MIGRESIVES: A RESEARCH PROJECT ON MIGRATION FROM ADHESIVES IN FOOD PACKAGING MATERIALS IN SUPPORT OF EUROPEAN LEGISLATION AND STANDARDISATION

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3 1 MIGRESIVES: A RESEARCH PROJECT ON MIGRATION FROM ADHESIVES IN FOOD
4 2 PACKAGING MATERIALS IN SUPPORT OF EUROPEAN LEGISLATION AND
5 3 STANDARDISATION
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24 11 **Abstract**
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27 12 Most food packages and food contact materials are manufactured using adhesives. The EU
28 13 regulates all food contact materials, as their constituents may not contaminate food and
29 14 endanger consumer's health. In contrast to plastics which are regulated by positive lists of
30 15 authorised ingredients, adhesives have not yet a specific regulation. The MIGRESIVES
31 16 project aimed to elaborate a scientific global risk assessment approach to meet current
32 17 general EU regulatory requirements and as a basis for future specific EU legislation as well
33 18 as to provide the industry, especially small and medium sized enterprises, a tool to ensure
34 19 that migration from adhesives is in compliance with the regulatory requirements. The idea
35 20 was to demonstrate that consumer's exposure to chemicals released by adhesives is in
36 21 many cases below levels of concern. Technical/scientific knowledge from industry and
37 22 research institutes will be merged into a collective research endeavour gathering all
38 23 stakeholders. The major milestones are (i) classification of adhesives according to chemistry
39 24 and uses, (ii) test strategies based on physico-chemical behaviour of adhesives, (iii)
40 25 modelling migration/exposure from adhesives, (iv) providing guidelines to integrate the risk
41 26 assessment approach into the daily life of companies, (v) feasibility of applying the
42 27 toxicological approach from EU BIOSAFEPAPER project and (vi) extensive
43 28 training/education to SMEs and large dissemination for general adoption of the concept in
44 29 Europe.
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31 **Key words: Food packaging, adhesives, migration, compliance**

Introduction

First of all, it needs to be considered that almost all food packages are manufactured using adhesives. Adhesives are used in flexible film-to-film lamination, paper-film/cardboard-film combinations, rigid multi-layer packaging systems, boxes, sacks, pouches, labels - in most cases without direct food contact but also in some cases with direct food contact. Other special applications are in refrigerators, microwaves, kitchen furniture or corks for alcoholic beverage bottles. In contrast to plastics and paper additives, the term 'adhesives' refers to an extremely large and complex pool of compounds which, by nature, are often subjected to changes in their composition and undergo chemical reactions before the finished packaging materials come to the marketplace (Gierenz and Karmann 2001). Secondly, a large variety of adhesive systems are used in food packaging materials. The European adhesives industry uses a large range of raw materials with altogether approx. 2000 chemicals (information from FEICA, the Association of European Adhesives Manufacturers) and manufactures adhesive formulations which can comprise up to 15 chemicals, even for the simplest systems. On the other hand, adhesives are used only in a relatively low mass fraction (up to 5 %) in food contact materials.

The EU regulates generally food contact materials, as their constituents should not be transferred into food in such amounts that may contaminate food and endanger consumer's health. This requirement laid down in Article 3 of Framework Regulation (EC) No. 1935/2004 includes also substances from adhesives. But in contrary to plastics which are specifically regulated by positive lists of authorised monomers and additives, adhesives are not covered by a specific regulation neither on European nor on national levels yet. At the same time, the demands to confirm compliance and ensure packaging safety are increasingly driven both by legislation and food industry. Specifically, a corresponding documentation and the need of accompanying conformity certificates are required by Article 16 of the Framework Regulation (EC) No. 1935/2004, this at each stage of the production chain of a food contact material in Article 9 of the Plastics Directive 2002/72/EG (in the version of the 4th amendment 2007/19/EC). This requirement is also addressed in the Regulation (EC) No. 2023/2006 on good manufacturing practice. Today for evaluation of adhesives existing rules and migration testing procedures have to be used which have been established for other materials (e.g. plastics) and which may not satisfy the specific demands of adhesives compliance evaluation. With other words this means where by chance another (EU or national) regulation or recommendation made for plastics, dispersions, elastomers, waxes or paper is applicable for evaluation a certain compound from an adhesives formulation, opportunity will be exploited for this purpose as far as applicable. An important basis for adhesives evaluation is today the US FDA regulation and substance list for adhesives in 21 CFR § 175.105.

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3 68 An large body of knowledge on migration from plastic materials has been accumulated in the
4
5 69 last 30 years but only a small number of scientific papers have dealt with the potential
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7 70 migration of adhesives constituents (Gruner and Piringer 1999), (Lawson, Barkby et al. 1996;
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9 71 Lawson, Bartram et al. 2000) (Lawson, Barkby et al. 2000), (Davies 2003), (Bradley and
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11 72 Castle 2006).. In addition, more specific studies on migration of primary aromatic amines
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13 73 from polyurethane adhesives in plastics have been carried recently (Brauer and Funke
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15 74 2002; Brede, Skjevrak et al. 2003; Störmer, Rüter et al. 2005). In 2001, the food control
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17 75 authorities in the Nordic countries organised a seminar to collect and compile knowledge on
18
19 76 migration from adhesives (Svensson, Binderup et al. 2001). One important outcome of this
20
21 77 seminar was that 'the development of methods of analysis for migrants from adhesives
22
23 78 should be prioritized'. The current regulatory 'deficiency' as well as the non-availability of
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25 79 methodological and conceptual compliance test systems in this area was the motivation for
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27 80 us to initiate the MIGRESIVES project within the 6th Framework programme of the European
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29 81 Commission.

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82 **The objective of the project**

83 The EU project MIGRESIVES is funded in the 6th Framework Programme within the
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85 Collective Research Programme which supports pre-competitive research for SMEs and their
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87 associations. In these kind of projects SMEs are typically represented by their associations
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89 and a core group of actively involved SMEs. Beneath some large multinational global
90
91 players, in the European adhesive industry there is a large number of small and medium
92
93 sized enterprises (SMEs). The adhesive sector in Europe comprises more than 500 SMEs
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95 spread throughout the continent with a majority in Germany, France, Italy and Great Britain.
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97 Most of these companies are affiliated to the Association of European Adhesives
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99 Manufacturers, FEICA, via 15 national member associations.

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92 Approaches to compliance testing and evaluation should consider these SME type industrial
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94 structure and the corresponding characteristics and needs: these are the large diversity of
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96 substances and at the same the small market share of adhesives in terms of relatively small
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98 production batches. With other words, approaches to be taken should be cost-efficient,
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100 pragmatic and nevertheless not compromise consumer safety.

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97 For specific regulation of adhesives in principle two potential regulatory approaches can be
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3 102 regardless whether they are expected to migrate into food or not. All other (unlisted)
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5 103 compounds would then need to be excluded from use. Building up such a positive list would
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7 104 be extremely time-consuming and would be an enormous cost burden on the adhesive
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9 105 industry due to the multitude of individual substances and because only a small fraction of
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11 106 the raw material substances are already evaluated by EFSA. Full toxicological evaluation
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13 107 and authorisation of all other substances would not only over-challenge the economics of the
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15 108 European SME industry but also the capacities of the EFSA. Furthermore, the functionality
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17 109 and processing of adhesives systems are by nature largely based on chemical reactions and
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19 110 hence the reaction products and by-products would also have to be measured and
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21 111 evaluated, meaning that even more toxicological data and knowledge would be necessary.
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23 112 From this it appears that the positive list approach may have more drawbacks than
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25 113 advantages and would in any case not be practicable. In this context it should be stressed
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27 114 that the exposure of consumers to contaminants released by adhesives is much smaller than
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29 115 by materials in direct food contact applications. This smaller exposure would justify a
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31 116 different approach to safety assessment.

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33 117 Approach 2, an alternative would be to consider the actual migrating substances and their
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35 118 exposure to the consumer, but not the full list of potential migrants (as per Approach 1). This
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37 119 different approach can be seen in analogy to the functional barrier principle for plastic multi-
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39 120 layers as introduced into the Plastics Directive 2002/72/EC by its 4th amendment
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41 121 2007/19/EC. According to its Article 7a, substances which are not in the positive list, may be
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43 122 used in non-food contact layers of a multilayer material if they do not migrate into the food in
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45 123 amounts exceeding 0.01 mg/kg food and if they are not classified as proved or suspect
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47 124 “carcinogenic”, “mutagenic” or “toxic to reproduction”, officially as well as under self-
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49 125 responsibility criteria. Adhesives are in most cases not in direct contact with the foods and
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51 126 are usually separated from the foods by a plastic, paper or cardboard layer. Furthermore,
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53 127 adhesives which make up only a very small fraction of the total mass of food contact
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55 128 materials, are likely to cause only a relative low consumer exposure. The classification of the
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57 129 substances in migration relevant ones and those which are not expected to be transferred
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59 130 into foods, can be achieved by consideration of the practical applications of adhesives and
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131 the parameters influencing the migration of adhesive constituents into foods.

132 The aim of the MIGRESIVES project was to provide the scientific basis and the necessary
133 tools to step into approach 2. In the underlying Collective Research Programme of the 6th
134 Framework Programme the specific needs of SMEs should be considered and corresponding
135 solutions be provided. The MIGRESIVES project addresses therefore the following
136 objectives:

- To develop a pragmatic, science based concept and methodological tools to ensure consumer safety related to adhesives used in food contact materials. This concept should find European recognition and could be an option for being integrated into a more specific European legislation on adhesives
- To train industry (especially SMEs) using the tools of the developed concept and to rationalise and disseminate the project outcome as rules and guidelines to the whole food packaging chain.
- To support and strengthen SME competitiveness within the adhesives industry and the added value chain by ensuring product safety through cost-efficient application of the concept and its tools. In this way existing markets should be saved and opening of new markets enabled.

Structure of the project

The project started in February 2007 with a duration of 3 years. It has funding of 3.09 Mio Euro and an EU contribution of 1.94 Mio Euro. The project consortium consists of 21 partners (table 1) with 7 associations, 7 SMEs and 7 research institutes from 6 European countries. The associations represent the SME adhesives industry with the European association FEICA and the national ones in Germany, France and Spain. Furthermore, plastics converter and the producer of paper & board packaging as well as cork stopper producers are represented by one association each. The SME core group consists of five adhesive producer and two retailers of cork stoppers. Altogether, the producers as well as the user of adhesives for food contact applications are involved in the project.

The project work is structured into 8 work packages (figure 1) which will be described below.

The concept frame

The basic idea is to elaborate a testing concept and tools in connection with a suitable classification of adhesives components and applications in FCM according to their migration potential. The tools will comprise of theoretical evaluations, analytical methods and mathematical migration modelling.

Adhesives components may be classified into the following five groups:

- Substances which do not migrate.
- Substances which do not migrate at a given functional barrier (application, contact conditions).

- Substances which are evaluated in an EU-list and have a specific migration limit which cannot be exceeded at the intended application.
- Substances which are evaluated in an EU-list and have a specific migration limit which need to be measured.
- Not yet evaluated substances, which can migrate in such amounts that a toxicological evaluation would be necessary.

Classification of adhesives, definition and preparation of test systems

A classification of adhesives can typically be made on the basis of chemical composition, setting mechanism, adhesion mechanism and form of application, application temperature and end-uses (Gierenz 2002). A classification according to the setting mechanism is compiled in Ullmans Encyclopedia (Gierenz 2002; Gruber and Rich 2002) and by (Onusseit 2008). A flexible classification in which each adhesive is characterised and classified according to various features such as chemical basis, form of application, application temperature, thermal behaviour and uses as proposed by Lucke ((Lucke 1967), cited in (Gierenz 2002)) is judged by Gierenz as highly comprehensive (Gierenz 2002). For evaluation of migration, considering a broad range of features from chemistry and composition to applications is necessary as well. The literature as mentioned above relates to all technical applications, none especially to applications for food contact materials. On the basis of common adhesives categories a specific classification is made in the project with respect to the intention of the project which means by considering also the potential of adhesive constituents migration into food. Such a classification is a complex issue and not available today. It requires an intensive discussion using the know-how and expertise of the project consortium.

The classification of the adhesives, adhesive compounds, applications and their migration potential should support the following objectives:

- Structuring adhesive compounds, adhesive types, applications as a tool for selection representative test systems (operational objective for the project)
- Collecting information on substance properties, regulations, existing toxicological evaluations, migration potential and on applications needed for
 - Experimental determination
 - Mathematical modelling
 - Choice of a suitable pathway to obtain the migration value by estimation or experimentation.

202 – Evaluation of the substance

203 For selection of representative test systems it was agreed within the consortium that it would
204 be the best approach to classify according to the raw material polymer type, the reactivity
205 and the solvent system. Adhesives where the polymer is made from pre-polymers or
206 monomers during curing are compiled as reactive ones and those which cure physically (e.
207 g. by drying or temperature application) as non-reactive. The solution type is divided in three
208 classes. 100 % systems compile all solvent free systems (solvent free reactive systems as
209 well as non-reactive hotmelt systems). The other two classes are the water based and the
210 (organic) solvent based systems (Figure 2).

211 Starting from this classification, the relevant adhesive types for food contact material
212 applications and their applications have been collected. The scheme (Table 2) was
213 established within the consortium. This classification reflects the chemistry of the adhesives
214 as well as the complexity arising from numerous parameters in the end use of the system
215 (Substrates, packaging design, means/type of application, etc.). In this scheme the adhesive
216 systems which are included as test samples in the project are marked. Finally the experience
217 of the affected industry, adhesive industry as well as packaging converters of paper & board
218 and plastics was included to obtain an as complete as possible overview on food packaging
219 related adhesive systems and applications and a representative selection of adhesive
220 systems for the research work.

221 Based on the classifications made above, 23 representative test systems had been defined
222 and selected by the consortium with the intention to be typical for adhesives formulations,
223 materials and structures used for food contact materials and to include different application
224 and handling conditions: like type of food, type of contact, temperature and storage
225 conditions. Furthermore a range of cork stopper applications with polyurethane adhesives
226 are investigated in the project. All these test systems are used for the comprehensive studies
227 within WP 2. Additionally to the project consortium, the selection of test samples has been
228 discussed within the converter associations, partner IK and MCAS, and their input has been
229 considered in order to ensure representativeness.

230 **Method development for screening multi-methods and quantitative approach to** 231 **groups and unknowns**

232 The objectives are the development of screening methods covering most chemical classes of
233 adhesive relevant substances up to a molecular weight of 1000 g/mol and the development
234 and validation of methods for semi-quantification of unknown substances by universal
235 standard substances.

The substances in adhesives derive from various chemical classes (functional groups) and cover the whole range of physico-chemical properties from volatile to non-volatile, from polar to non-polar. For investigation of these substances up to a molecular weight of 1000 g/mol, the development of methods is necessary which cover broad ranges of physico-chemical properties so that many compounds can be analysed simultaneously in one analytical run. For this in a first step methods are developed using standards and standard mixtures of known adhesive related substances. A list of more than 50 substances was established: monomers, additives, some solvents. The substances have different physico-chemical properties and are available as pure standards. The techniques which have been used were gas chromatography for the volatile and semi-volatile compounds, HPLC for the non-volatile ones. An aim was to minimise the number of techniques or chromatographic conditions necessary for obtaining the compositional information generally or in dependency of the adhesives class. The applicability and the boundaries of the existing and the new developed multi-methods were checked for the adhesive relevant substances and whole groups of substances.

Furthermore, WP2b endeavours to develop a quantitative approach to substance groups or unknowns. This approach, however, must implicate sufficient safety margins. This represents a scientifically challenging task within the project which would be of high importance not only for the adhesives compliance testing area but also for other migration potentials from other material categories. The approach to quantify unknown volatile to semi-volatile substances by universal internal standard substances with GC-FID is already used in various labs. The FID signal correlates to the mass of carbon atoms per time unit and therefore the signal should be more or less independent from the chemical structure and the derived concentration (w/v) should only depend on the ratio of carbon to non-carbon atoms related to that in the internal standard. However in reality further parameters like peak shape as well as the molecular structure and the functional groups influence the response factor. Comparative investigations had been mainly performed on alkanes and polyaromatic hydrocarbons (e.g. (Tong and Karasek 1984; Blanco, Canga et al. 1992; Slemr, Slemr et al. 2004)). Systematic work to predict the FID response from molecular structure was done e.g. by Jorgensen et al. (Jorgensen, Picel et al. 1990) and Kállai and Balla (Kállai and Balla 2002). The reactions within the FID are not yet completely understood so that empirical data especially for complex structures are necessary. First results on the comparison of relative response factors using *tert*-butyl-hydroxy-anisole (BHA) as internal standard look highly promising (Gruner, Yoon et al. 2008) and shall be published separately.

For the determination of non-volatile groups and unknowns using HPLC the situation is more difficult. The applicability of an universal standard approach to the non-volatile adhesive

related substances was tested. This however needed a HPLC detection system which is, in analogy to the GC-FID system, dependent on the mass only. Modern possibilities for that are in principle evaporative light scattering detectors (ELSD) or charged aerosol detection (CAD). Both detectors may work for this purpose because of their working principles. The CAD showed better sensitivity and was used for the study. First results are shown (Yoon, Ungewiss et al. 2008) and will be published separately.

Furthermore, for increasing sensitivity of determining volatiles a screening method base on solid phase microextraction coupled with gas chromatography was developed by Nerin et al. [to be referenced later: publication of Nerin et al in this issue on the ILSI conference].

Compositional analyses and studies

Any migration behaviour concept must include as a starting point the possible concentrations of potential migrants and their identities in the material itself. This is essential for any migration prediction. For non-reactive adhesives this concerns all the constituents in the raw materials and in the adhesives formulations and their end concentrations in the final food contact material applications. For reactive adhesives, where during processing or even storage in contact with food reaction products can be formed, or in case of thermal decomposition from non-reactive systems further chemical compounds are of interest and need to be considered.

The pure adhesives, the glued test systems as well as the reference substrates are extracted and submitted to a screening analysis using the multi-methods. The substances which are for migration studies were defined from these results. They need to be present in sufficiently high concentrations in the test system in order to obtain measurable values in the migration experiment. The initial concentrations of these substances are quantified. Furthermore additional peaks are characterised and as far as possible identified by coupling GC or HPLC with mass spectrometry. In addition, comprehensively, by a theoretical approach characteristic constituents of adhesives are checked on the possibility of forming reaction or degradation products from chemistry considerations.

Migration & partitioning studies

WP2c generates essential physico-chemical data such as diffusion coefficients and partition coefficients which control the mass transport phenomena in the test systems and which are used for establishing rapid and predictive migration test tools in WP3. For mathematical modelling of migration, knowledge on diffusion coefficients in the adhesives and the substrate layers as well as partitioning coefficients of the adhesive related substances between adhesive and substrate layers as well as between substrate and food simulant is

necessary. Estimation of diffusion coefficients in plastic layers is state of the art but data for estimating diffusion in adhesive layers and in paper and board are missing. Knowledge on partitioning coefficients is lacking, too.

For mass transport studies to be carried out in this WP there are no standard tests available especially for thin layers and for migration from paper and board where the classical simulants are not applicable. The liquid simulants will in many cases extract these packaging systems and may, therefore, lead to unrealistic high migration compared to foods which would not penetrate into these packaging systems. Therefore, especially simulants or, better to say, acceptor media for the migrating substances are applied which do not interact with the substrate. These are solid simulants e. g. the official simulant Tenax® (modified polyphenylene oxide), plastic films (LDPE) or paper and board. For testing plastic multilayers without interaction with the material, Brandsch and Piringer had successfully used LDPE-film as acceptor simulant (Brandsch, Gruner et al. 2005). For some relatively polar migrants as they are used in water based adhesives, LDPE showed too weak acceptor properties. Investigating the partitioning between adhesive and substrate as well as the diffusion in the adhesive and the substrate by using the virgin substrate (paper or paperboard) itself as acceptor medium turned out to be a good alternative. The diffusion in plastic layers or paper&board as acceptor media can be better modelled than in the Tenax® granules and is therefore preferred from a modelling sight for deriving the experimental data for partitioning and diffusion in adhesives and substrates. Tenax® experiments are carried out additionally to simulate the food contact especially for dry foods.

Two principal approaches for migration testing are performed: Kinetic test where migration is resolved by time and migration into a stack of acceptor layers where migration is resolved by distance from the contact surface. In the kinetic approach a thick LDPE layer (500 µm) or a cardboard is pressed on both sides of a test system (e. g. cardboard/adhesive/cardboard) in a stainless steel cell or Tenax is applied on one surface in a glass cell. The concentration in the acceptor layers is determined and correlated to the contact time. In the second approach migration is resolved by distance from the contact surface (Moisan 1980). For this, a stack of ten to twenty thin LDPE films or paper sheets is pressed onto the test system in the same steel cell for a defined time. After contact the concentration of the target migrant is determined in each layer of the stack and correlated to the distance from the test system surface. In order to obtain the temperature dependencies of the partitioning and diffusion coefficients, the migration experiments are carried out at different temperatures (e. g. 20 °C, 40 °C, 60 °C). The experimental data are used for calculation diffusion and partitioning coefficients by the multilayer migration model in WP 3.

As additional approaches diffusion coefficients of fluorescent dyes doted into adhesives are determined by Fluorescence Recovery After Photobleaching (FRAP) (Pinte, Joly et al. 2008) and partitioning coefficients between adhesives and substrates of supplementary additives mixed to those present in the test systems are measured in order to investigate into correlations between partitioning coefficients and polarity parameters.

Quick tests, mathematical modelling and predictive tools

Today, in compliance testing of food contact materials, it is common to apply conventional migration test procedures with standardised test conditions. These procedures do have the big disadvantage that they are very time and work consuming and therefore costly. On the other hand, based on scientific progress in the area, alternative compliance assessment approaches have been proposed and are increasingly used but still with too much hesitation. The aim of this work package is to establish with the WP2 results such alternative compliance assessment procedures for food contact materials based on adhesive technology. These procedures are combinations of experimental quick-tests and theoretical techniques with predictive character which, by definition, need to be more severe than conventional tests. The elements of these alternative procedures are called 'tools' in the following.

The numerical mathematical tools to model migration from multilayer materials (Piringer and Baner 2008) and software solutions to use it are already available (AKTS 2007; INRA 2007; FABES 2008). But the diffusion and partitioning parameters to be introduced into the model need to be established. For this the diffusion and the partitioning coefficients are fitted in the model to the experimental data derived from WP 2. This work is done by project partner FABES. Comparison of the derived parameter at different temperatures enables to extrapolate the modelling parameters to other contact conditions (time, temperature). Furthermore when having a sufficient amount of various data from different substances, extrapolation of modelling parameters to other substances will become possible. By linking the model with the results of the FOODMIGROSURE project, migration can be modelled into real foods (FOODMIGROSURE 2008).

It should be noted that modelling is only one of the tools in the concept. All information, experimental results and experiences with the test samples will be compiled to work out procedures starting from the knowledge on the adhesive composition and application in the finished food contact material via analytical tests and mathematical modelling resulting in a regulatory evaluation. For this, decision trees shall be established that structure the compliance concept. In some cases theoretical considerations might be sufficient to come to a compliance evaluation, in others analytical measurements will be necessary. Test

conditions for analytical quick tests (accelerated migration tests) shall be defined in order to obtain results for rapid evaluation of migration.

Screening of samples from the market

The applicability of the analytical quick tests and of the migration prediction tools which are developed in WP 2 and WP 3 to other adhesives formulations and food packaging applications are investigated in order to generalise the tools. Whereas in WP 2 all samples have been fully area laminated with adhesives, in WP 4 packages with real adhesive applications (e. g. lines, dots) are investigated. The tools from WP 2 and 3 are to be tested on some of the adhesives in WP 2 in finished packages but mainly on additional formulations and adhesives of further manufacturers. Also additional end-uses are considered, e. g. sterilisation, vacuum packaging or heating in microwave or oven. The aim is to verify the tools and to broaden the applicability. The materials are investigated according to the decision tree developed in WP3. This includes in any case a compositional analysis using the tools from WP 2. Quick tests and mathematical migration prediction (from WP3) will be applied and compared to conventional migration tests in food simulants.

Global in vitro bioassays – a feasibility study

The EU project 'Biosafepaper' (QLK1-CT-2001-00930, project duration 1.12.2001-30.11.2005) has been developing bioassays for paper & board as alternative approach for safety assessment of these materials compared to investigation of single substances. In that project a test battery of different in-vitro toxicological tests with different endpoints was selected as basis for a decision tree approach in safety evaluation, appropriate extraction methods for paper & board have been elaborated (Bradley, Honkalampi-Hämäläinen et al. 2008). The big advantage of such an approach would be in principle, not necessarily to investigate and to evaluate each single substance which migrates but to have global toxicological endpoints for evaluation of the total of migrating substances. Within the MIGRESIVES project the chance shall be taken to check the feasibility for additional applications related to adhesives using the tools elaborated for paper & board. Like paper & board, adhesives contain a large number of different migratable substances which makes this global approach in principle very interesting. The workpackage is designed as a small and limited feasibility study and will not investigate in further validation of such a bioassay approach. Ethanolic extracts of the pure adhesives, the laminates and the pure substrates are subjected to a RNA synthesis inhibition test as cytotoxicity/sublethal toxicity assay (Valentin-Severin, Laignelet et al. 2002; Jondeau, Dahbi et al. 2006; CEN 2008), to AMES test employing *Salmonella typhimurium* strains TA98, TA100, TA1535 and 1537 along with *Escherichia coli* strain WP2 uvrA (pKM101) both in the presence and absence of an

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exogenous metabolic activation system (OECD 1997) and to the Comet assay (Collins, Oscoz et al. 2008).

Education & training

Since the project is dedicated to small and medium sized enterprises they should be the first who should be able to use the concept of MIGRESIVES for their compliance evaluations. To realise this, the SMEs need to be trained to be able to apply the concept for their own products; this either alone or in cooperation with testing laboratories. Furthermore it is the intention of the project to reach more SMEs than those which will be able to attend a workshop within the project and to spread the concept to further countries which are not represented in the consortium by their associations. In order to achieve this, multipliers from different countries will be trained additionally so that they should be able to explain the concept to the associations and the SMEs in their countries. Detailed lessons with presentations and additional explanations will be provided in English language and translated within the project into German, Spanish and French. It is planned to make the lessons available in further languages in cooperation with the trained multipliers and the national associations after the end of the project. The training will consist of three modules: (1) Current legislation of food contact materials in the EU, (2) the MIGRESIVE concept and tools, (3) Use of the modelling software. At a later stage (after the project) the whole food packaging chain, i. e. the adhesive users, the packaging converters up to the food industry as well as the raw materials producers should have access to the project tools.

Standard test methods, guidelines and link to the stakeholders

The project results are intended to support legislation and standardisation. Analytical methods will be provided in standard format and the whole concept will be laid down in form of a guideline. They may be proposed to the European Standardisation Body CEN.

In order to enhance the awareness and recognition of the project and the approach at all parties concerned and to promote the European consensus, various activities are and will be undertaken on national and European level e. g. presentations at public conferences and workshops as well as at association meetings. Not only adhesives industry but the whole production chain from raw material producer to food packer is addressed. Furthermore the European Food Safety Authority EFSA as well as the European Commission (DG Sanco) will be kept informed and, at a later stage of the project when more results are available, invited to discuss the concept. At the end of the project, a closing conference is planned to give the possibility for a broad discussion by all stakeholders. These dissemination actions are subsumed in WP 8.

Conclusions and perspectives

The complexity of adhesive systems and applications in connection with various substrates makes the work highly challenging. Furthermore, only very limited publicly available information is available on adhesive composition and used of additives as well as no statistical data for food contact application uses. The representativeness of the adhesive systems chosen for the project is therefore based on a broad involvement of industries experience both from adhesive side and from packaging converter side. So it is ensured that the test systems in the project cover the most important adhesive types for food contact materials. An extensive experimental workload is necessary to establish the scientific basis for the project tools and the overall concept.

Conventional migration tests give results in simulants which can be very different from migration with real food applications (O'Neill, Tuohy et al. 1994; Castle, Honeybone et al. 2000; EFSA 2005; Franz 2005; Störmer and Franz 2008). From our perspective, the project outcome may be successfully connected with the results from the recent FOODMIGROSURE project (FOODMIGROSURE 2008) and with the recently started FACET (FACET 2008). This will allow into-food migration modelling and, in the future, also exposure estimation from adhesives used in FCM.

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Headings of figures and tables

Figure 1: Overview of project work packages

Figure 2: Classification of adhesives according to raw material polymer, reactivity and solvent system

Table 1: Overview project consortium

Table 2: Classification of adhesives for FCM according to base polymer, solvent system and curing type as well as typical applications.

Figure 1

Figure 2

Type	Partner	Country
RTD	Fraunhofer Institut für Verfahrenstechnik und Verpackung IVV	DE
IAG	FEICA - Association of European Adhesives Manufactures e.V.	BE
IAG	Industrieverband Klebstoffe e.V., IVK	DE
IAG	Asociación Espanola de Fabricantes de Colas y Adhesivos, ASEFCA	ESP
IAG	Association Club "Materiaux pour Contact Alimentaire et Santé" filiere papier/carton, Club MCAS	FRA
IAG	IK Industrievereinigung Kunststoffverpackungen	DE
IAG	Groupement pour la codification des mesures des bouchons de liège, Codiliège	FRA
IAG	Association Française des Industries de Colles, Adhesifs et Mastics, ASEFCA	FRA
RTD	Institut National de la Recherche Agronomique, INRA	FRA
RTD	FABES Forschungs-GmbH für Analytik und Bewertung von Stoffübergängen	DE
RTD	Universidad de Zaragoza, Instituto de Investigación en Ingeniería de Aragón (I 3A) -	ESP
RTD	Centre technique de la Conservation des Produits Agricoles, CTCPA	FRA
RTD	Institut Textile et Chimique de Lyon, ITECH	FRA
RTD	Université de Bourgogne-ENSBANA "ERT Sécurité alimentaire-Emballages"	FRA
SME	Eukalin Spezial Klebstoff Fabrik GmbH	DE
SME	Gludan A/S.	DK
SME	Türmerleim GmbH	DE
SME	Samtack S.L.	ESP
SME	MITOL	SLO
SME	Belbo Sugheri	ITA
SME	Pietec Corticas SA	POR

Explanations: RTD = Research institute, IAG = association, SME = small&medium sized enterprise

Table 1

Raw material polymer	100 % system		water based		solvent based	
	reactive	non-reactive	reactive	non-reactive	reactive	non-reactive
Acrylic	psa labels, film/film	psa		<u>film/paper, psa labels</u>		psa, film/film
casein				labelling, laminating, cork		
cellulose				paper sacks		
dextrin				labelling, most packaging, mainly with paper		
EVA ethylene-vinylacetate-copolymer		<u>boxes</u> , labelling, psa		all type of packaging		
VAE vinylacetate-ethylene-copolymer				<u>boxes, paper/paper</u>		
natural rubber				<u>cold seals</u>		<u>psa</u> tapes, labels, cork
polyolefine		<u>boxes, paper/film</u> hygiene art., psa, labelling				
polyurethane	<u>film/film, clear boxes, cork</u>	<u>film/paper</u>	<u>film/film, film/paper, cork</u>	paper/paper	<u>film/film</u>	
PVAc polyvinylacetate				<u>paper/paper, wood, cork packaging</u>		
PVOH polyvinylalcohol				<u>paper/paper, tissue laminating</u>		
starch				labelling, <u>paper/paper</u> , corr. board		
synth rubber		<u>paper/film</u> , hygiene art., boxes, labelling, psa		film/paper, film/board, alu/paper, <u>alu/board</u>		psa
epoxy based	structural applications					
melamine formaldehyde			wood, cork			
formalehyde condensation products				paper/paper		
PVP polyvinylpyrrolidone		labelling				
polyvinylether				<u>labelling</u>		
glucose				<u>paper/paper, tissue</u>		
water-glass				tissue		

Explanations: The test systems in the project are marked grey and the applications underlined

Table 2