above the advanced migration model D/K/D can be applied very broadly also for migration estimation from low diffusivity plastics into foods.
A prerequisite for this procedure is that no significant swelling effects would occur with the plastic.

Exposure estimation
For compliance evaluation purposes, migration estimation should be performed with the worst case values, i.e. upper limit diffusion coefficients and lower limit partition coefficients.

For exposure estimation the more realistic mean values for the mass transfer constants should be used.

5.6 WP 6 'Demonstration of representativeness, workability, applicability & validation of the migration model for exposure estimations

This work package had 2 major objectives:

1. To demonstrate the workability and reliability of the modelling approach, by comparing it with other estimates of exposure made by other independent routes
2. To establish a translation tool for food simulant migration data into food values

Objective 1:

The aim here was to link the migration model with exposure by drawing exposure scenarios and comparison with exposure case study results from food surveys.

The criteria established for the project required that the validity of the developed migration model when coupled with estimated food chemical intakes, should be tested thus:-

A = estimated intake (in mg / person / day)

B = true intake

C = present 'worst-case' exposure assessments using common assumptions made by SCF, CEU and/or EFSA

For validation the criteria is that: B < A < C

In terms of food concentrations respectively migration this means the following:

Migration level estimated by into-food migration modelling should be higher that the real migration into foods (and so be conservative) but should be less than the unrealistic 'worst-case' assumptions made for migration levels in safety evaluations performed currently by the Commission and by EFSA.

For this purpose, the 9 following test substances were selected and investigated:

Substance	Technological role(s)	Major FCM plastics
Di(2-ethylhexyl) adipate	Additive (plasticiser)	Plasticised PVC films
Epoxidised soybean oil	Additive (heat-stabiliser)	Plasticised PVC films
Irgafos 168	Additive (antioxidant)	Polyolefin films & articles
Styrene	Monomer	Polystyrene and co-polymers
Caprolactam	Monomer	Polyamides (nylons)
Antimony trioxide	Catalyst residue	PET containers and films
Anthranilamide	Additive (scavenger)	PET water bottles
PET cyclic trimer	None (oligomer residue)	PET containers and films
Bisphenol A	Monomer	Polycarbonate articles

These 9 cases are 3 more compared to originally planned 6 substance-scenarios. To allow the reader a better understanding of this: Initially, bisphenol A (BPA) was replaced by caprolactam because BPA migration is likely to be mainly a surface phenomenon which is not fitted by diffusion modelling. At the same time it was desirable to have as an example a low diffusivity plastic and so antimony trioxide and anthranilamide (an acetaldehyde quencher) in PET were included, too. In the end, it was decided to leave BPA in the exercise because it provides a useful contrast for a substance-plastic for which the modelling approach may not be suited.

The scenarios set selected

For each of the 9 substances a food contact scenario was set. This is summarized in the table below. The substances were allocated at a typical concentration ($C_{p,0}$,in ppm, mg/kg plastic) in a monolayer plastic and the nature and the thickness of the plastic was described. This plastic was then described to be intended to be used with a particular food type under a fixed set of time and temperature conditions.

Migration modelling into food was carried out using the advanced migration model as described above in work package 5 and based on the following assumptions/definitions:

Diffusion coefficients in plastics
Diffusion coefficients of migrants in plastics typically are estimated by the semi-empirical relationship developed by partner 03 which requires the additional input of the polymer specific constant for the plastic (A_P-value) and the molecular weight of the migrant.
For the estimation of the migrants diffusion coefficients in the polar plastics, i.e. polyamide and plasticised PVC, expert judgment was applied. For polyamide a polymer specific constant A_P^* = 9 and $A_{P,mean}$ = 6,5 characterising the fully water swollen state was used. For plasticised PVC a polymer specific constant of A_P^* = 14,6 and $A_{P,mean}$ = 10 was used.

Partition coefficients between plastics (polyolefines) and foods
Partition coefficients of migrants between plastics (polyolefines) and food groups are estimated from their linear relationships with the octanol/water partition coefficient of the migrant in the log/log-plots characterizing the food groups.
Despite the fact that the advanced migration model D/K/D is applicable only for polyolefines and low diffusivity polymers, the same estimation procedure for the partition coefficients between polar plastics and foods was applied for polyamide and plasticised PVC.

Diffusion coefficients in foods
Diffusion coefficients of migrants in food groups are estimated by an Arrhenius type relationship using the food specific constant (A_F-value) and the mean activation energy for that food group.

Finally the following should be noted:

- For compliance purpose migration estimation should be overestimative and therefore be performed with the worse case values, i.e. upper limit diffusion coefficients and lower limit partition coefficients.
- For exposure estimation the more realistic mean values for the mass transfer constants should be used

Table: . The food contact scenarios posed for the migration and exposure modelling work

Case No.	Substance	MW (Da)	Plastic monolayer	Thickness (µm)	$C_{p,0}$ (ppm)	Food	Temperature (°C)	Time (hours)
1	Di(2-ethylhexyl) adipate - DEHA	370	plast. PVC	10	100000	cheese with 25% fat	4	120
2	Epoxidised soybean oil - ESBO	950	plast. PVC	10	100000	cheese with 25% fat	4	120
3	Irgafos 168	647	HDPE	200	1000	3% fat milk	4	720
4	Styrene	104	GPPS	150	200	3% fat yoghurt pH>4	4	168
5	Caprolactam	113	PA	25	1000	Pork sausage with 20% fat	4	720
6	Antimony trioxide	292	PET	150	350	Soft beverage pH<4	25	2160
7	Anthranilamide	136	PET	150	500	Mineral water (without CO_2)	25	2160
8	PET cyclic trimer	576	PET	150	10000	Soft beverage, carbonated, pH<4	25	2160
9	Bisphenol A	228	PC	150	50	Infant formula with 5% fat	70	0.5

All applied migration modelling parameters together with the obtained worse-case migration estimates as well as the exposure-related, mean value-oriented migration data are summarized in the following table:

Table: Partition- and diffusion coefficients (including polymer specific constants for plastics) and estimated migration values in food

Case No.	log $K_{P,F}$ lower limit	log $K_{P,F}$ lower limit	log $K_{P,F}$ mean	log $K_{P,F}$ mean	D_P upper limit [cm²/s]	D_P mean [cm²/s]	A_P' upper limit	A_P' mean	tau upper limit	tau mean	migration worst case [mg/dm²]	migration mean [mg/dm²]
1	0,89467	7,8	2,16533	146	2,6E-09	2,6E-11	14,6	10	0	0	9,93	8,74
2	3,66667	4642	5,33333	215443	3,3E-11	3,3E-13	14,6	10	0	0	2,64	0,08
3	2,576	377	4,47	29512	2,8E-13	8,6E-15	13,5	10	1577	1577	0,082	0,005
4	-0,2133	0,6	0,98333	9,6	1,0E-14	1,4E-15	-1	-3	0	0	0,002	0,001
5	-0,824	0,1	1,176	15,0	2,0E-10	1,6E-11	9	6,5	0	0	0,25	0,244
6	2,32267	210	4,15333	14234	1,2E-13	2,2E-15	6,5	2,5	1577	1577	0,035	0,003
7	-0,8133	0,2	0,23333	1,7	8,2E-13	1,5E-14	6,5	2,5	1577	1577	0,142	0,019
8	1,23467	17,2	2,79333	621	9,5E-15	1,7E-16	6,5	2,5	1577	1577	0,31	0,041
9	-0,1147	0,8	1,10667	12,8	1,0E-12	5,0E-14	-2	-5	0	0	0,00024	5,4E-05

$D_F = 10^{-4}$ cm²/s for all foods.

Besides this, independent estimates of exposure in the presented test cases were being made using the following approaches:

- food consumption = 1 kg each day
- all food wrapped in plastic containing the substance or proportion that is wrapped in plastic containing the substance, is derived from packaging usage statistics
- substance migrates at max level, the SML
- migration levels are calculated from the distribution of migration values into simulants with application of reduction factors (according to EU Directive 85/572/EC)
- Estimation of exposure from National food survey data (analytical tests on retail foods) and food consumption statistics
- Estimation of exposure from urinary biomarker surveys

The levels of migration was calculated using the developed mathematical model by using both 'conservative' and 'best fit' modelling parameters were then compared with estimates of migration using a variety of conventional approaches in a tiered manner with 5 tiers up to and including migration levels into foods.

Tier 1: The total amount of substance is assumed to migrate from the whole monolayer of plastic.
Tier 2: The substance is assumed to migrate completely from the first 250 µm layer of plastic in contact with the food, as assumed as a worst case in CEN methods.
Tier 3: The substance is assumed to migrate with what has been described as a 1%-relationship adopted in Commission Regulations for e.g. vinyl chloride, butadiene, acrylonitrile and isocyanates. That is, a 1 mg/kg restriction in the plastic is intended to 'equal' a 10 µg/kg migration. To carry out this calculation on an area basis the conventional mass to surface area ratio of 1 kg food/simulant per 6 dm^2 contact area is used here.
Tier 4: Measured migration into the food simulant specified in EU legislation [Directive 85/572/EEC as amended] under the time and temperature test conditions specified [Directive 82/711/EEC as amended] are used. For simulant D the reduction factors called for in the legislation are applied.
Tier 5: Typical migration concentration data measured in food s are used. It should be noted that the allocation of food migration data here uses a weight of evidence and expert judgement approach.

The results of this exercise which are summarized in the following two tables demonstrated that for the different food scenarios posed the migration modelling meets the validation criteria established before the project started. i.e.
This means, that the estimated migration level from migration modelling are generally higher than the real migration into foods (and so are conservative) but are less than the unrealistic 'worst-case' assumptions made for migration levels in safety evaluations performed currently by the Commission and by EFSA. Using the 'conservative' modelling parameters gave a worst-case that may be useful in compliance testing by industry. More importantly, using the 'best-fit' modelling parameters gave a closer agreement with actual migration data measured in food and the best-fit approach is most suitable for exposure assessment work. This is shown by the bold hashed-line in the 2 tables below.

Table: Worse-case (conservative parameters) migration modelling versus tiered values

No.	Food	Substance	calc. migr wors.case mg/dm²	Tier 1 migr mg/dm²	Tier 3 migr mg/dm²	Tier 4 migr mg/dm²	Tier 5 migr mg/dm²
1	cheese with 25% fat	DEHA	9.9	10	---	3.3	5.0
2	cheese with 25% fat	ESBO	2.6	10	---	3.3	1.5
3	3% fat milk	Irg. 168	0.08	2	1.7	0.003	0.005
4	3% fat yoghurt pH>4	Styrene	0.002	0.3	0.33	0.009	0.001
5	Pork sausage with 20% fat	Caprolactam	0.25	0.25	---	0.25	0.20
6	Soft beverage pH<4	Antimony trioxide	0.035	0.525	0.58	0.005	8E-4
7	Mineral water (without CO_2)	Anthranil-amide	0.14	0.75	0.83	0.001	0.001
8	Soft beverage, carbonated, pH<4	PET cyclic trimer	0.31	15	16.7	0.008	0.006
9	Infant formula with 5% fat	BPA	0.0002	0.075	0.08	0.001	5E-4

Table: Calculated mean (best fit parameters) migration modelling versus tiered values

No.	Food	Substance	calc. mig mean mg/dm²	Tier 1 mig mg/dm²	Tier 3 mig mg/dm²	Tier 4 mig mg/dm²	Tier 5 mig mg/dm²
1	cheese with 25% fat	DEHA	8.7	10	---	3.3	5.0
2	cheese with 25% fat	ESBO	0.08	10	---	3.3	1.5
3	3% fat milk	Irg. 168	0.005	2	1.7	0.003	0.005
4	3% fat yoghurt pH>4	Styrene	0.001	0.3	0.33	0.009	0.001
5	Pork sausage with 20% fat	Caprolactam	0.244	0.25	---	0.25	0.20
6	Soft beverage pH<4	Antimony trioxide	0.003	0.525	0.58	0.005	8E-4
7	Mineral water (without CO_2)	Anthranil-amide	0.019	0.75	0.83	0.001	0.001
8	Soft beverage, carbonated, pH<4	PET cyclic trimer	0.041	15	16.7	0.008	0.006
9	Infant formula with 5% fat	BPA	5E-05	0.075	0.08	0.001	5E-4

During the conduct of this project two partners (P01 and P02) participated in a fundamental review of the state of the art on estimating consumer exposure to substances migrating from food contact materials. This review led to a workshop and then a publication by ILSI-Europe giving recommendations on how to assess consumer exposure (see Section 7).

It is clear that consumer exposure depends on 3 parameters:

- migration levels into the different food items that we eat (‘migration concentrations’)
- the amounts of these different food items that individuals eat (‘food consumption data’)
- the fraction (or frequency) of these food items that are packaged in materials that contain the substance of interest (‘packaging usage data’)

This being so, using mathematical modelling to calculate migration levels into foods contributes to the assessment of exposure. However, it clearly has no contribution to make in providing information on food consumption nor packaging usage. Consequently the usability of migration modelling in estimating consumer exposure rests on how reliably, or not, does it estimate migration levels into foods.

This notwithstanding, some more refine exposure estimates using further Tiers (6, 7 and 8) have been carried out by taking information from available literature for styrene and bisphenol A to Tier 6 and for DEHA to Tier 7 and 8.

- TIER 6 APPROACH FOR DEHA:
  Estimated daily exposure from the diet using food survey data and food consumption data
- TIER 6 APPROACH FOR STYRENE:
  Exposure calculated using dietary information and market share information
- TIER 6 APPROACH FOR BISPHENOL A
  Estimated daily exposure from the diet using food survey data and food consumption data
- TIER 7 APPROACH FOR DEHA
  Estimated daily exposure from a urinary biomarker study
- TIER 8 APPROACH FOR DEHA
  Use of probabilistic modelling to combine concentration data with food item consumption statistics

These comparisons further support the principle applicability of the advanced migration model for estimation of migration levels into foods.

<u>In conclusion: This work fulfils project Deliverable D8</u> “Compendium on exposure scenarios and case studies to demonstrate workability of the migration model for exposure assessment from packaging materials”.

Objective 2:

The aim here was to establish a tool to correlate food simulant migration data with foodstuff migration data or, with other words, to establish a 'translation' tool for migration data. This should allow to evaluate better already existing food simulant migration data.

This tool was established within the project and is based on the use of
(i) the validated migration model describing the migration from the plastic food contact material into food simulants and
(ii) the advanced migration model describing the migration from plastic food contact materials into foodstuffs.
This means: From the existing experimental migration data into food simulants the relevant mass transfer constants (diffusion coefficient of the migrant in the plastic and partition coefficient of the migrant between plastic and food simulant) can be derived by use of the validated migration model. Based on these constants the migration into food can be estimated by applying the advanced migration model.

It is important to note that the food simulant migration data to be translated into food migration values need a certain "quality" in terms of informations related to the plastic as well as the testing device and procedure used for determination of the experimental migration values into the food simulant.

Based on the information available the following three principle cases can be distinguished:

Case A: Initial concentration of migrant in the food contact material $\mathbf{C_{P,0}}$ and diffusion coefficient of the migrant in the food contact material $\mathbf{D_P}$ and partition coefficient between food contact material and food simulant $\mathbf{K_{P,S}}$ is **known**
⇒ substitute $K_{P,S}$ with $K_{P,F}$ and calculate migration into food with advanced migration model

Case B: **one parameter of $\mathbf{C_{P,0}}$, $\mathbf{D_P}$, $\mathbf{K_{P,S}}$ is unknown**
⇒ derive unknown value from migration data with food simulant by applying the validated migration model
⇒ substitute $K_{P,S}$ with $K_{P,F}$ and calculate migration into food with the advanced migration model

Case C: **two parameters of $\mathbf{C_{P,0}}$, $\mathbf{D_P}$, $\mathbf{K_{P,S}}$ are unknown**
⇒ make reasonable assumptions concerning one of the unknown values
⇒ derive second unknown value from migration data with food simulant by applying the validated migration model
⇒ substitute $K_{P,S}$ with $K_{P,F}$ and calculate migration into food with the advanced migration model

Correlation of food migration data from WP3b with food simulant data from the EU project G6RD-CT2000-00411 was possible. Food simulant data obtained under given test conditions (the usual and EU official ones) from the reference films were linked with foodstuff migration values obtained under the test conditions applied in WP3b and WP3c.

The procedure to be followed is described in details in Deliverable D9 where also examples for case A as well as case C are given.

5.7 WP 7 'Estimation of consumer attitude towards modelling'

The social acceptance of migration modelling versus chemical measurements, and its implications for exposure estimation by carrying out a consumer questionnaire and involvement of consumer protection representatives was investigated. In many projects end user opinions are involved. For the Foodmigrosure project it was discussed that food professionals should be the target as the topic of the project was more complex than simply the safety context of food packaging.

The first phase of the Work package was a review of literature to identify experts and existing state of the art in the field. The literary review was also finalized to find any correlation with existing projects related to e.g. consumer attitude, confidence within the field of food safety. Correlating EU projects offered the possibility to identify major expert participants which could be contacted for advice.

In a second phase, a brainstorm was then organised by invitation of a selection of the most relevant experts in the field. Experts received in advance materials describing the project FOODMIGROSURE, ideas of potential type of issues to address for focus group and visual stimuli for the discussion; a small brochure on simple explanations was developed, and a draft of example questionnaire was also developed as base material for the brainstorm; The brainstorm allowed to identify the prioritisation of the options; where the first one would be a focus group (qualitative approach), and quantitative approach could be attempted with questionnaires with a large polling base, and there could be also technical questionnaires for qualitative impressions from stakeholders.

The third phase consisted in the development and deployment of a focus group. The basis was the expertise gathered in a former EU project "TRUST" QLK1-CT-2002-02343 "Food risk communication and consumer's trust in the supply chain". This project was focused on the "evaluation strategies brought about consumer to assess the reliability of the message, the way they process risk information with regards to different food hazards, and the cultural gaps between professional risk managers and laypeople". In parallel, attention was given to the recently published Eurobarometer survey on risk perception from EFSA. Although materials in contact with foods were not treated as part of the many food issues in the polling, the basic questionnaire provided a good base to include such issue in a new poling venue. A specific questionnaire was developed based on the one used by EFSA and questions raised in the EU TRUST project, and checked both with the focus group experts and with consumer associations' experts.

The experiment was then conducted on citizens in full scale during the JRC Open Day which was highly publicised regionally (see picture below) in total.The event also involved the presence of the consumer association representative. Questionnaires and comments were colleted for 700 units which represented about 1400 visitors to the food contact activities.

Figure 1: the advertisement

Figure: Advertisement leaflet for the JRC open day

Deliverable D10, resulting from work package 7 is a comprehensive dossier on the project activities, investigation and results on the consumer attitude towards modelled versus measured migration.

6 Project presentation and publication of project results

Besides a project information folder and the project website
http://foodmigrosure.org or http://foodmigrosure.com
(also linked with the "EU Joint Research Centre website" http://cpf.jrc.it/webpack/)
numerous oral or poster presentations and scientific publications (manuscripts or posters) have been made during and after the project period.

6.1 Presentations

1. Poster presentation on the EURO FOOD CHEM XII Conference on 24-26 September 2003 in Brugge. The project summary is included in the conference proceedings books. Poster and manuscript have been made available to DG Research with the 1st interim report [Lit. 1) and 2) from the publication list in 6.2.] made by Partner 01.
2. Two poster presentations at the 8th International Symposium Hyphenated Techniques in Chromatography and Hyphenated Chromatographic Analyzers, 2-4th February 2004 in Brugges made by partner 06 [Lit. 3) and 4)] made by Partner 06.
3. Presentation at the DG Research (Unit E.2) Workshop "Overview on European Research related to Food Packaging, Migration and Contact" on 12th of February 2004 in Brussels made by the coordinator.
4. Oral presentation to an audience of approximately 100 participants from food and food packaging industry at the occasion of the Annual Conference of Fraunhofer IVV in May 2004 in Erding, Germany, made by Partner 01.
5. Poster presentation on the Austrian Food Chemistry Days in May 2004 in Vienna made by Partner 07 [Lit. 7)].
6. Oral presentation at the European Plastic News Conference 'Food contact Plastics' in Brussels on 30th June 2004 by Partner 04.
7. Workshop on food packaging at the Safe Food Conference in Bologna on June 9/10th of June 2004 by Partner P05.
8. Poster presentation on the '33. Deutscher Lebensmittelchemikertag' in Bonn in September 2004 by Partner 07.
9. Two poster presentations on the 9th Karlsruhe Nutrition Congress on 10 – 12 October 2004 in Karlsruhe, Germany, made by Partners 05, 07 & 08.
10. Presentation at the International Congress on Food Safety in Mexico on 13rd to 15th of October 2004 by Partner 06 [Lit. 8)]
11. Oral presentation at the 3rd ILSI Conference 'FOOD PACKAGING - ENSURING THE SAFETY, QUALITY AND TRACEABILITY OF FOODS' on 17th -19th November 2004 in Barcelona [Lit.12)]
12. 10 Poster presentations at the 3rd ILSI Conference 'FOOD PACKAGING - ENSURING THE SAFETY, QUALITY AND TRACEABILITY OF FOODS' on 17th -19th November 2004 in Barcelona.
13. 3 Poster presentation at the 2nd International Symposium on the Separation and Characterisation of natural and synthetic macromolecules in Amsterdam in February 2005 made by Partners 05 and 06 [Lit. 13),14), 15)].
14. Presentation on the EURO FOOD CHEM Conference 2005 in Hamburg, Germany, by Partner 07. [Lit. 10)].

15. 5 Poster presentations at the 9th International Symposium on Hyphenated Techniques in Chromatography Analyzers (HTC-9), York, UK, February 8–10, by Partner 06 [Lit. 16) – 20)].
16. 2 Poster presentations at the the 13th World Congress of Food Science & Technology 'Food is Life' 17-21 September 2006 in Nantes, France, made by Partner 06 [Lit. 21), 22)].
17. Oral presentation at the Conference 'Food Contact Plastics 2006' 13-14 June 2006, Brussels, Belgium, made by Partner 05.
18. Closing Conference on the Foodmigrosure Project 27-28 September 2006 in Baveno, Piemonte, Italy. Within the conference programme 15 oral presentations were made and 36 posters were presented. Oral presentations and posters can be downloaded from http://crl-fcm.jrc.it.
19. Oral presentation at the 23th PIRA International Conference Plastics & Polymers in Contact with Foodstuffs 11-12 December 2006 in Brussels, Belgium, made by Partner 01.
20. Oral presentation on the New International Conference 'Food Contact Polymers 2007' 21-22 February 2007, Brussels, Belgium, made by Partner 01.
21. Oral presentation on the outcome of the Foodmigrosure project and possible consequences for food packaging legislation at the workshop of the German Bundesverband Naturkost Naturwaren (BNN) Herstellung und Handel e.V.: BNN Fachtagung: 'Wechselwirkungen zwischen Verpackungen und Bio-Lebensmitteln.', 28th February 2007, Frankfurt, Germany, made by Partner 01.
22. Oral presentation on the outcome of the Foodmigrosure project and possible consequences for food packaging legislation at the 121. Meeting of the 'Plastics Commission' of the German Bundesinstitut für Risikobewertung (BfR), 26th April 2007, Berlin, made by Partner 01.
23. Oral presentation on the outcome of the Foodmigrosure project and possible consequences for food packaging legislation at the 16. VFV Tagung "Trends 2008 in der europäischen Lebensmittelverpackung" at ISEGA Aschaffenburg, 8. April 2008 Germany, made by Partner 01.

6.2 *Scientific publications*

1) *Franz R., Castle L., Cooper I., Paseiro P., Mandanis A., Piringer O., Simoneau C., Steiner I. Hinrichs K., Ribeiro A. and Gruner A.:* Modelling migration from plastics into foodstuffs as a novel and cost efficient tool for estimation of consumer exposure from food contact materials. Poster presented at the Euro Food Chem XII 'Strategies for safe food' Brugge, 24-26 September 2003.
2) *Franz R., Castle L., Cooper I., Paseiro P., Mandanis A., Piringer O., Simoneau C., Steiner I. and Hinrichs K.:* Modelling migration from plastics into foodstuffs as a novel and cost efficient tool for estimation of consumer exposure from food contact materials. Euro Food Chem XII 'Strategies for safe food' Brugge, 24-26 September 2003, Proceedings Volume 2, pp. 462-465.
3) *Sanches Silva, A. T., Sendon Garcia R. and Paseiro Losada P.* DETERMINATION OF TRICLOSAN MIGRATION IN FOODSTUFFS FROM PACKAGING MATERIALS, Abstracts Book of the 8th International Symposium Hyphenated Techniques in Chromatography and Hyphenated Chromatographic Analyzers, 2-4th February 2004, Brugges.
4) *Sendon Garcia R., Sanches Silva, A. T.and Paseiro Losada P.* DETERMINATION OF DIPHENYLBUTADIENE MIGRATION IN FOODSTUFFS FROM PACKAGING MATERIALS, Abstracts Book of the 8th International Symposium Hyphenated Techniques in Chromatography and Hyphenated Chromatographic Analyzers, 2-4th February 2004, Brugges.
5) *Franz R..* Modellierung der Migration aus Verpackungskunststoffen in Lebensmittel – Instrument zur Bewertung der verpackungsbedingten Belastung des Verbrauchers. Verpackungs-Rundschau 55 (5), TWB S. 87-90, 2004.
6) *Franz R..* Modellierung der Migration aus Verpackungskunststoffen in Lebensmittel - ein neues und kosteneffizientes Instrument zur Bewertung der verpackungsbedingten Verbraucherexposition. In: Deutsche Lebensmittel-Rundschau, 100. Jahrgang, Heft 10, 2004, p. 385-388
7) *Ingrid Steiner, Peter Volansky, Catherine Simoneau and Andrè Mandanis*, Modellierung der Migration von Kunststoffen in Lebensmittel als neues und kostengünstiges Verfahren zur Abschätzung der Belastung von Verbrauchern durch Lebensmittelverpackungsmaterialien - Auswahl der Prüflebensmittel nach ihren physikalisch-chemischen Eigenschaften und der Verzehrhäufigkeit. Poster presentation at the Austrian Food Chemistry Days, May 2004, Vienna.
8) *P. Paseiro Losada, Roland Franz, Laurence Castle, Rainer Brandsch, Ian Cooper, Catherine Simoneau, Ingrid Steiner, Andre Mandanis*: Modelado de la migración de los plásticos a los alimentos como un instrumento nuevo y de coste eficaz para la estimación de la exposición del consumidor a los materiales en contacto con alimentos. Proceedings of the International Congress on Food Safety in Mexico on 13rd to 15th of October 2004.
9) *Ana Sanchez Silva, Raquel Sendón-García, Julia López-Hernández, Perfecto Paseiro-Losada*: Determination od Triclosan in foodstuffs. Journal of Sep. Science, 28, p.65 – 72, 2005, Wiley VCH, Weinheim.
10) *I. Steiner; P. Volansky; C. Strasser*: Migration Kinetics of Benzophenone and Diphenyl Phthalate from Low Density Polyethylene in representative foodstuffs. Presented at the Euro Food Chem XIII in Hamburg 2005.
11) Project overview article by Roland Franz, to be published in Dt. Lebensmittelrundschau

12) *Roland Franz*: Migration modelling from food-contact plastics into foodstuffs as a new tool for consumer exposure estimation. Food Additives and Contaminants, October 2005; 22 (10); p. 920-937

13) *R. Sendón García; A. T. Sanches Silva; P. Paseiro Losada and Roland Franz*: STUDY ON THE MIGRATION BEHAVIOUR OF DIPHENYLBUTADIENE FROM LPDE INTO DRY FOODS, In: Proceedings of 2nd International Symposium on the Separation and Characterization of Natural and Synthetic Macromolecules, Amsterdam, The Netherlands, February 2–4, 2005.

14) *A. T. Sanches Silva; R. Sendón García; P. Paseiro Losada and Roland Franz*: KINETICS MIGRATION STUDIES OF DIPHENYLBUTADIENE FROM LDPE INTO MEAT PRODUCTS. In: Proceedings of 2nd International Symposium on the Separation and Characterization of Natural and Synthetic Macromolecules, Amsterdam, The Netherlands, February 2–4, 2005

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16) *A. Sanches Silva; R. Sendón García; J.M. Cruz Freire, R. Franz and P. Paseiro Losada*: Evaluation by HPLC-UV of two methods to contaminate polyolefin films with model migrants. Poster 175, in Proceedings of 9th International Symposium on Hyphenated Techniques in Chromatography Analyzers (HTC-9), York, UK, February 8–10, 2006.

17) *A. Sanches Silva; R. Sendón García; J.M. Cruz Freire, R. Franz and P. Paseiro Losada*: Time-temperature study of the kinetics of migration of DPBD (Diphenylbutadiene) from plastics into chocolate, spread chocolate and margarine.. Poster 176, in Proceedings of 9th International Symposium on Hyphenated Techniques in Chromatography Analyzers (HTC-9), York, UK, February 8–10, 2006.

18) *A. Sanches Silva; R. Sendón García; J.M. Cruz Freire, R. Franz and P. Paseiro Losada:* Study of the transport and partition processes of DPBD and triclosan in pork meat. Poster 177, in Proceedings of 9th International Symposium on Hyphenated Techniques in Chromatography Analyzers (HTC-9), York, UK, February 8–10, 2006.

19) *R. Sendón García, A. Sanches Silva, J.M. Cruz Freire, R. Franz and P. Paseiro Losada*: Migration kinetic studies of diphenylbutadiene from LDPE into cheeses with different fat levels. Poster 186, in Proceedings of 9th International Symposium on Hyphenated Techniques in Chromatography Analyzers (HTC-9), York, UK, February 8–10, 2006.

20) *R. Sendón García, A. Sanches Silva, J.M. Cruz Freire, R. Franz and P. Paseiro Losada:* Transport and partitioning processes of diphenylbutadiene and triclosan into and within flour and rice. Poster 187, in Proceedings of 9th International Symposium on Hyphenated Techniques in Chromatography Analyzers (HTC-9), York, UK, February 8–10, 2006.

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22) *A. Sanches Silva, J.M. Cruz; R. Sendón García, R. Franz and P. Paseiro Losada*: BHT, TRICLOSAN AND DPBD DIFFUSION BEHAVIOUR FROM PLASTIC INTO AND WITHIN CHEESES. Poster 735 of the 13th World Congress of Food Science &

Technology ‘Food is Life’ 17-21 September 2006 in Nantes, France.

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25) *P. Paseiro, C. Simoneau and R. Franz:* Compilation of analytical methods for model migrants in foodstuffs: Collection of method descriptions. European Commission – Joint Research Centre, European Report EUR 22232 EN, © European Communities 2006 (printed in Italy).

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29) *A. Sanches Silva; J. M. Cruz Freire, R. Sendón García, R. Franz and P. Paseiro Losada*: Time-temperature study of the kinetics of migration of DPBD from plastics into chocolate, chocolate spread and margarine. Food Research International 40 (2007), 679-686.

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31) *Franz, R and Stoermer A.:* ‘Migration of plastic constituents’. Chapter 11 pp. 400 – 407. In: Piringer, O.-G. and Baner, A.L. (editors): Plastic Packaging - Interactions with Foods and Pharmaceuticals. Wiley-VCH Verlag GmbH Weinheim, 2008. ISBN 978-3-527-31455-3.

32) *A. Sanches Silva; J. M. Cruz Freire, R. Franz and P. Paseiro Losada*: Time-temperature study of the kinetics of migration of diphenyl butadiene from polyethylene films into aqueous foodstuffs. Food Research International 41 (2008) 2, 138 – 144.

33) *J.M. Cruz, A. Sanches Silva, R. Sendón García, R. Franz and P. Paseiro Losada:* Studies of mass transport of model chemicals from packaging into and within cheeses. Journal of Food Engineering, in press. Available online: doi:10.1016/j.jfoodeng.2007.11.022.

34) *A. Sanches-Silva, J.M. Cruz, R. Franz and P. Paseiro-Losada*: Mass transport studies of model migrants within dry foodstuffs. Journal of Cereal Science, In press. Available online 18 March 2008. doi:10.1016/j.jcs.2008.02.006 .

7 Summary of project (and other important) findings in relation to comparison of migration into food simulants versus foods as a major issue relevant for EU food packaging legislation

The European food packaging compliance testing concept is based on the use of principally four food simulants with the pre-assumption that they serve as model contact media for all types of foods (EU Directive 85/572/EEC). To take account of the generally assumed higher extraction efficiency of the fat simulant D (olive oil) a reduction factor concept is legally applied to adjust the experimental results obtained from food simulant D to migration levels in foods. It needs to emphasize that this applied concept and the correlations between simulant and foods have been established approximately 30 years ago and that already at this time the authors of this Directive have been aware about the large conventional character of the assignments done in this Directive at this time. This becomes evident when reading article 3 of this Directive:
"Adaptations to be made to the Annex to this Directive in the light of progress in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC."

Scientific knowledge in the area of migration research has almost exponentially evolved, major deficiencies linked to this European concept were getting more and more evident. Again and again discrepancies and miscorrelations were found when comparing the actual migration in foodstuffs with that obtained from the fat simulant D according to the correlation as set by the EU legislation. An important study[1] which had a completely different aim, namely to develop a fatty contact test method in support of EU Directive 85/572/EEC, revealed with its systematic research programme clearly the weakness of the fat simulant D reduction factor concept. The data generated in this project demonstrated clearly that fatty foods cannot be so simply correlated with the fat simulant D migration results and that in particular cases such as migration into chocolate spreads or mayonnaise or cocoa powder or even dry foods such as biscuits would also be largely underestimated by the 85/572 approach.

Very early evidence had also been found that migration into milk products is likely to be underestimated when using aqueous simulants A and C for simulation[2]. In this study the migration behaviour of styrene monomer from PS into different milk products and water ethanol mixtures was investigated and the authors concluded that 50 % ethanol in water would simulate milks more appropriately. The scientific reason for that was found in the gas/liquid partition coefficients which were also determined for styrene in the investigated foods and simulants. These coefficients were largely higher in pure water compared to the milks and were found more or less identical for 50% ethanol and for regular milk containing 3.5 % fat.

During the Foodmigrosure project, by end of 2005, the so-called 'ITX crisis' came up and revealed again impressively the potential for simulant-to-food miscorrelations. ITX (isopropylthioxanthone) was used as a photoinitiator in food packaging inks and was transferred from the printing ink layer from the outside of the packaging material to the food contact side either by set-off (on the role or in stacked beakers before filling) or permeation through the packaging structure. Migration data which were made publicly available[3], demonstrated that ITX migration highly depended on the nature of the foods.

[1] Castle, L., Honeybone, C.A., Read, W.A: and Boenke, A., 2000, BCR Information Chemical Analysis 'Establishment of a Migration Test Method for Fatty Contact', EU Report 19376 EN.
[2] O´Neill ET, Tuohy JJ, Franz R. 1994. Comparison of milk and ethanol/water mixtures with respect to monostyrene migration from a polystyrene packaging material. International Dairy Journal 4: 271-283.
[3] EFSA (European Food Safety Authority) 2005, Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2-Isopropyl thioxanthone

For instance, for clear fruit juices ITX migration was not detectable (< 5ng/L) but for cloudy drinks migration values ranged up approximately 300 ppb (ng/L). Similar high values were also obtained for milk and soy drinks. It should be noted that the food simulants A, B and C would also not give any detectable migration above 5 ng/L, which is simply due to the low solubility of ITX in these aqueous matrices. Very recently a study originating from the Foodmigrosure project has been undertaken to investigate the reasons for the higher migration in cloudy fruit juices using as the case example orange juice in contact with an LDPE film containing diphenyl butadiene (DPBD), an optical brightener. After removal of solids by centrifugation and filtration from the orange juice matrix DPBD migration into the remaining clear filtrate was almost not detectable anymore compared to a high migration value obtained from the orange juice[4].

As described above in the Foodmigrosure project an extensive data set obtained from kinetic migration experiments as well as from measurements of concentration profiles in foods was elaborated. From these data sets the needed physico-chemical parameters (diffusion coefficients in foods and partition coefficients between plastics and foods) for into-food migration modelling were derived. From these experiments and findings the following important conclusions must be drawn in relation to the EU Directive 85/572 approach:

- EU assumptions for correlations between the fat test with olive oil and fatty foods are very problematic and are rather underestimative than realistic, if possible at all
- the aqueous simulants A, B and C do largely <u>not</u> reflect (and often underestimate) what occurs in aqueous foods, which is due to their too low solubility for many or even most migrants.

The <u>two major reasons</u> for these deficiencies in the 85/572 approach are the following:

1. The assignments made in the Directive have focused on the simulation of foods only and have never taken into account the material and structural properties of the food contact material. However: the simulant-to-food correlation depends severely on the type of plastics material (criterion: its basic diffusivity) and for a given plastics material, in particular for polyolefins (which have a high diffusivity), on the thickness. Moreover, the molecular weight of the migrant plays also a role as well as the test temperature, because these parameters are linked with the diffusion coefficient.

As a consequence the following general rule can be derived:

Reduction factors in the sense of 85/572 are very problematic or not applicable in cases:

(i) where the diffusion in the FCM is high and its thickness low (because this can lead to exhaustive migration understood as migration at time is close to maximum possible migration) and
(ii) where the diffusion in the FCM is (very) low and this largely independent on its thickness. These cases are so-called FCM-diffusion-controlled migration scenarios (infinite migration case) where partitioning effects do not play a crucial role for the migration test result.

2. The attempt to simulate so-called 'aqueous foods' with simulants A, B or even C (10 % ethanol) must be considered today largely as very critical and scientifically not appropriate when taking the

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(ITX) and 2-ethylhexyl-4-dimethylaminobenzoate (EHDAB) in food contact materials (Question numbers EFSA-Q-2005-240 & EFSA-Q-2005-241). The EFSA Journal 293, 1-15.

[4] A. Sanches Silva; J. M. Cruz Freire, R. Franz and P. Paseiro Losada: Time-temperature study of the kinetics of migration of diphenyl butadiene from polyethylene films into aqueous foodstuffs. Food Research International 41 (2008) 2, 138 – 144.

solubility of potential migrants in water or their log $P_{O/W}$ values into account. If a migrant has, for instance, has a log $P_{O/W}$ = 5.5 (which is the case for the ITX molecule), then one can assume a partition coefficient roughly of K = 100000 between the concentration in the FCM (for instance polymer P) and in simulant A. Consequently, the expectable concentration in simulant A will be $C_{Water} < 0.00001 \times C_{Polymer}$. This means, for instance, if there was a concentration of 10 ppm in the polymer then the migration into simulant A will not exceed 0.1 ppb. Similar considerations are applicable to lipophilic migrants such as phthalates and other plasticisers, hydrocarbons, oligomers of polyolefines, antioxidants etc and may lead to the conclusion that migration testing in simulant A, B or C may be unnecessary.

As a logic consequence of these findings, revision of EU Directive 85/572/EC, in the sense of its Article 3, appears to be urgently necessary. This is of particular importance because more realistic migration simulation is a high priority requirement in the light of the ongoing discussion on the exposure-related migration evaluation. Today, due to a lack of realistic migration values in foods, exposure calculations are often based on food simulant data which, from the reasons discussed above, is a critical undertaking and may lead to underestimations in many cases. In this context, we can assume today, that for given reasons and complications in context with the experimental determination of migrant concentrations in foods in general, more realistic migration simulation and 'into-food' migration modelling must be considered as one fundamental prerequisite for exposure estimations.

8 Dissemination & exploitation of project results at all stakeholders levels

From the beginning, the Foodmigrosure project has found high attention in the public domain at the level of all interested or concerned parties and potential stakeholders. To satisfy this public interest, many presentations and demonstrations of the projects intention, later of its results and findings and finally also of its conclusions and potential consequences for EU legislation and for migration control and evaluation laboratories (industry as well as public) have been carried out within national and international conferences, workshops, seminars and other gremia (see chapter 6.1).

In this respect, the closing conference in Baveno, Italy, in 2006 was for sure a highlight event. More than 100 participants not only from Europe but also from overseas did highly appreciate our demonstration of the project findings as presented by a 2 days programme including 36 posters. A high enrichment of this event was obtained by an oral presentation of an US-FDA representative, Mr. Tim Begley (his lab was involved in the project by making important experimental into-food migration data available) and by the active participation of European industry representatives as well as scientists from official control/surveillance laboratories.

Another very efficient dissemination action was conducted within Work Package 7 (see above) where the consumer attitude towards migration modelling was investigated and where a large audience of consumers could be reached and brought into a communication process with the Foodmigrosure project.

In addition, the project has originated more than 30 scientific presentations and publications (see chapter 6.2). Among them are, from an analytical point of view, two important EU reports (References 25) and 26) in chapter 6.2) have been published. These reports are very useful and supportive to any migration test laboratory since they contain comprehensive guidance for selecting migration test methods and contain standardised analytical procedures to determine migrants in foodstuffs.

As an important measure taken by the EU Commission to meet the findings of this project, the correction of the food simulant water for milk and milk products by replacing simulant A with 50% ethanol needs to be mentioned here. This regulatory consequence was implemented in 2007 with EU Directive 2007/19/EC which represents an amendment to the above mentioned EU Directive 85/572/EEC.
In the meantime, in the light of the outcome of the Foodmigrosure project, the EU Commission has considered further regulatory changes and is currently in the discussion on these changes with the member states. Implementation of these changes may be expected in 2009.

During the project duration, a successful cooperation was made with an expert group on estimation of exposure which was initiated and coordinated by the International Life Sciences Institute (ILSI) Europe. As an outcome of this expert group and with the contribution of the Foodmigrosure project, made through the project coordinator, a comprehensive and useful guidance document for exposure assessment was published in 2007 :

Brands B., Castle L., Duffy E., Franz R., Garcia L., Gibney M., Hart A. and Oldring P.:
Guidance for Exposure Assessment of Substances Migrating from Food Packaging Materials. Scientific report of an ILSI Europe Expert Group. ILSI (International Life Science Institute), Brussels, Belgium, 2007. ISBN: 9789078637097.

In this guidance document, the idea was stressed and supported that concentrations of migrants from food contact materials needed to estimate exposure can most likely only be obtained migration modelling on a broad scale and at economic time and cost expenditures. To establish such an 'into-food' migration model was indeed the objective of the Foodmigrosure project.

Finally, it needs to mention that due to large dissemination of the project results indeed all stakeholders have been made aware of the potential problems when carrying out their compliance test schemes. As a consequence it can be assumed that better and more efficient compliance testing is already carried out both at industry level and also in public or governmental control laboratories to the benefit of the consumer.

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Abstract

Between March 2003 and September 2006 the FOODMIGROSURE project, contract number QLK-CT2002-2390, was carried out by 9 European project partners with the intention to develop an 'into-food' migration model tool which should enable prediction of mass transfer of constituents from plastics food contact materials into foodstuffs in support of calculations/estimations of the exposure of consumers towards food packaging constituents. A further objective was to investigate the social acceptance of migration modelling versus chemical measurements, and its implications for exposure estimation. The project resulted in comprehensive sets of migration data for a wide range of substances and large sets of various foodstuffs. The data obtained allowed to validate a migration models on real foods both for compliance as worst case or refined for exposure assessment. The results also showed aspects of food chemistry that can influence migration, and initiated a new area of public risk perception specific to food contact materials safety. Systematic kinetics studies had an impact on Directive 85/572/EC on correspondence factors of foodstuffs and food simulants; as well as on the use of mathematical modelling,and on standardisation (CEN) stemming from the development of methods in foodstuffs.

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