FOOD MIGROSURE

Project Deliverable 6

Section 1: PROJECT IDENTIFICATION	NOT CONFIDENTIAL

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

Acronym: **FOODMIGROSURE**

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List of participants

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- **DEFRA Central Science Laboratory, York, UK (contractor)**
- **FABES GmbH, Munich, DE (contractor)**
- **Pira International Ltd, Leatherhead, UK (contractor)**
- **EC Joint Research Centre,IHCP, Ispra, IT (contractor)**
- **University of Santiago de Compostela, ES (contractor)**
- **Vienna University of Technology, AT (contractor)**
- **Nestlé Research Centre, Lausanne, CH (contractor)**
- **CEFIC, BIT-FCA, Brussels, BE (contractor)**

Section 2: Deliverable 6	NOT CONFIDENTIAL
Objectives: According to the Technical Annex: "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)"	
Achievements and documents versus objectives: - The report is attached in the Annex	

Freising, in January 2004

The project coordinator

QLK1-CT2002-2390 'FOODMIGROSURE'

Project Deliverable 6

Responsible partner: P03

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Annex

Modelling Migration from Food Contact Plastics

- State of the art and future perspectives for application to foodstuffs-

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1 Introduction

In most countries of the world the average time needed for the purchase as well as preparation of the daily diet of a citizen decreased from generation to generation due to sustained enhancements of cultivation procedures, processing and conservation technologies, as well as storage and preparation of foodstuffs. In industrialised nations this process was even more accelerated in the last century. Nowadays, a nearly complete transfer of nutrients from the farm to the fork can be realised by using modern technologies in agriculture, food industry and commerce enabled by the important contribution and various functionalities of packaging for foodstuffs. Packaging materials preserve and/or add value to the products through functionalities like the increase of mechanical stability as well as the quality preservation of the product during the transport from the farm to the food manufacturer and/or end consumer. Furthermore, packaging increases the shelf

live of foodstuffs, offers an improved consumer health protection and is also very important for the logistics, distribution and even advertising. Nowadays, in modern economies most of the manufactured foodstuffs are packaged.
However, the functionality of a packaging material cannot rule out the fact that due to direct contact interactions between packaging material and packaged food occurs. Looking at possible interactions between packaging material and foodstuff the transfer of substances from the packaging material into the foodstuff and from here to humans as end consumer has to be of main concern.

In the last fifty years many industrialised nations recognised that the increased use of food packaging and in this connection the emerging amount of various materials used as packaging for foodstuffs may represent a risk for the human health regarding the transfer of substances from the packaging to the food chain. As a consequence an adequate legislation for packaging materials has been established with respect to consumer protection, its aim being obliged to those guidelines already implied in food packaging as well as to comply with given standards of consumer health protection. Naturally, the risk assessment, the establishment of risk levels for human health as well as the control of the adherence of transfer limits is very cost as well as work intensive for the packaging/ food industry. But however, as long as the human health risk caused by the exposure to substances transferred from food packaging into foodstuffs can be correctly assessed and furthermore the economical benefits of packaging foodstuffs prevail additional costs of risk assessment; there is no reason to scrutinize modern food packaging technologies. The solution is to develop a framework in which an improved control of the mass transfer from packaging into foodstuffs is possible and to establish standards which correctly assess the risk of exposure of humans to this process.

2 Some considerations on the interaction between packaging and foodstuffs

Interactions between packaging and foodstuff can be principally distinguished into physical and chemical interaction processes. The physical interaction determines the shape and size of a packaged good, at least in part its mechanical properties and also its optical appearance, for example. The chemical interaction derives in principle from a transfer of substances between packaging and food as well as changes in their quality/properties due to this process. From the point of view of consumer protection the focus has to be on the health risks caused by substances possibly released from the packaging into the foodstuff. These substances are components of a packaging material which are not added intentionally to the foodstuff but migrate from a food contact material into the foodstuff through mass transfer processes. However, in most cases migration leads time depending to a change of the quality of foodstuffs and therefore is one of the key topics for quality assurance of foodstuffs on the way from the farm to the fork.

Depending on factors like concentration, mobility and solubility in the packaging and food as well as depending on temperature and duration of the food contact, substances inevitably migrate from the packaging, to a more or less extent, into the food. The following reasons demonstrate that analysing, quantifying and interpreting migration processes are a complex topic. First, the high number of substances nowadays used by the industry to manufacture food packaging materials has to be considered. This number is additionally increased when one considers the use of recycled materials. Then the number and variety of packaged foods is even higher and the spectrum of their physical and chemical properties is tremendous! Migration of a certain substance from the same type of material is different for solid and liquid foods, homogenous or heterogeneous ones and depends as well on the chemical nature (fat or alcohol content for example), pH-potential, etc. of the food. Finally the contact conditions between the packaging and foodstuff strongly influence migration and may vary between such extremes as there are long time deep-freezing and accelerated microwave cooking.

Migration always causes a change of food composition with time. This can be analytically measured as the concentration of a substance, $C_{F,t}$, in the foodstuff and then can be directly related to the quality of the foodstuff. The European food regulation is mainly based on limitations of $C_{F,t}$ on the food side by means of a positive list of substances under exclusion of all others and related specific migration limits /1, 2/. Migration of a substance from a packaging material into a foodstuff may be basically regarded as a succession of mass transfer processes from which the slowest one defines the overall time scale. In most cases of practical relevance the diffusion process within the packaging material is the slowest step of the migration process. On the other hand the relationship between the solubility of a substance in the packaging material and the foodstuff, i.e. the partitioning, strongly influences the overall amount of a substance migrated into the foodstuff and thereof the amount of migrant still left in the packaging material when the system reaches the equilibrium state.

3 Analytical assessment of migration

Historically, the quality assurance of materials intended to come into contact with foodstuffs has been assessed in a similar way as for substances directly added to foodstuffs, namely by analytical chemistry. However, there are differences between these two topics. If for example an ingredient of the recipe is added intentionally to the foodstuff the overall process is a succession of two mass transfer processes. The addition of the ingredient to the foodstuff might be instantaneous or done step-by-step and usually is followed by a mixing process were convection is applied to the foodstuff for homogenisation. On a general time scale, these two processes may proceed very fast for liquid preparations or take some time for viscous foodstuffs so that they can be considered as fast ones. The concentration of the ingredient in the foodstuff, chemical reactions or losses excluded, will be constant during the shelf life of the foodstuff.

Before analytical assessment a foodstuff is generally brought into contact with a food packaging material at a certain temperature for a given time. During this contact migration takes place. On a general time scale migration processes are in most cases expected to be slow. After the exposure for the time t the migrated substance/s is/are assessed analytically in the food and its/their level of migration, $C_{F,t}$, is/are determined. However, due to the fact that migration is a slow process, the concentration/s $C_{F,t}$ is/are most likely not constant during the shelf life of the

foodstuff. In the EU legislation the migration level $C_{F,t}$ of a substance from the positive list is compared with a specific migration limit (SML) which is given by the legislator /2/. In addition a simple gravimetric test is performed to determine the weight of all substances transferred from packaging to foodstuff during contact/exposure time t /3, 4/. Real foodstuffs are very complex matrices and the analytical assessment of low levels of food contact substances (migrants) is a challenging and expensive task. Therefore, a system based on food simulants was established and used to simulate migration from real foodstuffs /5/. Additionally, accelerated migration test conditions were defined to shorten the test time which otherwise should be as long as the projected shelf life of the packed food /3/. Food simulants and test conditions to be used in migration testing are subject of various regulations on national and European level /6/.
From the point of view of migration into foodstuffs the efforts to be undertaken to realise a high level of consumer protection are considerable. Packaging a foodstuff requires that food as well as packaging industry work together. The value chain starts from the raw materials and following several conversion steps leads to the finished foodstuffs as well as packaging materials. A consistent quality assurance system must cover the complete value chain for both products to be brought together at the final stage. The same considerations are valid for food contact materials used in processing equipment or household tools, which come into contact with foodstuffs at various processing steps during the production and preparation of food. The raw materials used for packaging materials can be divided in several main categories; glass, paper/cardboard, metals and organic materials. In practice most packaging materials are assemblies of several types of materials for example a glass bottle with a plastic lid, a metal can coated with a protective coating material or a plastic bottle sealed with an aluminium foil, etc. More than 90% of actual food packaging materials are made from organic materials or have at least one organic layer and this one is often the food contact layer.

All organic materials used in food packaging have specific molecular structures and their chemical nature can be assessed analytically. In practice, these materials are not 100% pure but contain, as a result of the manufacturing process, a certain amount of different molecular species. Another characteristic of these organic materials is that they are not inert. Thus, as soon as they come into contact with a foodstuff, migration of substances from the packaging into the food takes place. Usually the migration rate for small molecules with a low molecular weight is high due to the high mobility within the organic matrix and the high solubility in the foodstuff. The rate of migration decreases as molecules become larger and/or heavier; have a lower mobility within the organic matrix and low solubility in the foodstuffs. The organic matrix itself can be flexible or rigid, a factor which has also an influence on the migration rate. Last but not least, in migration processes the temperature, T, during the contact between the packaging material and foodstuff plays an important role; i.e. usually the rate of migration increases exponentially with T. Eventually, all factors described above have an influence on the level of food contamination with packaging components after a given contact time.

The substances which might migrate from the food contact material into a foodstuff during a contact time, t, should, in principle, be analytically identified and quantified before the foodstuff is packaged. A given packaging material might be suitable only for one category of foodstuffs, e.g. aqueous, and not for others. Other types of packaging might be more generally applicable. As already mentioned, the nature of the foodstuff also influences the migration process. The same packaging material and migrant might lead to different uptake profiles and quantities in various food types. Thus, the food law compliance of a food contact material should be strictly related to the food type, too.

In conclusion, a food producer using a packaging material to pack his products has to make sure that the applied packaging material is compliant with the food legislation. He can experimentally test the compliance with the food regulations by assessing all relevant packaging components migrated into the foodstuff analytically. Herewith, the test conditions (contact time and temperature) chosen for the exposure prior to the analytical test must be those specified by the regulation in force for the real packaging application considered /3/. Provided that validated analytical methods are available and implemented in the test laboratory this approach assumes that the food producer knows all components with regulatory concern of the packaging material and thus can assess them analytically or that he can identify unambiguously and assess analytically all potential packaging components with regulatory concerns without prior knowledge. Practice shows that the above made idealistic assumptions are generally not fulfilled. In most cases the food producer is neither in possession of all necessary information concerning the packaging components with regulatory concern, nor is the testing laboratory able to identify all of them unambiguously. Additionally, there are not enough validated analytical methods for migration testing of packaging components available so far. In practice, the necessary information is spread along the value chain starting from the raw material producer up to the converters and packers. Nowadays, the value chain is split into various specialised converters, which contribute to the realisation of the final packaging material. Each conversion step generates or integrates new components into the packaging material. The consequence is an increasing migration potential, which finally has to be assessed analytically.

Based on this discussion it is evidently, that the analytical assessment of migration which clearly is a solid and indispensable tool cannot cover exhaustively the whole spectrum of compliance testing of food packaging materials at reasonable expenditure of costs and work. In the past, increasing R&D efforts have been consequently undertaken in establishing migration modelling as a new alternative and complementary compliance testing tool.

4 Migration modelling controlled by diffusion in the plastic material

As already mentioned above the change of food composition with time is caused by mass transfer processes (migration and permeation) taking place during the contact between foodstuff and packaging. This type of processes were investigated experimentally as well as theoretically with an increasing involvement during the last five or six decades. As a result, on an academic/theoretical level, the understanding of migration and permeation is nowadays very advanced, which allows correct interpretations and even predictions of many experimental data. In the last decade significant efforts have been undertaken to implement this theoretical knowledge into migration models to be used for migration estimations in the framework of a quality assurance system for food contact materials.

In advance it is worth mentioning that estimating migration based on migration models by no means substitutes all experimental work and analytical assessment! Migration estimation should be rather considered as an additional tool for a more time and cost effective quality assurance of materials intended to come into contact with foodstuffs. For certain types of applications migration estimation can be used; i) to replace time consuming and expensive migration measurements, ii) for a quick screening of redundant experimental work, iii) for a much more complex interpretation of experimental assessment data and iv) as a tool to save costs and work in R&D. From the point of view of consumer health protection the main challenge of migration estimation is to proof from the beginning that its results provide the same or even higher level of safety margin as the analytical assessments have done until now.

The basic requirements for using migration estimation, based on theoretical migration models, for consumer safety purposes are:

- to understand a given packaging food system from the point of view of mass transfer and partitioning processes of substances existing in the matrix of the packaging,
- to develop an appropriate theoretical model which describes this system properly, and
- to customize this model in such a manner that, for similar packaging food systems, the migration of low molecular weight components with high migration potential is estimated with a certain safety margin.

It is obvious that, if the understanding of the processes which take place when a mass transfer (migration) between a food contact material and a foodstuff occur is not accurate enough, the theoretical migration model developed hereof will not describe correctly the real system. The migration estimations will either scatter around or deviate systematically from the real values. Such problems may occur in an analytical assessment, too. If the sample work up or the analytical methods are inadequate experimental results differ from the real ones. Therefore, to ensure that a model correctly describes a real system, or an analytical assessment is adequate for the system to be analysed, a validation procedure is necessary /7/. For the analytical assessment the validation procedure relies on recovery and stability experiments for the migration testing and sample workup. Concerning the analytical method, accuracy/trueness, robustness, within and in-between laboratory repeatability should be tested.

Validation of a migration model can be done on a statistical basis. Such a work has already been performed for several food contact materials in the framework of a European research project SMT4-CT98-7513 "Migration modelling" /8/. Using actually available scientific literature a comprehensive diffusion coefficients database was assembled /9/. In a first stage, the attention was focused on food contact materials for which enough data could be collected to allow a correct statistical evaluation of the parameters needed for the theoretical migration model. The statistical evaluation analysed the mean value, standard deviation and confidence interval of the collected data for each type of polymeric food contact material selected. All food contact materials assessed in the framework of the EU-project "Migration Modelling" were pure plastic materials. It is known that in such materials under contact conditions, which are encountered in the food packaging practice, the mass transfer of low molecular weight components obeys Fick's laws of diffusion /10/. Provided that the packaging foodstuff system obeys some specific boundary and initial conditions the diffusion equation describing migration can be solved analytically. The solution obtained allows to calculate the level of migration for all food contact materials considered in the database and for a wide spectrum of migrating substances /11/.

However, to perform these calculations the knowledge of two fundamental constants, the diffusion, D, and partitioning, K, coefficients of the migrant is needed /12, 13, 14/. In the framework of the EU-project "Migration Modelling" an approach was given to estimate these coefficients theoretically /15/. The specific feature of this approach is the fact that it leads to so-called "upper limit" D and K coefficients. Using these values in migration calculations leads to results which are, with a given statistical certainty, above the experimental ones /16/. This is a very important feature of the theoretical migration modelling because an additional safety margin for the consumer can be obtained. Comparing migration estimations obtained by using the approach described above with experimental migration tests on representative polymeric food contact material it was shown that the required agreement between calculated and experimental data is fulfilled and thus this concept of migration modelling is validated /17/.

It is worth mentioning that in all these experimental tests food simulants have been used. These contacting media can be assessed easily by modelling because they are all liquids for which the uptake profile of low molecular weight components is known. The partitioning behaviour of low molecular weight components/migrants between food contact materials and food simulants is closely related to their solubility in the food simulant. Data on the solubility of some potential migrants (food contact substances) from food contact materials in food simulants are given in the literature /18/.

In fact the migration potential estimated by using the model developed in the framework of the SMT4-CT98-7513 project "Migration Modelling" overestimates the real value because of the built-in safety margins mentioned before. Using an "upper-limit" diffusion coefficient, D, for the migrant, its diffusivity within the matrix of the polymeric food contact material is set to an upper limit which leads to a faster migration as compared to the real system. The partitioning process at equilibrium is considered to be completely on the food side if no information about the solubility of the migrant in the food simulant is available. From here additionally results an increased level of migration from the food contact material into the food simulant.

Summarizing, it can be stated that a food contact material can be assessed for compliance purposes by migration modelling if it fits in the material categories for which diffusion models were developed within the framework of the mentioned EU-project. Following additional requirements have to be fulfilled:

- the food contact material-contacting medium system must fulfil the initial and boundary conditions of the model,
- the contacting medium must be a well mixed liquid (condition which is fulfilled by the food simulants),
- the contacting medium should not interact with the food contact material in such a manner that a change in its functionality occurs (condition which must by fulfilled by a material otherwise it is not suitable for the intended use),
- the migrant to be assessed by modelling must be distributed homogeneously in the food contact material and is not consumed or built up during exposure of the material to the foodstuff, and
- no boundary resistance against the migration of the component at the interface between food contact material and foodstuff should exist.

If boundary resistance occurs the migration rate is lowered. Consequently, migration estimations which do not automatically take the boundary resistance into account lead to increased levels of estimation which offers in fact an increased safety margin.

5 Feasibility of migration modelling into real foodstuffs

From a conceptual point of view food legislation based on a system using food simulants instead of real foodstuffs for compliance testing is in fact a system based on an experimental modelling approach. In the EU legislation only four (4) food simulants are in charge to provide a model contact medium for all types of real foods. The discrepancy between the appearance and properties of a real foodstuff and the related food simulant are obvious. Reduction factors, R_f, are responsible for adjusting (lowering) the experimental results. Despite this is a crude approximation it is a usable one. However, its main drawback is, that in many cases, the migration in a real foodstuff behaves, qualitatively as well as quantitatively, quite differently to that in the liquid food simulant related to them by the EU legislation /19/. The result of this fact is that in some cases the actual EU approach leads to the assumption that the migration in a real food is considered to be considerably larger that it actually is and in other cases the opposite assumption is made. The first result is of course favourable from the point of view of consumer protection, a higher assumed level of migration than the real one is an increased consumer safety margin. But it means for the industry higher technological constrains and costs in developing and testing (new) formulations for packaging materials. The second result, i.e. the migration in a real food is in fact higher than that obtained by modelling the process with a liquid food simulant, is a problem for the consumer safety protection. The migration test according to the EU legislation may indicate that the food contact material is compliant, while in fact the migration level in the real food is above the specific migration limit.

For example the food simulant water has been assumed to model the uptake profile and partitioning behaviour for all foodstuffs considered to be aqueous. In the EU legislation milk is considered to be modelled appropriately by water and R_f=1. However, it was found that milk, which is a heterogeneous liquid consisting of a large amount of water (about 96%) in which small amounts (about 4%) of fatty substances are dispersed, exhibits a very different migrant uptake profile and partitioning behaviour than water /20, 21/. The experimental migration results show that milk actually takes up a larger amount of migrant than a similar amount of pure water. This may be attributed to the fact that the fatty substances in milk are dispersed in very fine droplets which have a large active contact surface, a low partitioning coefficient and thus an uptake potential which is considerably larger than that of pure water.

Experimental investigations of migration in real foodstuffs show other discrepancies to the modelling with liquid food simulants. Let’s take the example of lasagne pasta plates. This is a dry and non-fatty product, in weak contact with the packaging and surrounded by air. According to the actual EU legislation this type of real foods are excepted from migration testing, under the assumption that in such systems there is no transfer of substances from a packaging to the real food. However, recent experimental investigations show that this is not the real case. It was found that even in such a system there is a net migration from the food contact material into the pasta. This may proceed though direct contact between the pasta plates and packaging or/and through convection of migrant vapours in the inner atmosphere of the packaging and uptake by the plates. The experimental results and their theoretical modelling support this scenario and show a strong decrease of the migrant concentration in the stack of pasta plates from the plate in contact to the inner regions of the food. In an extreme case such migration behaviour in a real food may lead to unacceptable high concentrations of migrant in the contact regions while the inner pasta plates are not contaminated.

Discrepancies between migration in real foods and the experimental modelling of this process with a liquid food simulant are expected to occur for solid foods in which the mobility (diffusion coefficient) of the migrant is closer to the values found in some polymers than in liquids. In such solid foods, for example confectionary products in solid form, e.g. cheese with a high fatty content or preserved meet the migration process is quite different from that taking place in a liquid. The reason is that the mobility of the migrant in the matrix of the real food is several orders of magnitude lower than in liquids. Thus, the migrant does not mix from the beginning homogenously with the contacted food – as it was assumed to be the case for liquids (see requirements in the previous section). The migrant uptake profile, especially at the beginning of the contact, in such a solid food is steep and the migrant concentration in the food strongly decreases from the contact surface to the inner regions. Visually such a phenomenon is often observed when dyeing Easter eggs. If a dye permeates through the shell of the egg it penetrates into the egg white, too. But because the mobility of the dye in the egg white is much reduced, its contamination/ colouring is confined to a narrow region.

Recently an experimental investigation of migration in a series of real foods was carried out; the result obtained showed in most cases more or less severe deviations from what one would obtain with food simulants /20/. Let's take for example the result obtained for yoghurt with 3,5% fat. This is a real food in which, according to the EU legislation, migration must be modelled with an aqueous system (water as food simulant). However, it was found that migration in this real food exceeds the level of migration in water. The explanation is similar to that already given for 3,5% milk, namely yoghurt is a two phase system too, in which small fatty particles are surrounded by an aqueous medium. The mobility (diffusion coefficient) of a small molecular weight migrant in this later medium is quite high. That means that migrant molecules come readily in contact with the surface of the fatty particles where they are promptly taken up by the fat (the partitioning of the migrant between the aqueous medium and fat is strongly on the side of the later).

The migration in sugar and wheat flour with 2% fat was also carried out. According to the EU legislation these are dry foods and for such systems one assumes that there is no migration from the packaging. However, the obtained results showed that if sugar or wheat flour is in contact with a polymeric layer there is a net transfer of substances into the food. Sugar and flour are heterogeneous systems in which small food particles are surrounded by air. Thus the transfer of a substance from the packaging into such a food might take place by evaporation at the surface of the polymer, diffusion and convection in the inner atmosphere of the packing and finally uptake by the finely divided food particles. It was found that the migrated amount is influenced by the nature (particle size, pore volume, etc.) of the food. Investigating migration in several types of biscuits made mainly from sugar, wheat flour and fat it was found that an increase of their fat content leads to higher levels of migration compared to the individual constituents. This is most likely the result of the increased uptake of migrant in the biscuits with higher fat content.

The experimental results mentioned above show clearly the limits and possible pitfalls of the concept used in the actual EU legislation to model experimentally migration in real foods by conducting tests with liquid food simulants. Since the introduction of this legislation in 1985 the scientific knowledge about migration in real foodstuffs has continuously expanded. An important contribution comes from the development of new and more precise analytical sample preparation methods as well as the availability of the highly sensitive analytical instruments needed to measure low levels of substance concentrations. On the other hand the theoretical understanding of the migration in real foods was refined, too. With adequate theoretical models it is nowadays possible to estimate and interpret migration processes in many real foods which are not adequately covered by the actual EU legislation.

From the point of view of scientific results to be collected and elaborated to model migration into real foodstuffs we would like to emphasize the potentials of migration modelling in real foods.
In principle, according to their morphology, all real foods in contact with a packaging can be included in a few main categories. The morphology of the foodstuff defines the mass transfer processes which must be considered and the food composition defines the uptake potential of the foodstuff. A packaged real food may be:

- a homogenous liquid
- a homogeneous solid
- a heterogeneous liquid or solid, (with liquid and/or solid continuous phase)
- a heterogeneous solid (with gaseous continuous phase)

For packaged real foods which behave like homogenous liquids the actual EU legislation offers a consumer protection framework in which migration can be tested, both by experiments and modelling in an appropriate way. For all other categories mentioned above the actual EU legislation should be updated to consider more appropriately the effect of the morphology and constitution of a real food on the migration process.

A logical step towards such a goal is to develop and validate migration models for compliance purposes which include the properties of the real foodstuffs in the migration considerations. Such practical models can be developed on the basis of theoretical models of mass transfer between food contact materials and various types of media (others than homogenous liquids) which may come into contact with them. It is obvious that such models are more complex than the one used in the foundation of the actual EU migration estimation procedures. In heterogeneous media one must take into account that the uptake of a substance within the real food is influenced by several factors (diffusion and partitioning between the phases of the real food for example). These factors are most likely temperature dependent so that an appropriate model should consider this aspect, too. In real solid foodstuffs which are surrounded in the packaging by air the model also has to consider the evaporation of the migrant at the surface of the packaging and its diffusion/convection to the surface of the real food.

Through simple worst case considerations a forecast to the possible project outcome can be drawn. The diffusion model used until now for migration estimations into food simulants assumes that the migration in the food simulant is much faster than in the food contact material and hence has no influence on the time scale of the migration process any more. The migration rate is determined by the release of the migrant from the food contact material, e.g. the diffusion process and the migrated amount is determined by the relative solubility of the migrant in the food contact layer and the foodstuff (described by the partition coefficient). Because the volume of the foodstuff is commonly much higher than the volume of the packaging even if the migrant shows the same solubility in the packaging and the foodstuff the amount migrated in the foodstuff will be higher then the amount left in the packaging material. If moving from homogeneous liquid foodstuffs to homogeneous solid foodstuffs the diffusion process in the foodstuff will become more important in terms of migration rate. The uptake of the migrant is slowed down. Consequently the migration test into a homogeneous liquid foodstuff or food simulant represents a worst case for homogeneous solid foodstuffs, provided the solubility of the migrant in the liquid- is the same or higher than in the solid food. If no knowledge about the solubility in the solid foodstuff is available olive oil (simulant D) represents a worst case for lipophilic substances and water (simulant A) represents a worst case for hydrophilic migrants. The knowledge about the mass transfer processes within the foodstuff and especially about the diffusion process usually the slowest one, would make sure that the over estimation due to the worst case testing with the food simulants is not to sever.

For heterogeneous foodstuffs similar considerations can be made. As for homogeneous solid foodstuffs the time scale of migration is influenced by mass transfer processes taking place in the foodstuff. Again the diffusion process through the heterogeneous foodstuff will slow down the migration rate compared to a homogeneous liquid. If for a solid foodstuff the continuous phase is the gas phase, the evaporation process is commonly the slowest one and determines the time scale of migration. In addition the migrant has the possibility to partition between the continuous phase, e.g. water in milk, and the heterogeneities, e.g. fat droplets. The migrated amount is defined by the phase with the highest solubility for the migrant even if present only in a few percents. Consequently the migration test into a homogeneous liquid foodstuff or food simulant represents a worst case for heterogeneous foodstuffs as well, provided the solubility of the migrant in the homogeneous liquid is the same or higher than in the heterogeneous food. If no knowledge about the solubility in the solid foodstuff is available a food simulant should be used which show the same or higher solubility for the migrant like the food component with the highest solubility. The knowledge about the mass transfer processes within the foodstuff and especially about the diffusion- and evaporation process, would make sure that the overestimation due to the worst case testing with the food simulants is not too severe.

All theses aspects are nowadays mathematically manageable so that it appears to be possible to develop models to make realistic estimations of migration from food contact materials into real foodstuffs. The advantage of such an endeavour would be obvious both for the consumer and the industry. A more accurate theoretical understanding and estimation of migration processes in real foodstuffs are the basis for an improved consumer health protection. Law enforcement and industrial activities would benefit from such developments, too. The use of appropriate migration models in compliance testing and/or R&D can provide important information and optimise the cost and work factors.

We would conclude with the statement that the progress over the last two decades in the experimental analysis and theoretical understanding of migration processes in complex contact material-food systems has brought this field forward to a scientifically recognised stage which would allow to support necessary updates and revisions of the actual EU legislation in this area.

6 References

1 COUNCIL DIRECTIVE of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (89/109/EEC) (OJ L 40 , 11.2.1989, p. 38)

2 COMMISSION DIRECTIVE 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ L 220, 15.8.2002, p. 18)

3 COMMISSION DIRECTIVE 97/48/EC of 29 July 1997 amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (OJ L 222, 12.8.1997, p. 10)

4 CEN, 1999 European Standards ENV 13130, Materials and articles in contact with foodstuff - Plastics, Part 1-8. European Committee for Standardization, Brussels.

5 COUNCIL DIRECTIVE of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs

6 http://cpf.jrc.it/webpack/

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