EXTERNAL SCIENFITIC REPORT

Report of ESCO WG on non-plastic Food Contact Materials[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

This scientific output published on 30 March 2012, replaces the earlier version published on 25 July 2011[4]

ABSTRACT

An EFSA Scientific Cooperation (ESCO) Working Group was set up in February 2010 in order to collect the information present at Member State level and make proposals to anticipate emergency situations linked to presence in food of substances released by non-plastic food contact materials and for which no harmonised risk assessment is available. An ESCO inventory list, containing 2800 entries used in the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork, has been established. The substances on this list were divided into two groups, according to the date of evaluation. 230 of these substances were evaluated following publication of the Scientific Committee of Food Guidelines for Food Contact Materials (1991). Strategies for prioritization of the evaluations of substances and for providing preliminary advice in case of urgent need were proposed. They include toxicity and exposure assessment tools. For toxicity assessment, read-across approaches from structural similar substances can be used whenever possible. Alternatively an approach based on human exposure thresholds correlated to the chemical structure of the molecule can be used. A network of experts to be mobilised in case of urgent advice has been set up.

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[4] The Annex I, containing the compilation of lists of substances for non-plastic Food Contact Materials, evaluated in Member States, Switzerland and Norway, as collected by the ESCO Working Group, was added to the previous version.

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KEY WORDS

Non-plastic FCM, prioritization, emergency risk assessment, TTC, human exposure threshold, ESCO

SUMMARY

The Advisory Forum of EFSA, in its meeting in Bucharest in April 2009, emphasized that recent crises were originating from non-plastic parts of food contact materials (FCM), e.g. coatings, paper and board, adhesives, printing inks and rubber. These materials are not covered by a specific regulation and thousands of substances used to manufacture them have not been evaluated for their safety at the EU level.

The Advisory Forum also stated that useful experience about evaluations of such substances is already available in Member States and agreed that the collection and the compilation of this knowledge would allow obtaining an overview of the current situation.

The Executive Director of EFSA proposed to set up an EFSA Scientific Cooperation (ESCO) Working Group, in order to collect evaluations available in Member States, to prepare inventory lists of evaluated substances and classify them according to the way they were evaluated (guidelines, risk assessment background), identify gaps and strengths in different approaches, establish the principles of setting the priorities for further evaluations and identify the most knowledgeable experts in the field, who could be mobilized in case of further need.

The WG met six times, from February 2010 to April 2011. Representatives of stakeholders were invited to a WG meeting held in Milan, in March 2011. The main outcomes of the ESCO WG and the criteria for setting priorities for evaluation of substances with no available toxicological data were then presented and discussed.

Substances used for the manufacture of paper and board, printing inks, coatings, rubber, colorants, wood and cork and evaluated at national level were inventoried. The final ESCO inventory list contains 2800 entries. The WG divided these substances into two groups, according to their date of evaluation: after (list A) and before (list B) the publication of SCF Guidelines for Food Contact Materials (1991). List A contains 230 substances.

The ESCO WG has proposed strategies for both **prioritization of the evaluations of substances** and for providing preliminary advice in case of **emergency** situations.

Where toxicological data are available on substances with similar chemical structure, read-across can be used to draw preliminary conclusions on the toxicity of the substance. (Q)SAR approaches can also be useful.

Where little or no toxicological data are available, human exposure threshold approaches, based on the chemical structure of the substances (such as the Threshold of Toxicological Concern - TTC – approach) can be used. A table with these human exposure thresholds below which there is a very low probability of adverse effects to human health is given indicatively in this report.

It should be emphasized that the above approaches are not designed to replace full risk assessment. These principles may be of value to industry to define which studies should be undertaken in priority.

Evaluation of possible dietary exposure of consumers can be based on uses and concentrations of the substances in the non-plastic FCM, associated to migration modelling. Usual migration models are based on molecular weight of the substance, which is also derived from the chemical structure. More or less realistic assumptions and scenarios can be designed, depending on the material and the applications.

Substances for which the **dietary exposure** is likely to exceed the corresponding exposure threshold value should be considered as a priority for risk assessment.

A network of experts to be mobilised in case of crises was set up. It is composed from experts from national authorities and experts from industry who will provide EFSA with the relevant information, within a short notice.

The ESCO WG identified the general principles for prioritization of lists of substances for safety evaluation. Harmonised guidelines may be useful, depending on evolution of the regulatory context, e.g. if specific rules are set for the non-plastic FCM.

TABLE OF CONTENTS

CHAPTER I: INTRODUCTION AND BACKGROUND

I.1. Introduction

In recent years, EFSA had to provide urgent advice to risk managers, due to finding of substances in food migrating from food contact materials (FCM) by enforcement laboratories. Such situations are named here 'crises' for simplicity purposes. Crises in the area of FCM not only harm the confidence of consumers but they also jeopardize the ongoing work of EFSA on scheduled safety evaluations of substances for FCM.

The event which stimulated the work described in this report occurred in February 2009, when the European Commission had asked EFSA for urgent scientific advice on the safety of 4-methylbenzophenone, a substance migrating from the printed layer of packaging into breakfast cereals. EFSA then had to take this task in priority in order to provide sound advice in very short time and to postpone all scheduled tasks. Similarly, the need for urgent safety evaluations occurred in the past for mineral hydrocarbons migrating from paper and board, BADGE and NOGE from coatings, aromatic amines from adhesives, nitrosamines from rubber, ESBO from closure gaskets of baby food jars and ITX from printing inks.

The Advisory Forum of EFSA (AF), in its meeting in Bucharest in April 2009, emphasized that while plastics are covered by a specific regulation, with positive lists of substances, crises were originating from non-plastic parts of FCM, e.g. coatings, paper and board, adhesives, printing inks and rubber. These materials are not covered by a specific regulation and thousands of substances used to manufacture them have not been evaluated at the EU level for their safety.

The AF also stated that useful experience about evaluations of such substances is already available in Member States. The Advisory Forum and the Scientific Committee (SC) agreed that the collection and the compilation of this knowledge would allow obtaining an overview of the current situation and facilitating future discussions at the EU level. The Executive Director of EFSA then proposed to set up an EFSA Scientific Cooperation (ESCO) Working Group, in order to collect the relevant information, to highlight gaps and to propose priorities for future actions.

According to the terms of reference of this working group (as described in its mandate, signed on December 3, 2009), the CEF Unit was invited to give scientific and administrative support for this ESCO working group, in order to:

Collect information available in Member States on the evaluation of substances for FCM other than plastics:

- Collecting the evaluations available in Member States
- Preparing inventory lists of evaluated substances including information of the data used and the outcome of the evaluation
- Identifying the most knowledgeable experts in the field, who could be mobilized in case of further need

Analyze the information collected:

- Classifying the substances according to the way they were evaluated (guidelines, risk assessment background).
- Identifying the gaps and strengths in different approaches and underlying guidelines.
- Establish the principles of setting the priorities for further evaluations

Organize a workshop to discuss the draft ESCO report.
Prepare the final report including proposals for further actions to the Executive Director of EFSA.

I.2. Background

Regulatory background

This section presents the background of the evaluations available in the EU, in Member States and at the Council of Europe. The approaches and procedures used in Member States for the evaluations are presented in Chapter III.

Existing EU legislation

The Regulation (EC) No 1935/2004 (EC 2004) is the framework EU legislation that covers all food contact materials and articles. It defines food contact materials and articles and sets basic requirements: food contact materials shall not endanger human health, shall not bring about an unacceptable change in the composition of the food, shall not bring about deterioration in the organoleptic characteristics thereof. The Annex of the Regulation sets out a list of materials for which specific measures may be adopted at EU level.

All food contact materials have to be manufactured in accordance with good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006 (EC 2006).

Specific EU legislation exists for plastics (Commission Regulation (EU) No 10/2011 (EC 2011), for ceramics (Council Directive 84/500/EEC) (EC 1984), for regenerated cellulose films (Commission Directive 2007/42/EC) (EC 2007) and for active and intelligent materials and articles (Commission Regulation (EC) No 450/2009) (EC 2009). Lists of authorised substances included in the specific EU legislation are based on the risk assessment performed by EFSA or the Scientific Committee on Food (SCF).

For rubber teats and soothers, only the migration of N-nitrosamines and N-nitrosatable substances is regulated (Commission Directive 93/11/EEC) (EC 1993). For coated materials, only the epoxy derivatives BADGE, BFDGE and NOGE are regulated (Commission Regulation (EC) No 1895/2005) (EC 2005).

In fact for the majority of FCMs (paper and board, glass, wood, cork, metals and alloys, textiles, adhesives, ion-exchange resins, printing inks, silicones, varnishes and coatings, waxes), listed in Annex I of the Regulation 1935/2004, no specific EU measures are in place. These materials are only covered by the general provisions of the framework Regulation which apply to all FCM. Member States have the possibility to keep existing legislation and adopt new national legislations on FCMs for which specific EU measures are not in place. An overview of existing national measures can be found on DG SANCO website:
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf

Council of Europe recommendations for non-plastic food contact materials

The *Council of Europe* has established general recommendations for various types of materials which are frequently used in production, distribution, processing and consumption of foodstuffs. The following (non-plastic) materials have been addressed: coatings, cork, glass, inks, metals and alloys, paper and board, resins for ion exchange and adsorption, rubber, silicones.

For all materials, the requirement is present that they should not transfer their constituents to foodstuffs in quantities which could endanger human health, bring about unacceptable change in composition or deterioration of organoleptic characteristics. Specific requirements are set in the supplementary Technical Documents and substance inventories can be found in the Appendixes of the resolutions (see Annex II). The substance inventories are based on notifications by industry or national authorities. Listed substances have not necessarily been risk assessed.

At the Council of Europe, the Committee of Experts on packaging materials for food and pharmaceutical products (P-SC-EMB) has started revising the previously established resolutions on cork, paper and board, printing inks and glass (see Annex 1). This Committee operates under the aegis of the Consumer Health Protection Committee (CD-P-SC) and is composed of official representatives from 36 Member States (EU countries and non-EU countries) and from the European Commission and EFSA. The activities are coordinated by the European Directorate for the Quality of Medicines and Health Care (EDQM) (contact: susanne.bahrke@edqm.eu).

Scientific literature on data useful for risk assessment of non-plastic FCM

General introduction

Plastic and non-plastic packaging materials may release chemicals into food products and beverages which are in contact with them. The exposure (which is related to migration and uses) and the toxicity of the substance(s) in question are the two main factors which define the human health risk linked to FCM. This section presents a general overview of the work published in the recent scientific literature. Scientific papers focusing on analytical methods, risk and exposure assessment approaches and migration data for the major non-plastic food contact materials have been considered.

In 1991, the Scientific Committee for Food has introduced a tiered approach for **risk assessment** of plastic FCM, which is still used by EFSA (*Barlow 2009, SCF Guidelines*). The legal European background and the **challenges in the assurance of compliance** with Article 3 of the 1935/2004 Framework Regulation within the production chain, particularly for non-plastic materials, have been addressed (*Grob et al., 2009a*). Compliance of FCM considering both specific **requirements of legislation** and **good manufacturing practices** (GMP) has been discussed (*Grob et al., 2009b*). In the frame of the LD-CAST Project (Italy) guidelines for the application of the Regulation (EC) 2023/2006/CE on GMP in the supply chain of FCM, in particular for the chains of aluminium, paper and board, flexible packaging, plastics, coated and uncoated metals and alloys, wood, cork and glass, were developed (*Milana et al., 2009*).

Two types of data are required to estimate the exposure or dietary intake of a chemical from packaging materials: **migration data** (concentration of the substance in food or food simulant) and **food consumption data**. Migration values may be obtained from monitoring levels of chemicals in real food systems; from migration experiments, carried out under standard conditions of time and temperature of contact between the materials and a food simulant and/or through recognised mathematical diffusion models. Several efforts on conducting surveys to gather qualitative information on the types of packaging materials used for foods and consumer patterns of packaged food, have been performed to allow for **exposure assessments** (*Duffy et al., 2006a,b and 2007; Bouma et al,. 2008; Poças et al., 2009; Foster et al., 2010*). **Probabilistic approaches** have been applied for coupling exposure assessment (*Holmes et al., 2005*) and migration modelling (*Poças et al., 2010*). According to a probabilistic study, changes in eating habits over time have a smaller impact on dietary exposure to migrants than changes in packaging usage, packaging composition and migration levels (*Northing et al., 2009*). Glass and plain (uncoated) metal are not included in the scope of this working group.

Review, material by material

Migration from **paper and board** has not been as extensively studied as migration from plastic materials. A number of scientific articles provide data on real or potential migration of organic substances (trimethyldiphenylmethane, phthalates, perfluorochemicals, diisopropylnaphthalene, benzophenone and derivatives (such as Michler´s ketone), bisphenol A, resin acids, 3-choro-1,2-propanediol) and inorganic substances from paper and board (mainly recycled) into both actual food products (mainly solid food matrices but also others) and food simulants (solids, and food simulating solvents) (*Sturaro et al. 2006; Summerfield and Cooper 2001; Aurela et al. 1999; Begley et al.*

2005,2007 Summerfield and Cooper 2001; Boccacci Mariani et al. 1999; Ozaki et al. 2006a Ozaki et al. 2006b; Pace and Hartman 2010; Parry and Daston 2004). More recently migration of mineral oils from printed paperboard into dry foods has been reported (*Vollmer et al. 2011; Biederman and Grob 2010*). Different analytical methods have been applied for the analysis of migrants from paper and board such as pentachlorophenol, metals (eg. chromium, cadmium, lead), diisopropylnaphthalene, phthalates, chlorophenols, fluorescent whitening agents (*Bononi and Tateo 2009; Domeño et al. 2005; Skrzydlewska et al. 2003; Zhang et al. 2008; Diserens 2001; Aurela et al. 1999*). Extensive research on factors affecting migration using surrogate contaminants and the effect of different barrier layers have been performed (*Castle 2004; Choi et al. 2002; Johns et al 1996*). Furthermore, several studies have focused on the kinetics of migration and modelling of potential contaminants in paper and board towards food and food simulants, as well as on the partition behaviour of volatile substances between cardboard and the gas phase (*Triantafyllou et al. 2005; Nerín and Asensio 2004; Castle 2004; Choi et al. 2002; García-Gómez et al 2004; Haack and Franz 2000*). Consumer dietary exposure estimation based on the combination of simulated migration into foods, with consumption data of food packaged in paperboard has also been approached (*Pocas et al. 2010*).

In Europe, the need for urgent actions on **ink components** used for printing paperboard and multilayer packaging found in food (eg. isopropylthioxanthone, 4-methylbenzophenone) has triggered research work. Related publications have mainly focused on the development of analytical methods and on migration data of photoinitiators into foods and on the mechanisms of migration of substances from the printed packaging surface into the food: set-off, permeation and through gas phase transfer. Analytical methods (GC-MS, LC-MS, HPLC-UV or HPTLC) have been described for the detection of photoinitiators and other substances (2-isopropylthioxanthone ITX, benzophenone, 4-methylbenzophenone, 2-ethylhexyl 4-dimethylaminobenzoate, 1-hydroxycyclohexyl-1-phenylketone, ethyl 4-dimethylaminobenzoate, acrylic esters, alkylbenzenes) in the material itself and in foods (*Morlock and Schwack 2006; Allegrone et al. 2008; Benettia et al. 2008; Van Hoeck et al. 2010;Papilloud et al. 2010; Koivikko et al. 2010; Gallart.Ayala et al. 2011; Sanches-Silva et al. 2008*). Techniques for the determination of migration have been developed for testing the potential transfer under controlled conditions of inks components into food/simulants, including the assessment of the suitability of simulants and in some cases kinetics studies (*Papilloud and Baudraz 2002; Jung et al. 2010; Sanches-Silva et al. 2009; Rodriguez-Bernaldo et al. 2009*). Procedures to detect the transfer of colorless components of printing inks from the outer printed surface onto the food-contact surfaces (set-off) have been developed(*Bradley et al. 2005*). Many data on photoinitiator levels in different foods packed in cartons, plastic and foils, especially milk products, beverages and fatty food, are available (*Rothenbacher et al. 2007; Sagratini et al. 2008; Anderson and Castle 2003*). The migration into food of other substances no related to UV inks, such as alkylbenzenes (*Aurela et al.2001*) or bis(2-ethylhexyl) maleate has also been reported (*Rutschmann et al. 2010*). With the aim of preventing or reducing the migration of substances from printed cardboard into food, the effect of different plastics as functional barriers has been studied (*Johns et al., 2000; Pastorelli et al., 2008*), and also new low migration off-set printing inks are being developed (*Gude and Simat, 2009*).

Adhesives are a complex group of chemical formulations, widely used in different types of food packaging and in different applications: manufacture of rigid packs and multilayers, attachment of labels, sealing flexible packaging, etc. Several research papers have been published on the potential migration of adhesives components (volatiles and non-volatiles) used in different packaging materials, such as paper and board or laminates (*Gruner and Piringer, 1999; Nerín et al., 2009; Canellas et al., 2010*). These studies include the development of testing protocols for the screening of the adhesives constituents, as well as methodologies used for migration testing into food simulants. Techniques such as HS-SPME-GC-MS, GC-TOF-MS, UPLC-TOF-MS or UPLC-HDMS are reported. Migration models for the adhesives were developed. A software, developed in the frame of the European project MIGRESIVES, can be downloaded from the INRA web site "Safe Food Packaging Portal": http://sfpp3.agroparistech.fr/.

In **rubbers and elastomers**, screening and migration studies of plasticizers, benzothiazoles and related vulcanization residues, nitrosamines and nitrosatable substances, using analytical techniques such as two-dimensional GC–MS, Automated Thermal Desorption Gas Chromatography and LC-MS (LC-APcI-MS) have been referred (*Forrest et al. 2006; Fankhauser-Noti and Grob 2006; Yokoe et al. 2008; Bouma et al, 2003; Barnes et al 2003*).

Strategies for safety evaluation of **coatings** used for metal packaging have been proposed. Several screening and quantification techniques for the migration of BADGE, NOGE, Bisphenol A (BPA), Bisphenol F (BPF), cyclic oligoesters, trimellitic acid and melamine from coatings of different nature have been described. Analytical techniques included 2D-GC, GC-MS, SEC and NPLC (*Grob et al. 2010; Bradley et al. 2009, 2010; Zhang et al. 2010; Petersen et al. 2008; Thomson and Grounds 2005; Simoneau et al 1999; Fankhauser-Noti and Grob 2004; Schaefer and Simat 2004a,b; Schaeger et al. 2004; Goodsin et al. 2002; Dionisi and Oldring 2002; Biedermann and Grob 2006a,b; Suárez et al 2000; Montanari et al.1996*).

Silicones utensils, particularly baking moulds and baby soother and teats have been studied in terms of volatile compounds and siloxane oligomers. Overall migration into simulants and food using H-NMR techniques was performed (*Lund and Petersen 2002; Forrest and Sidwell 2005; Meuwly et al 2007; Helling et al 2009,2010*).

Migration from agglomerated **cork** stoppers was studied: potential migrants originating from the adhesive component and from lubricants and surface treatments were identified. A general approach was proposed for the evaluation of commercial chemicals as well as a procedure to determine NIAS (like primary aromatic amines formed by hydrolysis of isocyanates) (*Six and Feigenbaum 2003*). The swelling effect of the penetration of a wine into the cork whole structure of the cork was demonstrated (*Six et al. 2002*).

Non-intentionally added substances (NIAS)

Impurities of substances which are intentionally used in manufacture and processing (e.g. of monomers, additives) or reaction products formed from intentionally added substances during the manufacturing process (e. g. because of thermal decomposition of substances) are examples of NIAS and they can migrate from FCMs. The identity of the NIAS is not always known (*Grob*, 2002; *Bradley and Coulier*, 2007).

Examples of reaction products formed during polymerization are semicarbazide formed by degradation of the blowing agent azodicarbonamide (*Stadler et al. 2004*), resoles (*Grob et al.* 2010), 3-chloro-1,2-propanediol (*Pace et al*. 2010), polydimethylsiloxanes (*Meuwly et al*., 2007; *Helling*, 2010), 4-phenylcyclohexene (*Landy*, 2004). Pentenoic acid and crotonic acid are formed by thermal degradation of poly(4-hydroxybutanoate/valerate).

Substances related to stabilizers and antioxidants (*Pospíšil*, 1991; *Al-Malaika et al*. 1994) are formed by intentional degradation of these additives. Nonylphenol (*Fernandez*, 2008; *Soto* 1991), primary aromatic amines (*Az and Dewald*, 1991), N-nitrosamines and N-nitrosable substances and 2-mercaptobenzthiazole (*Fiddler*, 1996) are products formed by non intentional degradation of additives.

Threshold approaches

The Threshold of Toxicological Concern (TTC) approach is a risk assessment tool based on human exposure threshold values for chemicals below which there is a negligible risk to human health. This approach is based on the chemical structure of the molecules.

The TTC approach might be used in situations where there is limited or no information on toxicity of the compound. This approach is used by EFSA for the evaluation of flavouring substances and represents part of the recommendations of this WG for prioritisation and emergency evaluation of non-plastics FCM.

The initial Threshold of Regulation (ToR) approach was derived by FDA from a distribution plot of the chronic dose rates, the dose descriptor TD_{50} (the daily dose rate required to induce a calculated 50 % tumour incidence) based on the analysis of 343 chemicals from the carcinogenic potency database (The Carcinogenic Potency Database (CPDB), http://potency.berkeley.edu/) (*Gold et al.*, 1984), and linear extrapolation to a $1x10^{-6}$ risk. The ToR concept was further extended by incorporating acute and short-term toxicity data, results of genotoxicity testing, and structural alerts to identify potent and less potent carcinogens confirming the validity of the approach.

In order to assess whether non-cancer endpoints impact the ToR, additional analyses were conducted from the Registry of Toxic Effects of Chemical Substances (RTECS) database on 3306 chemicals with oral reproductive toxicity data, and on 2542 chemicals with data from other repeat-dose toxicity studies. Based on the results, a tiered TTC approach considering structural alerts, genotoxicity test results and short-term toxicity data was suggested to extend the ToR approach.

Munro and co-workers (1996) evaluated the use of TTC related to endpoints other than carcinogenicity. They used structural information based on a classification developed by *Cramer et al.* (1978). Chemicals were grouped into three structural classes based on a "decision tree" approach. **Class I** substances have simple chemical structures and efficient modes of metabolism, suggesting a low order of oral toxicity; **Class III** substances have chemical structures that permit no strong initial presumption of safety or may even suggest significant toxicity or have reactive functional groups; and **Class II** gathers substances with intermediate properties. Human exposure thresholds of 1800, 540, and 90 µg/person/day (corresponding to 30, 9, and 1.5 µg/kg bw/day) were proposed for Cramer class I, II and III, respectively, using a body weight of 60 kg, and a safety factor of 100 (*Munro et al*., 1996). A specific threshold of 18 µg/person/day was derived for organophosphate/carbamate substances.

Further to additional expansion of the database, it was concluded that chemicals with specific structural alerts for high carcinogenic potency require compound-specific toxicity data (e.g. aflatoxin like, azoxy and nitroso compounds) and are excluded from any threshold approach. A threshold of 0.15 µg/person/day was proposed for all other chemicals with structural alerts for genotoxicity which are not part of the "cohort of concern" (*Kroes et al., 2004*, Barlow, 2005).

In 2011 the Scientific Committee of EFSA (SC) reviewed the TTC approach (Scientific Committee of EFSA, 2011, opinion to be adopted). The TTC approach is not applicable for some categories of substances. These include substances known to accumulate in the body (e.g. polyahlogenated, dibenzodioxins, -dibenzofurans, –biphenyls and heavy metals), those substance classes not included in the original database (e.g. non-essential metals in elemental ionic or organic forms and proteins) or substances to which the Cramer classification does not apply (e.g. polymers, inorganic compounds).

The conservatism of the TTC approach is further consolidated by a work done by the CEF Unit at EFSA. Data evaluation has shown that the human exposure threshold derived from the TTC approach (Munro *et al*., 1996) is lower than that based on experimental toxicity data in more than 96 % of cases derived from FCM substances and active pesticide components already evaluated by EFSA (*Pinalli and al., 2011*). For a few substances (below 5%), the TTC approach was less conservative than the risk assessment based on the toxicity studies, without the presence of any structural alert in their structure.

An overview of different thresholds is presented in Table 1. More guidance on this issue will be found in the opinion of the Scientific Committee of EFSA, to be published in 2011.

Table 1: Thresholds for toxicity testing prioritization and for emergency safety assessment

		Threshold (µg/person/day)	*Threshold (µg/kg bw/day)*
Carcinogens	Substances with a structural alert for genotoxicity	0.15	0.0025
	Substances without a structural alert for genotoxicity	1.5	0.025
Non-carcinogens	Organophosphates/carbamates (neurotoxicants)	18	0.3
	Cramer Structural class III	90	1.5
	Cramer Structural Class II	540	9
	Cramer Structural Class I	1800	30

I.2.3. Scientific projects funded by EC

The projects presented here are the most recent ones, dealing with evaluation of migrants by alternative methods for verification of content (BioSafePaper), with migration of adhesives (MIGRESIVES), with dietary exposure (FACET) and with migration modelling (MIGROSURE).

BIOSAFEPAPER project (2001 - 2005)

The aim of the BioSafePaper project was to develop and intercalibrate a reliable and easy-to-use test battery of biological tests, based on a decision-tree approach, for the global safety assessment of food contact paper and board. The authors also mention that the usual enforcement approaches do not sufficiently take into account minor constituents and NIAS. Hence the project went for a global approach, using biological tests on the whole extracts of the paper FCM.

The research project produced a standard procedure for extraction of migrants from paper and board, a number of in vitro toxicity tests looking at different end-points, a decision-tree for safety evaluation, and a new risk evaluation approach (*Severin et al., 2005*; *Bradley at al*., 2008; *Bradley at al*., 2010; *Honkalampi-Hämäläinen et al., 2010*).

MIGRESIVES project (2007 – 2010)

The overall objective of the project was to establish a ”toolbox” of methods and approaches to estimate migration from adhesives of food contact materials. Packaging producers and risk assessors should have the same toolbox.
The project did a first and important step into migration modelling of adhesives
Partitioning and diffusion parameters of 38 test migrants for various adhesives layers (polyolefin, rubber, EVA, VAE, PVAc, acrylic) and substrates (paper, cardboard, non-polar plastic) have been determined. Based on these data a multilayer migration model has been established to model migration from adhesives into food simulant(s). In addition, analytical methods for screening purposes have been developed (to be downloaded from http://sfpp3.agroparistech.fr/).
The database of modelling parameters will be enlarged in the future for a broader applicability, based on further experimental work.

FACET project (started 2008 - 2012)

The FACET European project intends to create tools to estimate exposure to substances migrating from food contact materials, among others. It will create a comprehensive European database on food packaging usage patterns and a database of substances that are likely to be contained in the different

packaging materials used across Europe, with the help of a consortium of industry partners. It will develop a new, scientifically-based, classification of foods according to their migration behaviour, help derive realistic migration values for exposure estimation. FACET will conduct migration research to derive fundamental partition and diffusion parameters that describe the migration process for packaged foods in particular for non-plastic materials and for multi-layer multi-materials. It will develop a mathematical modelling tool to estimate migration from all packaging materials into foods under real conditions of use, with both deterministic and probabilistic outputs for exposure estimates. A Structure Activity Relationship (SAR) approach will be developed, validated and used to evaluate the toxicological significance of exposure to packaging substances.

MIGROSURE (2003 – 2006)

The main objective of the project was to provide a tool for estimation of consumer exposure to chemicals migrating from FCM and to investigate the acceptance of migration modelling versus chemical measurements, and its implications for exposure estimation.
The tool was based on a physico-chemical migration model that describes mathematically the migration processes from plastics into actual foodstuffs under any foreseeable contact conditions.
The model is applicable as a tool to estimate exposure related to migration by applying either a standard worst case exposure scenario or results from food consumption and food plastics packaging surveys.
Details on this project can be found at http://www.foodmigrosure.org/.

OTHER projects

Projects financed by EC could be found at the following link:

http://cordis.europa.eu/fetch?CALLER=FP7_PROJ_EN&QZ_WEBSRCH=food+contact+materials&QM_EP_PGA_A=&QM_EN_OC_A=&USR_SORT=EN_QVD+CHAR+

CHAPTER II: COMPOSITION AND OUTCOMES OF THE WORKING GROUP

II.1. Composition of the working group

This ESCO Working Group was composed of the following experts : F. Bolle (Scientific Institute of public health, Belgium), J. Bustos (Centro Nacional Alimentacion, Spain), V. Dudler (Swiss Federal Office of Public Health, Switzerland), T. Ø. Fotland (Norwegian Scientific Committee for Food Safety (VKM), Norway), T. Heinke (Federal Institute for Risk Assessment (BfR), Germany), E. Kakouri (State General Laboratory (SGL), Cyprus), L. Jorhem (National Food Authority, Sweden), S. Mannino (University of Milan, Italy), T. Hallas-Moeller (DTU National Food Institute, Denmark), F. Pocas (Catholic Portuguese University, Portugal), P. Sauvegrain (LNE, France), J. Sosnovcova (National Institute of Public Health, Czech Republic), M. Sycova (National Reference Laboratory for Food Contact Materials, Slovak Republic), D. Theodosiou (General Chemical State Laboratory, Greece), B. M. van de Ven (RIVM, the Netherlands).

Hearing expert: A. Von Wright (University of Kuopio, Finland).

The experts were proposed by the competent authorities in their country, following a call circulated through EFSA Advisory Forum members. The experts were selected on the basis of their scientific excellence and independence. Their annual declarations of interest were screened and evaluated.

Members of the CEF Panel: A. Anadón (Universidad Complutense de Madrid, Spain), J.C. Lhuguenot (University of Bourgogne, Dijon, France), M.R. Milana (Istituto Superiore di Sanità, Rome, Italy).

Observers: S. Bahrke (Council of Europe); F. D'Atri, A. Schaefer (European Commission)

EFSA Scientific Officers: A. Feigenbaum (head of the CEF Unit, chair of the WG), A. Lupu, D. Spyropoulos.

II.2 Substances evaluated in Member States, Switzerland and Norway for use in non-plastic FCM

An overview of the information on each non-plastic food contact material, present in different countries, was initially given by all the experts participating in the working group. Based on this, the following materials were taken on board to be discussed by the WG: paper and board, rubber, colorants, printing inks, silicones, coatings, cork and wood.

Some Member States have Regulations with positive lists which are legally binding; others publish recommendations which include substances evaluated by national risk assessment authorities. In many cases Member States only refer to or use regulation of other Member States. Therefore it is important to know in case of crisis, if a risk assessment in accordance with internationally recognised standards was performed, which body actually performed the risk assessment and which authority is in possession of the toxicological and exposure data. As far as possible, this information was retrieved by the working group.

II.2.1 Compilation of lists of substances for non-plastic FCM

The first objective of this working group was to collect the evaluations carried out in Member States, Switzerland and Norway. Therefore, updated national lists of the relevant substances, for each material, were provided by the experts. The lists provided by the national experts were compiled in a unique electronic list by the EFSA Secretariat (see Annex I).

After 1991, the majority of evaluation committees used as a reference document the guidelines adopted by the Scientific Committee for Food (SCF) for the evaluation of substances used for plastics FCM. For many substances evaluated before 1991, the data and background for their evaluation could not be traced back. Therefore it was decided to record whether the substances were evaluated before

or after 1991, as this information was generally available. In some cases, the rules of these guidelines had been transposed to the case of non-plastics FCM.

Some Member States have listed substances evaluated by the SCF or EFSA in the context of plastics for materials other than plastics.

II.2.2 Classification of substances according to the evaluations performed

According to the mandate, an output of this WG was an inventory of substances evaluated in Member States. The substances were classified into two lists by the WG:

> ***List A:*** substances evaluated after 1991;
> These substances have probably been evaluated according to the SCF/EFSA guidelines.
> ***List B:*** substances evaluated before 1991.

These substances have not been evaluated according to the SCF guidelines, but according to the national criteria. In many cases it was not possible to trace back how these substances had been evaluated.

WARNING: The ESCO list is a compilation of evaluations, but not of Regulations.

II.2.3 Information on the evaluated substances

The information on substances evaluated, as compiled in the lists, includes:

- Name of substance;
- CAS RN numbers;
- Commission PM references, where available;
- Restrictions of use where available;
- Classification into an SCF list if available;
- C.I. name (only for pigments and dyes);
- Information on possible reaction products (not all Member States provided this information. Sometimes these substances are not available in lists and/or are part of confidential sections in the respective dossiers);
- Date of evaluation: before or after 1991 (see above).

The lists reflect the information as present at national level, but do not cover all available information (e. g. about by-products which have been assessed but are not mentioned in the respective positive list).

Seven separate lists of substances, for paper and board, printing inks, colorants, rubber, silicones, coatings, cork and wood, were collected from Member States, Norway and Switzerland, participating at the ESCO WG. In total, the final inventory list of substances contains number of 2800 entries.

Discrepancies between data from different Member States (e.g. the same name was given with different CAS RN numbers) were identified. Therefore, when this compilation was completed, EFSA launched a tender to check the consistency of the information collected. This work was outsourced in a procurement contract taken up by the Decernis Company.

The aim of this procurement was:

- To determine whether the CAS RN is correct;
- To add CAS RN where missing;

- To determine and provide whether alternative CAS RNs may exist;
- To review the chemical name, using the name or the approach used in EC, in the lists of the Council of Europe Resolutions, if available or the EC type nomenclature (e.g. EINECS).

Each expert checked the results in his remit and some corrections were made by Decernis. Where different views were identified between the contractor and the Member State expert, the final decision was taken by the expert. The same substance may be recorded under different synonims.

This work was completed in April 2011.

II.3 Tools for prioritization of safety evaluation and for urgent advice

The ESCO WG has identified the TTC approach as a useful tool for prioritization and for urgent advice when only the chemical structure of the migrant is known.

II.3.1 Criteria for setting priorities for evaluations of substances used for non-plastic FCM

Substances for which the dietary exposure is likely to exceed the corresponding TTC value should be considered as a priority for risk assessment.

Taking into account the chemical structure of the substances, the corresponding TTC can be allocated (see Table 1). For substances for which the TTC approach cannot be used, risk assessment may require compound-specific toxicity data.

Evaluation of possible **dietary exposure of consumers** can be based on **uses** and **concentrations of the substances in the non-plastic FCM, associated to migration modelling**. Usual migration models are based on the molecular weight of the substance. Migration can also be calculated, assuming that a 100% transfer of the migrant into food occurs.

In general, if no information on uses is available, the default assumption (currently 6 dm^2 packaging 1 kg food, consumed daily) can be used.

If uses are known, refined scenarios could be set up, considering e.g. high or average consumers, children as well as brand or pack type loyalty.

If relevant, there may be needed to consider the exposure from non FCM sources, as this could influence prioritisation.

Possible link with ECHA: Information on level of exposure from other sources, on high production substances and on substances where the FCM application represents only a small fraction of the total production (small tonnage for FCM, large tonnage etc) can be obtained by using the database of ECHA.

Example of application of the prioritization approach: as an example the photoinitiators for printing inks of the Swiss Regulation were classified into the corresponding Cramer classes, as described in Annex III. This classification can be a useful start for prioritisation, together with e.g. exposure data or scenarios.

II.3.2 Emergency risk assessment

For emergency risk assessment, in situations where few data are available, different tools can be used, combining exposure and toxicity approaches (TTC, thresholds, read-across, SAR and OECD toolbox).

The TTC approach (*Munro et al., 1996*) is not designed to replace full risk assessment, as the thresholds represent the 5th percentile of distribution curves of no effect levels. For substances which have a NOEL below the 5th percentile, the TTC thresholds are not enough conservative.

On the other hand, the TTC approach can be several orders of magnitude more severe than full evaluation (*Pinalli et al. 2011*).

As an example, the TTC of 4-methylbenzophenone (Cramer Class III) is 1.5 µg/kg b.w./day, which is lower than the estimates of dietary intakes from breakfast cereals [2-13.2µg/kg b.w./day (for children) or 0.8-5.2 (for adults)]. These levels of intake had been considered acceptable, based on individual risk assessment and read-across from benzophenone, a substance with similar uses and applications (*EFSA, 2009*).

For dietary exposure, if data are available for substances with similar structure and uses, they can be extrapolated to the substance to be evaluated. In absence of such information, standard or worst case scenarios can be used: e.g. assumption of 1 kg food wrapped with 6 dm² FCM, scenario of a complete migration etc. If physical parameters (diffusion and partition coefficients, activation energy …) describing migration from the given material are available, migration modelling can be used. It is also expected that the FACET program will provide tools to correlate these data with dietary exposure.

Although this is not in the scope of this ESCO WG, it has to be emphasized that guidelines to organise the different methodologies and approaches for emergency risk assessment would be useful.

II.3.3 Network of experts

Developing a network of experts from public administration and from industry, to be mobilized in case of crisis, will be very useful. The objective of this network is to provide information on substances, for which an alert is issued and a request for urgent scientific advice is placed to EFSA. In such situations EFSA would need to have access to information from industry useful for the risk assessment of the substance.

The ESCO WG provided a list of experts from Member States. At the WG meeting with the stakeholders, the industry participants proposed that representatives of industry associations are members of the network. Following this meeting, EFSA informed these associations which designated each a contact point for the network. This contact point should be able to either provide directly the information to EFSA or indicate which persons have the relevant information and could provide it to EFSA within a short notice in case of emergency.

The training of the network could be considered as a follow up of the ESCO WG, with the aim of implementing a permanent network. The possibility to widen the scope of this network by training and a work program was raised at the stakeholder meeting.

CHAPTER III: CONTRIBUTIONS FROM THE MEMBER STATES

III.A Overview of the risk assessment and of the national Regulations, as provided by the Member States

1. In ***Czech Republic***, a national regulation Act No 258/2000 Coll, on Public Health Protection and a specific measure: DECREE No. 38 of the Ministry of Health of 19 February 2001 Coll., on hygiene requirements on products intended for contact with foodstuffs and foods are in place. The general requirements, positive lists with restrictions for use and requirements for final materials or products are laid down. The risk assessment for substances in positive lists was performed by the national authority for risk assessment, the National Institute of Public Health (NIPH), based on the technical dossiers submitted by the petitioners according to national rules. Safety evaluation was always approved by the Ministry of Health. Since 2004 the risk assessment is performed by the NIPH and is based on the dossiers submitted by the petitioners, according to the SCF-FCM guidelines and the Note for Guidance of EFSA for plastic FCM. Some substances present on national positive lists for specific materials (particularly for paper and board) come from BfR recommendations. National requirements are set as maximum content in the materials, substance purity specifications, SML for individual chemicals or groups of chemicals into food simulants, or extract into solvents. For some materials, restrictions are formulated only as maximum content in the material.

2. In ***France*** the risk assessment is performed by French Agency for Food, Environment and Occupational Health and Safety (ANSES). It is based on the dossiers submitted by the petitioners, according to the SCF-FCM guidelines and Note for Guidance of EFSA for plastic FCM. Consequently, the evaluation is done according to the usual tiered approach, but in case of very low migration and in absence of genotoxicity structural alerts, a threshold of 0.5µg/kg food is applied. The advices and scientific opinions are usually endorsed into laws, or considered as major recommendations. A compendium of these regulatory decisions is edited by the Journal Officiel de la République Française (JORF) and is known as Brochure 1227 JORF 1994. Matériaux au contact des denrées alimentaires, produits de nettoyage de ces matériaux. Brochure 1227. 5Paris : Journal Officiel de la République Française (éditeur), collection *Brochure 1227*, 1994/01, 260 p., tabl., ISBN 2-11-073441-8, FRA).

3. In ***Germany*** the conclusions of risk assessment are published in form of "Recommendations" on FCM (*The BfR Recommendations*), which are not legal norms. They represent the current state of the scientific and technical knowledge for the conditions under which consumer goods made of high polymer substances meet the requirements of Article 3, paragraph 1 a of the Regulation (EC) No 1935/2004 in respect to their health safety. The Recommendations mainly consist of substance lists; general requirements are also included. Each recommendation focuses on a specific kind of food contact material (e.g. silicones). Restrictions are normally formulated as maximum content in the material. For the inclusion of a substance in the list, a petition has to be filed which has to follow the Note for Guidance of EFSA for plastic FCM. Risk assessment is done by the Federal Institute for Risk Assessment (BfR) which is supported by the respective Subcommittees of the BfR Committee for Consumer Products. If all requirements are met the respective substance is included in the Recommendation. The BfR Recommendations were first published in 1958. For substances which have been included into the Recommendations during the very early years, no documented risk assessment is available. Such substances have not been included in the ESCO Working Group list.

4. In ***Italy***, the Risk assessment is performed according to the SCF-FCM guidelines, implemented since 1994, amending the previous national guidelines. To get positive listing, a technical dossier submitted by the petitioners has to be evaluated by the Istituto Superiore di Sanità (ISS), the Technical/Scientific Body of the Ministry of Health, where the risk assessment is performed. The final decision on the positive listing is laid down by the Ministry for Health, the Management Body, after advice from the Consiglio Superiore di Sanità (Higher Health Council).

5. In t*he* ***Netherlands***, new substances are evaluated by Commission G4, in which the Ministry of Health, the National Institute for public Health and the Environment (RIVM), the Inspectorate, and the Industry are represented. Nowadays, risk assessments (Summary Data Sheets) are made according to the same method used by EFSA for plastics, with sometimes some adjustments on the exposure scenarios, e.g. for some special products, lower surface to content ratio's (than the 6 dm^2 per kg food as used for plastics) are used. Most substances however have been put on the list decades ago on basis of only limited information. Restrictions are set in the form of a specific migration limit (SML), a maximal quantity of substance in the finished product (QM), the surface in contact with foodstuffs (QMA) or as a requirement on purity (*Food Contact Materials Regulation in Netherlands*). Some general requirements are made to all materials, e.g. primary aromatic amines are not allowed to migrate in detectable amounts, additives should not be used in amounts more than needed to exert the function they are used for, the overall migration should not exceed a certain quantity, which varies between the different materials and products made of these materials.

6. ***Norway*** has no national legislation on the non-plastic FCM. In general, all food contact materials shall comply with article 3 of the EU Regulation 1935/2004. Producers are also recommended to consider guidance documents and Regulations from international organisations or other countries, such as Resolutions from the Council of Europe, BfR Recommendations, national Regulations from the US Food and Drug Administration (FDA) or the Netherlands. Risk assessments of non-plastic FCM are conducted by the Norwegian Scientific Committee for Food Safety (VKM) on requests from the Norwegian Food Safety Authority.

7. In ***Slovak Republic***, the requirements for harmonised and some non-harmonised areas of FCM are established in Decree of Ministry of Agriculture of Slovak Republic and Ministry of Health of Slovak Republic of 9 June 2003, which issued the fifth head of the Food Code governing materials and articles intended to come into contact with foodstuffs. The general requirements, positive lists, restrictions for use and requirements for final products are laid down in above mentioned decree. The risk assessment is not part of this decree and for preparation of this decree was used previous legislation of Czechoslovakia before splitting and recommendations of other member state e.g. Germany.

8. In ***Spain***, the national legislation (Resolución de 4 de noviembre de 1982 - B.O.E. 24.11.1982) for polymeric materials lists the substances to be used for the manufacture of macromolecular compounds and includes under its scope silicones, rubbers, coatings, ion exchange resins and adhesives. Also restrictions limits are formulated in the form of overall, specific migration limits and purity criteria for the colorants.
Risk Assessment is performed by the Spanish Food Safety and Nutrition Agency (AESAN) and petitioners can be official administrations, industry, consumers associations or the AESAN. So far, no toxicological evaluations have been performed of substances used in non-plastic FCM.

III.B Overview of non-plastic FCM in Member States, Switzerland and Norway

Paper and Board

Definitions

According to the ***French*** definition, paper and cardboard, hereafter called 'paper', are manufactured from undyed or whitened cellulose base natural fibres, including recycled cellulose fibres from recovered recyclable paper and cardboard. Artificial fibres from regenerated cellulose can also be used in mixture with natural fibres. The paper can be white, undyed, coloured or be printed on the side which is not in contact with the food. Furthermore, the paper can contain synthetic fibres such as polyethylene fibres and functional additives. Materials and objects in stiff paper made up exclusively of paper and/or cardboard or composed of two or more layers of fibres each of which is made up exclusively of paper and/or cardboard and as a finished product are intended to be in contact with food products are also concerned. Coated papers or those which have undergone a surface treatment such as polymeric bonding for organic or mineral pigments are also concerned.

German definition: Single and multi-layered commodities (articles, materials) made of paper or paperboard which are intended to come into contact with or affect foodstuffs.

In ***The Netherlands***, paper and paperboard are defined as the sheets, foils or formed utensils, made from fibres of organic materials.

Spanish definition, recycled paper and board are defined as manufactured from cellulose-based fibres, from bleached or unbleached fibre material, made in part or in full from recycled fibres.

National provisions and other guidance

1. ***Belgium*** has very old legislation and uses the Council of Europe resolutions.

2. ***Cyprus*** has no national legislation, just global recommendations.

3. In the ***Czech Republic*** there are legal requirements for paper and board for FCM covering raw materials (fibrous materials, additives for raw materials and fillers), products aids and specific paper refining agents paper and board for food contact materials. Many substances come from the BfR recommendations and their safety evaluation was performed by the German authority for risk assessment. Other substances were evaluated by the national authority for risk assessment, the Czech National Institute of Public Health, and approved by the Ministry of Health before 2000. The national provisions set specific provisions for recycled fibres. A list of the authorized substances is established. The requirements including purity specifications of substances used during paper and board manufacture, levels of contaminants and conditions for testing were also established.

4. In France, Recommendations are published, with a list of evaluated substances. These recommendations include purity specifications for some organic compounds used during paper and board manufacture (e.g. optical bleaching agents), levels of contaminants (e.g. PCP, PCB’s) and testing protocols already published by official bodies (e.g. CEN).

5. In Germany, there are four Recommendations concerning paper and board. They include lists of substances and specifications (e.g.levels of primary aromatic amines or phthalates in paper made from recycled fibres as raw materials).

Recommendation XXXVI Paper and board for food contact
Recommendation XXXVI/1 Cooking papers, hot filter papers and filter layers
Recommendation XXXVI/2 Paper and paperboard for baking purposes
Recommendation XXXVI/3 Absorber pads based on cellulosic fibres for food packaging

Recommendation XXXVI covers paper and board which are used at room temperature (It is intended to extend the scope of Recommendation XXXVI to paper and board used up to 90 °C). Papers used for special purposes (e.g. baking) are covered by other Recommendations. Napkins and kitchen towels are also covered by Recommendation XXXVI.
It contains a preamble giving overall conditions and an annex which describes the preconditions for the use of recycled fibres as raw materials for the production of paper.

The specific chapters are:
A. Raw materials (fibrous materials; additives to raw materials; fillers)
B. Production aids (sizing agents; precipitating, fixing and parchmentisation agents; retention agents; dewatering accelerators; dispersion and flotation agents; defoamers; slimicides; preservatives)
C. Special Paper refining agents (wet-strength agents; humectants; colorants and optical brighteners; surface refining and coating agents)

Recommendation XXXVI/1 covers cooking papers, hot filter papers and filter layers, for the purpose of hot extraction (e.g. boil-in-bag packages, tea bags, hot filter papers) or the use of filter layers whose intended purpose involves them being subjected to extraction (filtration).
Recommendation XXXVI/2 applies to paper and paperboard that comes into contact with or affects foodstuffs during baking.
Recommendation XXXVI/3 covers absorber pads based on cellulosic fibres for food packaging.
The restrictions given in these recommendations are mostly use levels which is for historical reasons, e.g. "x *%, based on the dry fibres weight*" or "*no more than x mg substance per dm*^{2}". The restrictions can also be in the form of limits in an extract (e.g. "*The transfer of … into the water extract of the finished products must be as low as technically achievable, a limit of 12 µg/l must not be exceeded in any case*.") or *migration limits (*e.g. "*max. x mg substance/kg foodstuff or simulant*").

For the inclusion of a substance into the respective recommendation a company has to file a petition. Then BfR checks the petition and discusses it in the respective Subcommittees of the BfR Committee for Consumer Products. If all requirements are met the respective substance is included.

Since about 1991 "Note for guidance of applicants" is used. That means that the petitioners have to follow the respective format and have to deliver the respective information. Some additional conventions are necessary because of the differences between plastics and paper. Risk assessment is based on the transfer from a paper treated with the maximum requested use level. The assumptions currently used are: a 100 g/m^2 paper and 6 dm^2 paper are in contact with 1 kg food. In practical work two groups of experts are working on the evaluation of the data in the petition: one group focuses on technical, chemical and analytical aspects and the exposition and the other one focuses on toxicological questions.

6. In ***Greece***, the Greek Code of Food and Drinks, in article 24, provides the requirements for a material to be used as a food packaging material. Maximum concentration limits on cadmium, lead, mercury and pentachlorophenol are set, taken from Council of Europe resolution. Also various requirements are set (such as the food contact paper should not transfer colorants to the food, paper should be coloured with safe colorants etc).

Paper coated with organic coatings should abide with article 28 of the Greek Code of Food and Drinks that sets the requirements for organic coatings as food contact materials and contains a list of allowed monomers and starting substances (Table I) and a list of allowed additives (Table II), with specific migration limits or maximum content concentrations, taken from Council of Europe resolution.

7. In ***Italy*** specific legislation is in place from 1973. Paper and boards are regulated by the D.M. 21.3.1973 and further amendments. The regulation contains positive lists of constituents (fibrous matter, fillers, auxiliary substances, and optical brighteners) and processing aids. Compositional and purity requirements are established. Dry foods may have higher content of fillers.
Overall migration test is not required. The legal analytical methods to check compositional requirements are in Annex IV of the DM 21.3.1973

Specific provisions are indicated for recycled fibres, which are admitted only in special cases. In Italy, recycled paper and board can be used for contact with foods for which no migration test is prescribed in the EU conventional classification (Directive 85/572/EEC), provided that the finished products comply with specific compositional and purity requirements. The only derogation to this provision is for multilayer boards, with at least 200 g/m^2 weight and with at least three layers (cover, intermediate and direct contact layer); the layer in direct contact with foods must have a weight at least of 35 g/m^2. In these products, only the layer in direct contact with food has to respect the purity requirements. These boards may be put in contact only with a list of foodstuffs (e.g. cereals, dry pasta, sugar, salt, shelled fruit etc.). It must be underlined that the description of the board for which this derogation applies does not fit with corrugated boards.

8. In ***the Netherlands***, paper and board are regulated by means of positive lists. There are two separate positive lists, one for "paper and board for general use", and one for "paper and board for use as food contact material during cooking and for filtering of beverages at temperatures above 80 °C". Specific restrictions, mostly in the form of a specific migration limit, apply to a number of substances that are allowed to be used.

9. ***Norway*** has no specific regulation on paper and board. The ***Nordic Report on paper and board FCM*** is used as a guidance document for paper manufacturers, food industry, other business operators and interested parties in the production chain, as a tool for ensuring that the end-product fulfils Article 3 of Regulation (EC) No 1935/2004. The report is based on the Council of Europe Resolution AP (2002) 1 (see Annex I) and, for some aspects, the Regulation (EC) No 1935/2004. An important supplement compared to the Council of Europe Resolution is that the Nordic Report requires that the substances used in the production of food contact paper and board are evaluated by EFSA, BfR or FDA. This includes both migration as well as other conditions of use.

10. In ***Slovak Republic*** a regulation on paper and board is in place and a list of authorized substances is established. The list consists of substances which were evaluated by other Member States. For the manufacture and refining of materials and articles from paper and board which are intended to come into contact with food can be used only raw materials, additives, auxiliary and other substances listed in this Annex of the legal act.

General requirements are established for products from paper and board and the use of some substances are regulated with limits (maximum amount).

Requirements for the finished product: SML are established for polychlorinated biphenyls, phenols and polychlorinated phenols (such as pentachlorophenol), polycyclic aromatic hydrocarbons (such as benzo(a)pyrene), formaldehyde, primary aromatic amines, dialkyl phthalates and metals (Cd, Pb, Cr, As, Hg).

11. In ***Spain***, no specific legislation exists, but Guidelines for recycled cellulose fibre, published by the *Scientific Committee* of AESAN (*A*gencia *E*spañola de *S*eguridad *A*limentaria y *N*utrición) 2007 and these are based on CoE Resolution AP(2002)1 (*AESAN, 2007*). Guidelines make reference to the list of substances of CoE Resolution AP(2002)1- Technical document 1 and to Technical document 2: (see Annex I) General restrictions, purity specifications and also specifications for the final product (SML, QM) are established. These are the same as in CoE Resolution AP(2002)1.

12. ***Switzerland*** has only general requirements on the quality of paper and board materials. Pending a specific Swiss or EU legislation, it is accepted by the legislator and the control authorities that the industries apply the CoE Resolutions (Annex 1) as reference to define the compliance of paper and board articles in regard to the general requirements of the regulation 1935/2004 (art. 3).

13. ***Portugal*** has no legislation. The CoE Resolution is used as a guidance document to assist on the fulfilment of Article 3 of (EC) No 1935/2004, but is not enforced.

Printing inks

Definitions

1. In ***France***, packaging inks are all preparations, with or without colorants, applied using a printing process or coating on the outside (or not in contact with food) of materials and articles intended to come into contact with food. The inks, coatings, varnish printing referred to as "inks for packaging" are of all formulations made from dyestuffs (pigments, dyes), binders, plasticizers, solvents, driers and additives. These systems are solvent based, water-borne systems, oil or resin or curing by UV radiation or electron beam. These inks are applied using a printing process such as flexography, gravure, letterpress, offset, screen printing, digital printing or roller coating.

2. In ***Switzerland***, packaging inks are preparations of printing inks and varnishes applied to the non-food contact surface of materials and articles intended to come into contact with foodstuffs. Inks intended for direct food contact application are regulated as food additives.
Packaging inks are any preparations manufactured from colorants, binders, plasticizers, solvents, driers and other additives. They are solvent-based, water-borne, oleo-resinous or energy-curing (UV or electron beam) systems. They are applied by a printing or a varnishing process, such as flexography, gravure, letterpress, offset, screen, non-impact printing or roller coating.
In their finished state, packaging ink layers are thin films of dried or hardened printing ink or varnish on the surface of the materials and articles.

National provisions and other guidance

1. The ***Czech Republic*** has only general requirements on printing inks. Requirements on volatility of solvents are established (residual content less than 10 ppb).

2. In ***Finland*** there is no regulation on printing inks, but some research programs are ongoing on migration from printing inks: methods of analysis, toxicity testing.

3. In ***France***, Recommendations on inks from ANSES, Opinion from 1995, are used in FCM. They have list for solvents, containing 33 solvents, 12 with SML and an exclusion list. Pigments assessed for plastics can be used in printing inks.

4. In ***Norway***, no specific regulation on printing inks is in place. A risk assessment of *N*-ethyltoluenesulfonamide (NETSA), used as a plasticizer in printing inks on food packaging materials, has been conducted by the Norwegian Scientific Committee for Food Safety (VKM) in 2008. VKM then concluded that it was not possible to establish a TDI/TWI value for NETSA, based on the submitted data from the applicant. Hence, a conclusion could not be reached regarding maximum allowable migration levels of NETSA, because the mutagenic and genotoxic potential of the substance was not determined with certainty.

In 2009, NETSA was evaluated in *Switzerland* and *Germany* based on additional data from the applicant. NETSA has now been listed in list A of the Swiss regulation on printing inks with a specific migration limit of 5 mg/kg.

5. In the ***Netherlands***, no positive lists exist for printing inks. The restrictions set for colorants of plastics apply for printing inks, both for migration and purity requirements (see below, §10 Colorants).

6. The ***Slovak Republic*** has a Regulation similar to the Art.3 of the Framework Regulation 1935/2004, purity criteria for printing inks, polyaromatic amines, polychlorobiphenyl derivatives. Some general requirements for printed products and the purity criteria for printing inks are established.

7. In ***Switzerland,*** packaging inks are regulated by a modified Resolution of the Council of Europe (see Annex I). Switzerland transposed it in the national legislation (*Classified compilation of federal laws*) and issued an updated list of permitted substances (*List of permitted substances for the manufacture of packaging ink*). The list is divided in two parts, A and B. Part A includes the "evaluated" substances whose toxicological data are sufficient for a risk assessment in a food contact application. Their use can be limited by a SML or a QM restriction as for plastic materials. The part B contains substances whose toxicity profile is incomplete. These "non-evaluated" substances can be used to the condition that they are non-detectable in the food or in a migration test at a 10 µg/kg limit (analytical tolerance included). Presently there are no testing protocols recommended for the enforcement authorities and the analyses are conducted directly in foods. Work on the list of substances is continuing with collaboration of the European industry (*see European Printing Ink Association reference*) and Germany.

The Swiss regulation **on packaging inks** entered into force on April 1, 2010. The scope, definitions and requirements (positive list of substances, specific migration limits, non detectable limit fixed at 10 ppb, use of GMP guidelines) are identical to the CoE resolution. But the regulation establishes a notification procedure with direct market entry for new substances.

Part A (evaluated substances) comprise only substances evaluated for food contact application but not necessarily for their use in printing inks by national authorities (e.g. ANSES, BfR, Federal Office of Public Health (FOPH)…) or international risk assessment bodies (e.g. EFSA). The part B (non

evaluated substances) lists substances evaluated by industry itself and notified to the Swiss authorities. Packaging inks may only be manufactured from the substances set out in these lists or in the positive lists for plastics materials and are subjected to the restrictions set out therein. The next revision (2011) of the lists will contain 5106 substances (1085 in part A and 4021 in part B). Parts A and B are subdivided into five lists that depict the functional class of the substances:

I List of binders (monomers)
II List of dyes and pigments
III List of solvents
IV List of additives
V List of photoinitiators

The substances listed in Part B of lists have not been subjected to any officially recognized scientific risk assessment. The use of these substances is permitted if no transfer of these substances to foodstuffs or food simulants can be detected. The relevant proof can be provided by means of an "extreme case" calculation or by a practical experiment.

The use of any additional substances that are listed is possible but should first be reported to the Federal Office of Public Health (FOPH) through a notification procedure. The notification must be accompanied by a dossier that shall in particular include the following information:

- the toxicology of the substance;
- the nature and the concentration of the substances migrating to the foodstuffs or to the food simulants;
- the trace analysis methods used in relation to the substances;
- the technical necessity for using the substances.

For substances to be listed in part A the requirements for the dossier are identical to the EFSA note for guidance on FCM. After receiving the dossier, the FOPH stipulates the conditions for using the reported substances and notifies the control authorities on the new entry.

Colorants

Definitions

1. The Greek Code of Food and Drinks provides only for colorants for plastic food contact materials in article 26a. In this article, the term “colorant” is used for every substance that is used for the coloring of plastic food contact materials. It includes the dyes, the organic and inorganic pigments, white and black being considered as colorants. In the definition of colorants are not included the colorants that are predispersed in a plastic medium carrier.

National provisions and other guidance

1. In the ***Czech Republic*** colorants and pigments are allowed for use in food contact materials if they meet the legal requirements with respect to the maximum amount of extractable elements (heavy metals) and aromatic amines from the colorants and pigments.
Purity criteria on extractable PCBs in carbon black were established before joining the EU. Requirements on purity of colorants are the same as France and they are based on the CoE Resolution.AP (89).

2. ***France*** has recommendations on colorants. The work started in 1959 and a Draft Decree was published recently. It contains two lists, (A) authorised organic and inorganic pigments (evaluated following the EFSA guidelines for plastic, varnish and coatings, not printing inks) and (B) pigments temporarily accepted (for 4 years, pending submission of requested data). It contains also purity criteria, almost identical to those of the Council of Europe Resolution on colorants, and possible restrictions. There are specifications for heavy metals, aromatic amines, PCB and carbon black.

3. Regarding the colorants for plastic food contact materials in article 26a of the ***Greek*** Code for Food and Drinks, various requirements are set (e.g. the coloured plastic materials must not show visible migration of colorants in the simulants used, the coloured plastic materials should have a homogeneous colour and a steady shade under conditions of use, the colorants should endure processing temperature 150-300oC, etc).
The purity criteria for colorants were adopted from other Member States legislations (Italy and Germany).

4. ***Italy*** has general requirements on colorants for plastic, rubber and paper (purity in metals, aromatic amines).

5. In *the* ***Netherlands***, colorants and pigments are allowed for use in food contact materials if they meet the requirements with respect to the maximum amount of extractable elements and aromatic amines from the colorants and pigments. Furthermore, soot and other carbon products should meet purity requirements.

6. ***Slovak Republic*** general recommendations and requirements for printing inks and colorants.

7. ***Spain*** has purity criteria for colorants used in polymeric materials for food contact, no positive lists.

8. ***Germany*** has general requirements and purity criteria for colorants which are published in a recommendation with the title: “Colorants for Plastics and other Polymers Used in Commodities”.

Rubber

Definitions

1. ***French definition***: rubber is a natural or synthetic polymer with a high elastic stretch rate made up of carbonaceous macromolecules generally obtained by cure the rubber latex and dry natural origin and the rubber latex and dry synthetic origin, consisting of homo or copolymers of organic. Thermoplastic elastomers, which do not require cure, are included in rubbers.

2. ***German definition***: natural and synthetic rubber, thermoplastic elastomers.

3. The ***Greek*** Code of Food and Drinks in article 28a refers to elastomer or rubber teat and soothers on which maximum limits on released N-nitrosamines and N-nitrosatable substances are set.

No specific definition is given for elastomer or rubber in the Greek Code of Food and Drinks or any other national provision.

4. In *the **Netherlands***, rubber products are defined as elastomer-based products to which one or more additives have been added. The rubber products are obtained from mixtures of elastomers and additives as a result of crosslinking on a molecular scale, usually at elevated temperatures and with or without the application of pressure.
Elastomers are defined as the macromolecular natural and synthetic materials which, after having been deformed under the action of a deforming force at temperatures from 18 °C to 29 °C, rapidly and vigorously return to their original shape after removal of the force.
Specifications of the elastomers:

- The molecules of elastomers are built up of at least 500 structural moieties (monomers). They can be chlorinated and/or brominated.
- Elastomers can be vulcanized to a state where they are practically insoluble in boiling benzene, in methyl ethyl ketone or in an azeotropic mixture of ethanol and toluene, although swelling of the elastomers may take place under the influence of these liquids.
- Elastomers in the vulcanized state and containing no other substances than those necessary for vulcanization, do not break when stretched to three times the initial dimension at a temperature between 18 °C and 29 °C and contract within one minute to less than one and a half times the initial dimension after having been stretched to twice the initial length and held in that state for one minute.

National provisions and other guidance

1. In ***Belgium,*** the lists from CoE are used.

2. The ***Czech Republic*** has specific measures for rubber and elastomers. Industry has sent dossiers to a national risk assessment body, the NIPH and it has performed the risk assessment. Now some substances are under re-evaluation. National requirements were established as maximum content in the material, substance purity specifications, SML for individual chemicals or groups of chemicals into specified food simulants. For some chemicals or chemical groups restrictions are formulated as maximum content in the material.

3. ***France*** has Positive lists from 1994 completed by the positive list of monomers of plastic materials (Arrêté 9/8/05), with limits for teats and soothers, containing more than 18 monomers and starting substances and 188 additives, sometimes also in the positive lists for plastic, but with different limits. A large part of the other substances being in the positive lists have been evaluated on the basis of a reduced dossier not in agreement with the SCF guidelines requests.

4. ***Germany*** has a recommendation for rubber with different lists (categories). (For the legal status of the recommendations and how substances are included see the respective section for paper and board). This recommendation also include overall migration limits including test conditions. However the lists are very old and a revision is planned.

5. In ***Italy,*** rubber is regulated by the D.M. of 21.3.1973 and further amendments, containing positive lists distinct for elastomers and additives, migration limits and standardized migration tests.

Food simulants and reference contact conditions are indicated to check compliance with both overall and specific migration limits. The available legal analytical methods are in Annex IV of the same D.M. No recycled rubber is allowed.

6. Rubbers are regulated in *the* ***Netherlands*** by means of three positive lists: one for low-exposure products (cat. III), one for high-exposure products (cat. II) and one for products for babies and toddlers (cat. I). The classification of low- or high exposure product is estimated using a formula that takes into account the relative contact area, the contact time, the temperature of food in contact with the product, and the number of times of reuse of the product. Migration of substances from low-exposure products does not need to be measured as the migration is considered to be negligible. For high-exposure products, SMLs have been derived for a number of substances; these SMLs, divided by 10, also apply to the products for babies and toddlers. For teats and pacifiers, the migration limit is applicable per teat/pacifier instead of per kg food.

7. ***Slovak Republic*** has a list of authorized substances consists of substances which were evaluated by other member state (for preparation was used previous legislation of Czechoslovakia before splitting and recommendations of other member state e.g. Germany), some restrictions, requirements on final products and test conditions. The final products are divided into to 5 categories according its usage and for each category a specific test conditions and requirements (limits) exists.

8. ***Spain*** has an old legislation (1982, amended in1985) for polymeric materials, including rubber, with a positive list (no CAS numbers) and migration limits, no test conditions are defined. Evaluations were adopted from other Member States or from FDA.

Common principles: several Member States use the Dutch R factors.

Silicones

Definitions

1. ***French definition***: The silicone elastomers used to produce materials and articles intended to be in contact with foods shall be made exclusively by organopolysiloxanes. These include, on the silicon atoms, methyl groups can be partially replaced by the following groups: C2-C32 alkenyl, C2-C32 alkyl, hydroxyl, hydrogen, disubstituted alkylamines and / or alkylhydroxyl, acetoxy and/or alkoxy and their condensation products with polyethylene glycol and / or propylene glycol: the specific migration of ethylene oxide in food or their simulants should not exceed 0.15 milligrams per kilogram, N-fluorinated alkyl and phenyl: the silicone elastomer does not include, among its components, more than 2 per 100 in weight with less than 5 methyl-phenyl-cyclosiloxanes siloxy units. In addition, the silicone elastomer, no cyclic polysiloxane should be on the same silicon atom, a phenyl group and a hydrogen atom or a methyl group.

2. ***German definition:*** organopolysiloxanes

National provisions and other guidance

1. In the ***Czech Republic*** the national requirements, including a positive list of substances are a mix between French regulation and the German BfR recommendation. They have positive list for monomers and additives and requirements on final product. The positive list is under re-evaluation by the national body for risk assessment (the NIPH), because it needs to be up-dated.

2. In ***France,*** a regulation, with positive list of additives with more than 39 substances is in place. There is no list of monomers, just an explanation on the starting substances used to produce silicones. Overall migration, specific migration of monomers and/or residual quantity of monomers, specific migration of additives or quantity of additives in the material or object, volatile organic materials, organotins and peroxides are set. EN Standards for overall and specific migration tests (EN 1186 and EN 13130 standards) are used, the test methods for volatiles are set in the French Order of 25/11/92 and for peroxides the French Pharmacopea.

3. In ***Germany***, a recommendation with general restrictions on volatile substances is in place. (For the legal status of the recommendations and how substances are included see the respective section for paper and board.)

4. In ***Italy*** according to the provisions of the DM 21.3.73 and amendments, positive list for additives are present. The overall and specific migration limits indicated for plastics are applied.
5. In ***Slovak Republic***, no specific measures for silicones are present, the same rules as for rubber are used.

6. In ***Spain*** regulation for polymeric materials (including silicones) has a positive list and restrictions set as overall and specific migration limits.

7. In ***Switzerland***, the Council of Europe Resolution was transposed into national legislation. The list of substances was not up-dated. The verification of compliance with the migration limits (overall and specific migration limits) are conducted according to the tests conditions for plastic materials. The testing procedure of volatile organic materials and maximal release quantity (0.5 % w/w) was transposed from the French regulation.

Coatings

Definitions

1. In ***the Netherlands***, a surface coating is identified as a continuous layer applied to an already existing substrate, regenerated cellulose film not included. The continuous layer is applied by means of dispersions of macromolecular substances in water or organic liquids, dispersions of paraffins and waxes in water, by means of a solution in water or in organic solvents, from solvent-free materials, from fluoropolymers or as a metallic layer.

2. ***French definition***: Coatings mean the finished material prepared mainly from organic materials applied to form a layer/film on a substrate in such a way as to create a protective layer and/or to impart certain technical performance.

3. The ***Greek*** Code of Food and Drinks in article 28 refers to surface coatings as food contact materials. According to it, coatings are defined as organic materials that are applied with the form of a

continuous film over a substrate in such a way that they form a protective film between the substrate and the food.

National provisions and other guidance

1. The ***Czech Republic*** has specific measures for coatings and lacquers. *A* positive list of permissible substances for coatings and surface treatment as lacquers of products intended for contact with foodstuffs. National requirements were established as maximum amount used chemicals, SMLs for individual chemicals or groups of chemicals into food simulants. The overall and specific migration limits and the rules indicated for plastics are also applied.

2. In ***France***, Recommendations have been published and it is proposed to use the evaluated substances listed in the Resolution of the Council of Europe on Coatings (Res 2004 (1)) which includes also limitations for some major substances.

3. ***Germany*** has recommendations for coatings for high temperature uses (frying, cooking and baking utensils). (For the legal status of the recommendations and how substances are included see the respective section for paper and board.) Another recommendation focuses on plastic dispersions. These recommendations have not been incorporated into the ESCO list of substances.

4. Coatings as food contact materials are mentioned in article 28 of the ***Greek*** Code for Food and Drink. The coatings should not transfer to the food substances that exceed 10mg/dm^2 of the final food contact material that has been coated.

5. In ***Italy*** according to the provisions of the DM 21.3.73 and amendments, coatings are covered by the same rules applied for plastic FCMs. The overall and specific migration limits and the rules indicated for plastics are applied, too.

6. In ***the Netherlands*** coatings are regulated in the Netherlands by means of positive lists. Nine separate lists exist for 9 different kind of coatings, namely: dispersions of macromolecular substances in water; dispersions of paraffins and waxes in water; dispersions of macromolecular substances in organic liquids; solutions in water; solutions in organic solvents; solvent-free surface coatings on the basis of waxes and wax-like products; other solvent-free materials; metalic layers; and the last one: polytetrafluoroethene, for use as coating for cooking-, baking- and roasting utensils for use at temperatures of maximal 140, respectively 230 °C.

7. The ***Slovak Republic*** has positive list from 2003, without CAS number, and with requirements on final product. For preparation was used previous legislation of Czechoslovakia before splitting and also recommendations of other Member State (Germany).

8. In ***Spain*** coatings are under the regulation for polymeric materials which includes a positive list, overall and specific migration limits. Substances listed were adopted from the lists of other Member States or from the CoE lists.

Wood and cork

Definition

1. In the ***Netherlands,*** wood and cork food contact materials include packaging materials and utensils made of, or based on, wood or cork.

National provisions and other guidance

1. Wood is regulated in ***France*** with a positive list of species completed by a recommendation of 2006 with others species.

2. Wood and cork are regulated in *the* ***Netherlands*** by means of a positive list.

3. For products from wood, there are some general safe criteria in ***Slovakia***. Cork is regulated by means of a positive list and some criteria for final products are established.[5] For preparation was used previous legislation of Czechoslovakia before splitting.

[5] According to the Council of Europe Resolution, "cork stoppers or the cork part of stoppers should contain at least 51% of manufactured cork w/w".

CHAPTER IV: ESCO WORKING GROUP MEETING WITH THE STAKEHOLDERS

To present and discuss with stakeholders the work of the WG, and in order to exchange views on risk assessment issues related to the non-plastic food contact materials, EFSA invited stakeholders' representatives as hearing experts to a WG meeting in Milan on March 9-10, 2011.

The stakeholders included representatives of different areas of non-plastic FCMs (coatings, printing inks, paper and board, rubber, silicones, adhesives, wood, cork), of food industries and of consumer organizations.

The announcement had been disseminated through the EFSA web site in December 2010 and through the Stakeholder Consultative Platform of EFSA. The participants were selected in January 2011 on the basis of their experience in the field of risk assessment of non-plastic food contact materials. They represented a broad coverage of the risk assessment in different areas of the non-plastic food contact materials. In total, there were 60 participants (see Annex IV) coming from industry, packaging producers and users, mainly delegated by professional organisations (30), Member States representatives (14), European Commission (1), Council of Europe (1). 7 scientific officers of EFSA (from CEF and EMRISK Units), members of the CEF Panel (7) and of the Scientific Committee of EFSA (1), including the Chairs of CEF and SC.

The introductory session of the meeting was chaired by A. Feigenbaum. The reporting back from break-out groups session was co-chaired by V. Silano and P. Oldring.

After an introduction to the workshop through presentation of the ESCO WG activity, the stakeholders were invited to express their views and discuss on the progress of the work, mainly on the inventories of substances evaluated in Member States and on principles for prioritization set by the WG. Stakeholders also had the opportunity to present their own approaches for risk assessment in perspective of future actions to be taken in this area.

The objectives and expectations from the meeting were presented by D. Spyropoulos (EFSA), A. Schaefer (DG SANCO), F. Bolle (Belgium) and M. Bonuomo (giving the views of Industry).

From this session, it became clear that all the parties involved have common expectations from the objectives of the meeting: (i) to discuss a systematic approach to deal with prioritization of safety evaluations by industry for the substances used in non-plastic FCM; (ii) a scheme for providing urgent scientific advice in emergency situations and analytical and toxicological generally accepted tools for this purpose, which should be made available to all the stakeholders.

The risk assessment principles were presented, material by material, alternating presentations of representatives of industry and of ESCO WG members.

A. Feigenbaum (CEF Unit, chair of the ESCO WG), A. Lupu (EFSA), J. Sosnovcova (Czech Republic) and D. Theodosiou (Greece) presented the work of the ESCO WG: the general approach, the methodology of the work, including set-up, composition and terms of reference of the WG.

The compilation of evaluations from Member States and the other EU countries participating in the WG, including format and content of the lists of substances was described by A. Lupu. The final inventory list contains about 2800 entries, subdivided into lists A and B, depending whether they were evaluated after 1991, according to EFSA/SCF guidelines or before 1991. ESCO list A contains 320 entries. Substances in list B are often under re-evaluation. Many substances which are neither in list A or B are currently under evaluation, such as rubber in Italy and printing inks in Switzerland (the Swiss list is also under evaluation in Germany).

Many substances in use for the production of non-plastic FCM are neither in list A nor in list B. Moreover, substances in list B have not been evaluated according to recent SCF guidelines. Therefore, in a first step, common tools for prioritization of evaluations need to be used. The tools

proposed by the WG for the prioritisation of evaluations were presented by A. Feigenbaum, particularly the use of a TTC decision tree.

The need of a network of experts from public authorities and from industry, to be used in emergency or critical situations, was stressed.

The ***general criteria used by Member States for the evaluation of substances*** were presented by M.R. Milana. The risk assessment as performed by the Member States for regulation purposes (to set up positive lists) was distinguished from enforcement actions (control activity). For risk assessment, technical dossiers from industries are evaluated by a public body, and the authorization is published in the form of a law, decree or recommendation. The principles in the SCF/EFSA Guidelines (a tiered approach with more toxicological information required for higher migration levels) are used but with different adaptations for materials and restrictions. The TTC concept is used only in some countries. In control activities, general principles (Art.3 Regulation 1935/2004/CE) are used and a case by case risk assessment is often carried out, using expert judgment. The tools used are national or international Guidelines or Recommendations, (e.g. CoE Resolutions).

The s***pecificities of RA of paper and board*** in Germany and Italy were presented by *T. Heinke* and *M.R. Milana*

Risk assessment in case of paper and board in Germany (general considerations): Risk assessment in general is based on toxicological risk assessment (RA) and exposure estimation. Toxicological RA is nearly independent from the special kind of food contact material (matrix). Exposure estimation however has to include the special properties of the respective material. In case of paper and board it can be done via different approaches:

1. a simple calculation based on the assumption of 100 % transfer from 6 dm^2 paper in contact with 1 kg food, based on the use level of the chemical;
2. testing the paper itself for the concentration of the chemical followed by calculation based on the assumption of 100 % transfer from 6 dm^2 paper in contact with 1 kg food;
3. testing an extract of a treated paper;
4. doing migration tests using food simulants if possible (however, non-treated paper will normally disintegrate if liquid food simulants are used).

In Italy, risk assessment for paper and board is a stepwise process, that starts when a dossier is received (checking the quality of the submitted toxicological and non toxicological data), goes along with the evaluation (the higher the potential exposure, more toxicological data needed) and ends with acceptance (safe use) or rejection. Conditions of acceptance are tailor made for each substance (restrictions of permitted amount, limitation of use etc) and no more than what is required is given in the positive lists. The default scenario (1 kg food/day, 60 kg bw, 6dm2/kg food) is generally used.

Paper and board in industry – *E. Cavallini*, Confederation of European Paper Industries (CEPI)

The paper and board industry complies with the Framework Regulation (EC) No 1935/2004 and the GMP Regulation (EC) No 2023/2006, as presented in two documents published in 2010 by CEPI: the CEPI-CITPA Industry Guideline (May 2010) and the CEPI GMP (September 2010). A special attention is paid to raw materials as one of the vehicles of potential contamination, especially due to the fact that many existing national legislations on paper and board, as well as the Council of Europe Resolution on paper and board AP (2002) 1 allow the use of recycled fibers in food contact paper and board grades. Directions are given to define specifications for raw materials and to ensure accordance with current regulatory requirements, i.e. the established food contact positive lists. The commitment

of the industry in this field is continuing through a re-assessment of the biological tests battery described in the BioSafePaper project.

Case of rubber and coating; issues of repeated exposure and NIAS - NL - *B. Van de Ven*
The approach used in the Netherlands for the dietary exposure assessment to substances used for manufacture of rubber articles was presented, taking into account different scenarios corresponding to low (re-usable objects, objects with small contact area or short contact time) or high (teats and pacifiers) exposure. Examples on risk assessment of NIAS in coatings were also presented.

Rubber in industry – *L. Zullo*, European Type and Rubber Manufacturers Association (ETRMA)
The EU rubber industry complies with Regulation (EU) No 1935/2004 Art. 3 by means of two Council of Europe Resolutions: AP-2004-4 (rubber products intended to come into contact with foodstuffs) and AP-2004-5 (silicones used for food contact applications). Migration tests are conducted according to the basic rules for testing migration constituents of plastic materials. In the presentation it was underlined that the EU rubber food contact industry operates in a non harmonized legislative framework, and expects harmonized requirements and test strategies applicable to rubber, thermoplastic elastomers and silicone articles. Specific characteristics of materials and of their uses should also be taken into account. Industry supports mutual recognition of testing procedures across EU. At the same time, industry expects that the criteria for including new substances in a (possibly harmonized) positive list should be based on risk assessment methodologies defined at European level.

Coatings in industry – *P. Oldring*, European Confederation of Paint, Printing Ink and Artists' Colours Manufacturers Associations
The approach of the can coating supply chain including food industry and raw material suppliers in order to demonstrate compliance with Art.3 of Regulation (EC) No 1935/2004 was given with emphasis on how the potential risks from migrants could be assessed. Proposals were made to resolve the issue of substances not fully evaluated by SCF or EFSA. The calculation of realistic exposure and the use of TTC approaches were strongly endorsed as being both scientifically-sound and pragmatic tools for RA of listed substances used in manufacture and also for the NIAS.

Adhesives in industry – *H. Onusseit*, Association of the European Adhesive and Sealant Industry
The approach of the adhesives industry supply chain including food industry and raw material suppliers in order to demonstrate compliance with Art.3 of Regulation (EC) No 1935/2004 and how the risks from migrants could be assessed was explained. A more detailed explanation on the approach of the adhesives industry how to perform risk assessment and how to comply with Food Contact Legislation can be found in a paper published by FEICA (Food Contact Status paper, explaining how to comply with Art.3 of 1935/2004) and a Guidance on how to comply with Regulation (EC) No 2023/2006 on Good Manufacturing Practice for articles intended to come into contact with food (http://www.feica.eu/ehs-sustainability/food-contact).

Printing inks evaluations in CH and DE - V. Dudler
The development of the Swiss regulation on printing inks was described, with emphasis on the evaluation process of the listed substances. The data to be supplied for evaluation of a notified substance were explained and the common strategy of Germany and Switzerland in the risk assessment of substances was discussed.

Printing inks in industry – *A. Boon*, European Printing Ink Association
Approaches to be used for risk assessment of migration from printed packaging were presented. The alternative of evaluating what is migrating into food instead of what is added in the ink formulation was discussed. The influence of several factors (including packaging and print design, substrate selection, printing conditions and ink formulation) on the level of migration from printed packaging was demonstrated. The way to deal with the many substances not yet evaluated at official level proposed a prioritisation using exposure (e.g. FACET) and making better use of what is already known, including REACH data, read across and grouping, modelling and SARs, genotoxicity screening, structural alerts, as well as the TTC approach.

Scientific aspects of risk assessment of non-plastic parts of FCM:
The second part of the meeting was concentrated on scientific aspects of risk assessment of non-plastic FCMs. This part was organised in break-out sessions: three parallel groups were set up, two focused on exposure tools and one on toxicological tools, followed by report back from break-out groups to plenary group. The chairs of the groups were R. Eisert, P. Oldring, V. Silano and rapporteurs were L. Castle and M. Pocas, R. Franz and S. Leuenberger, J.C. Lhuguenot and L. Spack, respectively).

The main topics discussed by the all three groups were:

- **Tools and strategy for prioritization of evaluations**: Many substances used are not evaluated. How to prioritize these evaluations at level of industry?

- **Tools and strategy for emergency risk assessment**: If a non evaluated substance is detected in food, how do you manage to give advice on the safety of that substance, in two days time?

The workshop participants agreed that the threshold approach appears to be a reliable scientific tool which could provide a helpful decision tree for prioritization of substances to be evaluated.

It was also underlined that a **network of experts** from industry is needed, to be mobilized in case of crisis. Substances for which an alert is issued because they appear as "non-evaluated" may have been evaluated by industry (and according to Art.3 of Regulation (EC) No 1935/2004 must have been evaluated). A system should be in place to make information on risk assessments held by industry available to EFSA within a short notice upon request. Confidentiality needs have to be taken into account. The network must be able to access this information.

Training of the network could be also considered. A permanent network, with work program has been proposed.

Dietary exposure assessment was extensively discussed**.** The participants to the meeting underlined that the FACET European project will provide useful tools, which could be used by both industry and national risk assessment bodies. The project covers all types of food packaging except glass (although the caps and closures for glass are included) and collects data on packaging composition and packaging usage from across Europe. There are descriptions of more than 200 material types. It also incorporates toxicological tools to assess toxicological potential of the substance based on its structure. The project includes food consumption data, using national dietary surveys for 18 food categories, further divided to 56 and then to 172 lower tiers of more refined food group descriptions. The data on packaging composition, packaging usage and consumption of packaged foods is combined with migration modelling to derive migration concentrations and then probabilistic estimates of exposure. Rubber is not

covered by FACET, but the procedure would be applicable to this material if the data were collected. FACET is expected to be finalised by the end of 2012.
Other tools:

- Migrosure (see Chapter I, 3.4 of the report) and Migresives (see Chapter I, 3.2 of the report) projects;
- Migration and exposure calculations, modelling and testing;
- Surveys for substances of similar technical functions;
- Documentation, record keeping at industry.

Toxicological tools

There are computer based programs for identification of structural alerts for genotoxicity, such as: DEREK (‘‘deductive estimation of risk from existing knowledge”; http://www.chem.leeds.ac.uk/luk/derek/) MCase. (Multi Computer Automated Structure Evaluation, http://www.multicase.com/products/prod01.htm). ToxTree-Carc which will also identify the structural alerts needed for application of the TTC decision tree (Benigni and Bossa, 2008). This program is freely available on the website of the European Commission’s Joint Research Centre: http://ecb.jrc.ec.europa.eu/qsar/qsar-tools/index.php?c=TOXTREE .
The OECD QSAR Toolbox:
http://www.oecd.org/document/54/0,3746,en_2649_34379_42923638_1_1_1_1,00.html

Conclusions of ESCO WG the meeting with stakeholders

The workshop participants welcomed the outcome of the ESCO WG work, as given in summary form in presentations made at the workshop. In fact the participants did not get to see the draft ESCO report. Rather they saw summary presentations only.

It was obvious from the work of the ESCO WG that there is a great number of substances used in non-plastic FCM which either have never been evaluated by any national authority or the evaluation was performed before the adoption of the SCF guidelines and the data used cannot always be traced and retrieved. Hence, industry and regulatory agencies will likely need to address a great number of chemicals used in non-plastic FCM. This is particularly challenging given the limited resources available for this task within both government and industry.

Therefore it was agreed that a pragmatic and practical risk assessment approach is needed, as a priority setting tool and as a means to enable fast preliminary advice about the possibility of health risks for substances with no experimental toxicological data.

There was a consensus that the TTC approach is a reliable scientific tool which could serve this purpose. This concept refers to the establishment of generic human exposure threshold values for chemicals below which there would be negligible risk to human health.

These generic thresholds for human exposure are based on an exploration of the relationship between chemical structures and toxicity and they are shown in Table 1.

The application of this decision tree is considered an appropriate tool for setting priorities for safety evaluations of substances used to make non-plastic FCM. Exposure and TTC concepts are also very appropriate for providing preliminary advice in emergency situations and *de novo* for the evaluation of the NIAS.

Of course, classification of substances in structurally-related groups and read-across in cases where there are toxicity data on one or more members of the group is another valid method which may be used. (Q)SAR approaches can also be useful.

The dietary exposure assessment can be done by using standard default assumptions or use migration data or migration modelling, in simple deterministic or more sophisticated probabilistic calculations. The approaches and data provided by FACET European project should be very useful and could be the basis of a harmonised approach for estimating exposure across Europe.

It was decided that an industry network is needed in case of urgent advice to make information available to EFSA within a short notice upon request.

CHAPTER V: OVERALL CONCLUSIONS OF THE ESCO WORKING GROUP - GAPS AND PROPOSALS FOR FUTURE ACTIONS

V.1. Overall conclusions

An EFSA Scientific Cooperation (ESCO) Working Group was set up in order to collect the relevant information and make proposals in order to anticipate situations linked to presence in food of substances released by non plastic FCM and for which no harmonised risk assessment is available. These objectives were achieved, as follows.

ESCO lists: The ESCO inventory list has been established. It contains 3000 substances used to manufacture non plastic FCM, collected from Member States participating in the ESCO WG. 320 of these substances have been evaluated after 1991, following the publication of the SCF guidelines for plastics. These substances are gathered in ESCO list A. Other substances listed (ESCO list B) were assessed according to older criteria. The inventory list, comprising parts A and B, will be published shortly.

Criteria for prioritization: The ESCO WG has identified the TTC approach as a useful tool for prioritization of the evaluations of substances in ESCO list B. From the chemical structure of the substances, the corresponding TTC threshold can be derived. Various other tools can be used for inferring the toxicological potential of a substance from its structure, such as DEREK, Mcase ….

Substances for which the dietary exposure is likely to exceed the corresponding TTC value should be considered as a priority for risk assessment.

Evaluation of possible dietary exposure of consumers can be based on uses and concentrations of the substances in the non-plastic FCM, associated to migration modelling. Usual migration models are based on molecular weight of the substance, which is also derived from the chemical structure. More or less realistic assumptions and scenarios can be designed, depending on the material and the applications.

Emergency risk assessment: in emergency situations, a preliminary advice may be provided based on the TTC approach. However for a more robust scientific opinion, conclusions should be drawn on the basis of a read-across with structurally similar substances or of data on the substance itself.

Similar tools as for prioritisation can be used in crises, combining exposure and toxicity approaches (TTC, read-across, (Q)SAR and OECD toolbox). The TTC approach (*Munro et al., 1996*) is not designed to replace full risk assessment, as situations where it is either more or less severe than the full risk assessment have been reported.

Tools for estimating dietary exposure are: default assumptions, migration modelling, surveys on substances with similar function, FACET tools etc.

A network of experts to be mobilised in case of crises, was set up. It is composed from experts from national authorities and experts from industry who will provide EFSA within a short notice with the relevant information available in industry.

V.2. Gaps and proposals for future actions

In the meeting with the stakeholders, it was emphasized that a large number of substances used in non-plastic FCM have not been evaluated by a Member State. These substances are of course not listed at all by the ESCO WG.

On the other hand, it was also said that some substances evaluated by MS are not in use. If industry is going for a prioritization, the list B should be updated and it may be useful to consider substances never evaluated by MS.

The Member States have not evaluated all types of substances (e.g. there is no list of processing aids) and the ESCO inventory list may be completed in the future.

A further training of the network of experts, to be used in crisis situation would be a very useful follow up of the ESCO WG. This was a strong proposal of stakeholders.

The non-intentionally added substances represent a major problem while scientific knowledge on this area is poor. Some information can be found in literature or reports (*AFSSA, 2009*). More scientific research work in this area is needed to identify the fate of the substances used to manufacture non plastic FCM. Exposure and TTC concepts are very appropriate for the *de novo* evaluation of the NIAS for which the alternative, obtaining experimental toxicological data, may be justified in only a limited number of cases, depending on the exposure.

The general principles for risk assessment proposed by the ESCO WG and described in Chapter II can be used for prioritization of list of substances for safety evaluation. Harmonised guidelines for prioritization in risk assessment may be useful, depending on evolution of the regulatory context, e.g. specific rules are set for the non-plastic FCM. As a comment to a draft version of the current report, the European Commission informed EFSA that they will establish by the end of 2011 “a roadmap for the not yet harmonised areas of food contact materials taking into account the conclusions of the ESCO WG on the non-plastic food contact materials”.

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APPENDICES

ANNEX I COMPILATION OF LISTS OF SUBSTANCES FOR NON-PLASTIC FOOD CONTACT MATERIALS, EVALUATED IN MEMBER STATES, SWITZERLAND AND NORWAY, AS COLLECTED BY THE ESCO WORKING GROUP (EXCEL FILE ATTACHED)

ANNEX II: LIST OF RESOLUTIONS OF THE COUNCIL OF EUROPE, PARTIAL AGREEMENT OF PUBLIC HEALTH; MATERIALS IN CONTACT WITH FOOD

Resolution AP (96) 2 on maximum and guideline levels and on source-directed measures aimed at reducing the contamination of food by lead, cadmium and mercury (G***lass)*** and Guidelines for Lead Leaching from Glass Tableware into Foodstuffs;

Resolution AP(2002) 1 on ***paper and board*** materials and articles intended to come into contact with foodstuffs;

Framework **Resolution ResAP (2004) 1** on ***coatings*** intended to come into contact with foodstuffs;

Resolution AP (2004) 2 on ***cork stoppers and other cork materials and articles*** intended to come into contact with foodstuffs;

Resolution AP (2004) 3 on ***ion exchange and adsorbent resins*** used in the processing of foodstuffs (superseding Resolution AP (97) 1)

Resolution AP (2004) 4 on ***rubber*** products intended to come into contact with foodstuffs;

Resolution AP (2004) 5 on ***silicones*** used for food contact application**s .**

Resolution AP (2005) 2 for ***packaging inks*** applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs;

Details on the content of these documents could be find at:
http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/COE%27s%20policy%20statements%20food%20contact.asp#TopOfPage

Further recommendations are given in the Guidelines on *metals and alloys used as food contact materials (currently under revision, draft Resolution and Technical Guide subject to public consultation in 2011).*

ANNEX III: CLASSIFICATION OF PHOTOINITIATORS

This annex shows the Cramer classification of some photoinitiators used for printing inks, taken from the Swiss list of permitted substances for the manufacture packaging inks, subject to requirements. This classification has been carried out as an example of the prioritization approach proposed in Chapter II. See *Pinalli et al., 2011* for details of evaluation approach.

NB: The not evaluated substances listed in the Swiss Regulation have not been subjected to any officially recognised scientific risk assessment (such as that of the scientific committee of the EFSA). The use of these substances is permitted if no transfer of these substances to foodstuffs or food simulants can be detected.

CAS N° Name	Chemical Structure (SMILES codes)	Cramer Class
0000084-51-5 2-Ethylanthraquinone	O=C(C1=C2C=CC=C1)C3=CC=C(CC)C=C3C2=O	**III**
0073003-78-8 1H-Azepine-1-propanoic acid, hexahydro-, 2,2-bis[[(1-oxo-2-propenyl)oxy]methyl]butyl ester	O=C(OCC(COC(C=C)=O)(COC(C=C)=O)CC)CCN1CCCCCC1	**III**
0000090-93-7 4,4'-bis(diethylamino)benzophenone	O=C(C1=CC=C(N(CC)CC)C=C1)C2=CC=C(N(CC)CC)C=C2	**III**
0125051-32-3 Bis (eta(5)-cyclopentadienyl)-bis(2,6-difluoro-3-[pyrrol-1-yl]-phenyl)titanium	FC1=C([Ti](C2=CC=CC2)(C3=CC=CC3)C4=C(F)C=CC(N5C=CC=C5)=C4F)C(F)=C(N6C=CC=C6)C=C1	**III**
0007189-82-4 2,2-Bis-(2-chlorophenyl)-4,4',5,5'-tetraphenyl -1,2-biimidazolyl	ClC1=CC=CC=C1C2(N3C(C4=CC=CC=C4)=C(C5=CC=CC=C5)N=C3C6=CC=CC=C6Cl)N=C(C7=CC=CC=C7)C(C8=CC=CC=C8)=N2	**III**
0074227-35-3 Bis(4-diphenylsulphonium)phenylsulphide-bis (hexafluorophosphate)	F[P-](F)(F)(F)(F)F.F[P-](F)(F)(F)(F)F.C1([S+](C2=CC=CC=C2)C3=CC=CC=C3)=CC=C(SC4=CC=C([S+](C5=CC=CC=C5)C6=CC=CC=C6)C=C4)C=C1	**III**
0071786-70-4 Bis(4-dodecylphenyl)iodonium hexafluoroantimonate	CCCCCCCCCCCCC1=CC=C([I+]C2=CC=C(CCCCCCCCCCCC)C=C2)C=C1.F[Sb-](F)(F)(F)(F)F	**III**
0060565-88-0 Bis-(4-Methylphenyl)iodonium hexafluorophosphate	CC1=CC=C([I+]C2=CC=C(C)C=C2)C=C1.F[P-](F)(F)(F)(F)F	**III**
0061358-25-6 Bis(4-tert-butylphenyl)iodonium Hexafluorophosphate	CC(C1=CC=C([I+]C2=CC=C(C(C)(C)C)C=C2)C=C1)(C)C.F[P-](F)(F)(F)(F)F	**III**
0194655-98-6 4,4'-Bis(methylethylamino)benzophenone	O=C(C1=CC=C(N(C)CC)C=C1)C2=CC=C(N(C)CC)C=C2	**III**
0067362-76-9 Butoxyethyl-4-(dimethylamino) benzoate	O=C(OCCOCCCC)C1=CC=C(N(C)C)C=C1	**III**
0010373-78-1 d,l-Camphorquinone	CC12C(C(C(C(C)2C)CC1)=O)=O	**II**
0142770-42-1 1-Chloro-4-propoxythioxanthone	O=C1C2=C(SC3=C1C=CC=C3)C(OCCC)=CC=C2Cl	**III**
0076275-14-4 9,10-Dibutoxyanthracene	CCCCOC1=C2C=CC=CC2=C(OCCCC)C3=CC=CC=C13	**III**
0006175-45-7 2,2-Diethoxyacetophenone	O=C(C1=CC=CC=C1)C(OCC)OCC	**I**
0082799-44-8 2,4-Diethyl-9H-thioxanthen-9-one	O=C1C2=C(SC3=C1C=CC=C3)C(CC)=CC(CC)=C2	**III**
0024650-42-8 2,2-Dimethoxy-2-phenylacetophenone	O=C(C1=CC=CC=C1)C(OC)(OC)C2=CC=CC=C2	**III**
0068400-54-4 1-[4-(1,1-Dimethylethyl)phenyl]-2-hydroxy-2-methylpropan-1-one	CC(C)(O)C(C1=CC=C(C(C)(C)C)C=C1)=O	**II**

CAS N° Name	Chemical Structure (SMILES codes)	Cramer Class
0075980-60-8 Diphenyl-(2,4,6-trimethylbenzoyl)phosphine oxide	O=C(P(C1=CC=CC=C1)(C2=CC=CC=C2)=O)C3=C(C)C=C(C)C=C3C	III
0068156-13-8 Diphenyl(4-phenylthiophenyl)sulfonium hexafluorophosphate	F[P-](F)(F)(F)(F)F.[S+](C1=CC=CC=C1)(C2=CC=CC=C2)C3=CC=CC=C3SC4=CC=CC=C4	III
0075482-18-7 Diphenyl[(phenylthio)phenyl]sulfonium hexafluorophosphate	F[P-](F)(F)(F)(F)F.[S+](C1=CC=CC=C1)(C2=CC=CC=C2)C3=CC=C(SC4=CC=CC=C4)C=C3	III
0012345-97-0 Erbium oxide sulfide (Er2O2S)	Cramer classification not applicable	
0001603-79-8 Ethyl benzoylformate	O=C(C(C1=CC=CC=C1)=O)OCC	I
700368-63-4 2-Hydroxy-[4'-(2-Hydroxypropoxy) phenyl]-2-methylpropanone	CC(C)(O)C(C1=CC=C(OCC(O)C)C=C1)=O	III
0007473-98-5 2-Hydroxy-2-methylpropiophenone	CC(C)(O)C(C1=CC=CC=C1)=O	II
0000947-19-3 1-Hydroxycyclohexylphenylketone	O=C(C1(O)CCCCC1)C2=CC=CC=C2	III
0106797-53-9 1-[4-(2-Hydroxyethoxy)phenyl]-2-hydroxy-2-methyl-1-propanone	CC(C)(O)C(C1=CC=C(OCCO)C=C1)=O	II
0344562-80-7 Iodonium, (4-methylphenyl)[4-(2-methylpropyl) phenyl]-hexafluorophosphate-(1-)	CC(C)CC1=CC=C([I+]C2=CC=C(C)C=C2)C=C1.F[P-](F)(F)(F)(F)F	III
0071868-10-5 Methyl-1-(4-methylthio)phenyl-2-morpholinopropan-1-one	CC(N1CCOCC1)(C)C(C2=CC=C(SC)C=C2)=O	III
0015206-55-0 Methyl benzoylformate	O=C(C(C1=CC=CC=C1)=O)OC	I
0178233-72-2 [4-(1-Methylethyl)phenyl](4-methylphenyl)-iodonium tetrakis(pentafluorophenyl)borate	CC1=CC=C([I+]C2=CC=C(C(C)C)C=C2)C=C1.FC3=C(F)C(F)=C(F)C(F)=C3[B-](C4=C(F)C(F)=C(F)C(F)=C4F)(C5=C(F)C(F)=C(F)C(F)=C5F)C6=C(F)C(F)=C(F)C(F)=C6F	III
0083846-85-9 4-(4-Methylphenylthio)benzophenone	O=C(C1=CC=CC=C1)C2=CC=C(SC3=CC=C(C)C=C3)C=C2	III
0149260-52-6 Mixture of 1-Propanone, 2-hydroxy-2-methyl-1-[4-(1-methylethenyl)phenyl]- homopolymer with 2-Hydroxy-2-methyl-1-phenylpropan-1-one	CC(C)(O)C(C1=CC=C(C(C)=C)C=C1)=O	II
	CC(C)(O)C(C1=CC=CC=C1)=O	II
0048145-04-6 0000606-28-0 0119313-12-1 0010287-53-3 Mixture of Phenoxyethyl acrylate Methyl 2-benzoylbenzoate 2-Benzyl-2-(dimethylamino)-4-morpholinobutyrophenone Ethyl-4-Dimethylaminobenzoate	C=CC(OCCOC1=CC=CC=C1)=O	II
	O=C(OC)C1=CC=CC=C1C(C2=CC=CC=C2)=O	III
	CCC(CC1=CC=CC=C1)(N(C)C)C(C2=CC=C(N3CCOCC3)C=C2)=O	III
	O=C(OCC)C1=CC=C(N(C)C)C=C1	III
000402-990-3 Mixture of 3-(4-(2-Hydroxy-2-methylpropionyl)phenyl)-1,1,3-trimethylindan-6-yl 2-hydroxyprop-2-yl ketone and 3-(4-(2-Hydroxy-2-methylpropionyl)phenyl)-1,1,3-trimethylindan-5-yl 2-hydroxyprop-2-yl ketone	O=C(C1=CC2=C(C(C)=C1)C(C)(C3=CC=C(C(C(C)(O)C)=O)C=C3)CC2(C)C)C(C)(O)C	III
	O=C(C1=CC2=C(C(C)(C)CC2(C3=CC=C(C(C(C)(O)C)=O)C=C3)C)C=C1)C(C)(O)C	III
0159120-95-3 A mixture of: bis[4-diphenylsulfoniumphenyl]sulfide bishexafluoroantimonate; thiophenoxyphenylsulfonium hexafluoroantimonate	F[Sb-](F)(F)(F)(F)F.F[Sb-](F)(F)(F)(F)F.C1([S](C2=CC=CC=C2)C3=CC=CC=C3)=CC=C(SC4=CC=C([S](C5=CC=CC=C5)C6=CC=CC=C6)C=C4)C=C1	III
	F[Sb-](F)(F)(F)(F)F.C1(SC2=CC=C([S](C3=CC=CC=C3)C4=CC=CC=C4)C=C2)=CC=CC=C1	III

CAS N° Name	Chemical Structure (SMILES codes)	Cramer Class
1003557-16-1 Oxirane, 2-methyl-, polymer with oxirane, 2-benzoylbenzoate	CC1OC1	III
	O=C(OCCO)C1=CC=CC=C1C(C2=CC=CC=C2)=O	III
0442536-99-4 Oxyphenylacetic acid 2-[2-hydroxy-ethoxy]-ethyl ester	O=C(OCCOCCO)C(C1=CC=CC=C1)=O	I
0211510-16-6 Oxyphenylacetic acid 2-[2-oxo-2-phenyl-acetoxy-ethoxy]-ethyl	O=C(OCCOCCOC(C(C1=CC=CC=C1)=O)=O)C(C2=CC=CC=C2)=O	I
0065894-76-0 1-Phenyl-1,2-propanedione-2-(O-ethoxycarbonyl)oxime	C/C(C(C1=CC=CC=C1)=O)=N\OC(OCC)=O	III
0002128-93-0 4-Phenylbenzophenone	O=C(C1=CC=CC=C1)C2=CC=C(C3=CC=CC=C3)C=C2	III
0145052-34-2 Phosphine oxide, bis(2,6-dimethoxybenzoyl)(2,4,4-trimethylpentyl)- (9CI)	CC(C)(C)CC(C)CP(C(C1=C(OC)C=CC=C1OC)=O)(C(C2=C(OC)C=CC=C2OC)=O)=O	III
0000791-28-6 Phosphine oxide, triphenyl-	O=P(C1=CC=CC=C1)(C2=CC=CC=C2)C3=CC=CC=C3	III
0111497-86-0 2-Propenoic acid, (1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)] ester, reaction products with diethylamine Evaluation based on starting substances	CC(OCC(OC(C=C)=O)C)COCC(OC(C=C)=O)C	III
	CCNCC	III
0067906-98-3 2-Propenoic acid, 1,6-hexanediyl ester, polymer with 2-aminoethanol Evaluation based on starting substances	C=CC(OCCCCCCOC(C=C)=O)=O	I
	NCCO	I
0068002-34-6 2-Propenoic acid, 2-ethyl-2-[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester, reaction products with diethylamine Evaluation based on starting substances	C=CC(OCC(COC(C=C)=O)(CC)COC(C=C)=O)=O	I
	CCNCC	III
0144177-00-4 2-Propenoic acid, polymer with 1,2-ethanediamine, N-ethylethanamine and a,a',a''-1,2,3-propanetriyltris[w-hydroxypoly[oxy(methyl-1,2-ethanediyl)]] Evaluation based on starting substances	C=CC(O)=O	II
	NCCN	III
	CCNCC	III
0068002-33-5 2-Propenoic acid, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol, (chloromethyl)oxirane and 4,4'-(1-methylethylidene)bis[phenol], reaction products with diethylamine Evaluation based on starting substances	C=CC(O)=O	II
	OCC(CO)(CO)CO	I
	ClCC1OC1	III
	CC(C1=CC=C(O)C=C1)(C2=CC=C(O)C=C2)C	III
	CCNCC	III
0194944-42-8 2-Propenoic acid, polymer with 2-aminoethanol, (chloromethyl)oxirane, 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 4,4'-(1-methylethylidene)bis[phenol] and oxirane	C=CC(O)=O	II
	NCCO	I
	ClCC1OC1	III
	OCC(CO)(CO)COC	III
	CC(C1=CC=C(O)C=C1)(C2=CC=C(O)C=C2)C	III
	O1CC1	III
0156376-93-1 2-Propenoic acid, polymer with 2-aminoethanol, 1,2-ethanediol and 2-ethyl-2-(hydroxymethyl)-	C=CC(O)=O	II
	NCCO	I
	OCCO	I

CAS N° Name	Chemical Structure (SMILES codes)	Cramer Class
1,3-propanediol	OCC(CO)(CO)COC	**III**
0103694-73-1 2-Propenoic acid, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol and methyloxirane, reaction products with N-ethylethanamine	C=CC(O)=O	**II**
	OCC(CO)(CO)COC	**III**
	CC1OC1	**III**
	CCNCC	**III**
0071449-78-0 4-Thiophenyl diphenyl sulfonium hexafluoroantimonate	F[Sb-](F)(F)(F)(F)F.[S+](C1=CC=CC=C1)(C2=CC=CC=C2)C3=CC=C(SC4=CC=CC=C4)C=C3	**III**
0000086-39-5 Thioxanthen-9-one, 2-chloro-	O=C1C2=C(SC3=C1C=CC=C3)C=CC(Cl)=C2	**III**
0083817-60-1 9H-Thioxanthene-2-carboxylic acid, 9-oxo-, ethyl ester	O=C(C1=CC(C2=O)=C(SC3=C2C=CC=C3)C=C1)OCC	**III**
0591773-92-1 9H-Thioxanthenium, 10-[1,1'biphenyl]-4-yl-2-(1-methylethyl)-9-oxo, hexafluorophosphate	O=C1C2=C([S+](C3=CC=C(C4=CC=CC=C4)C=C3)C5=C1C=CC=C5)C=CC(C(C)C)=C2.F[P-](F)(F)(F)(F)F	**III**
0000954-16-5 2,4,6-Trimethylbenzophenone and others	O=C(C1=CC=CC=C1)C2=C(C)C=C(C)C=C2C	**III**
0084434-11-7 2,4,6-Trimethylbenzoylphenylphosphinsäure ethylester	O=P(C(C1=C(C)C=C(C)C=C1C)=O)(C2=CC=CC=C2)OCC	**III**

ANNEX IV LIST OF HEARING EXPERTS INVITED AT THE ESCO WG MEETING WITH THE STAKEHOLDERS, HELD IN MILAN ON 9-10 MARCH, 2011

Jan Arnauts	Geleen
Nathalie Arnich	ANSES
Stefan Akesson	Tetra Pak Processing Systems
Andy Boon	SunChemical
Maurizio Buonuomo	Barilla
Beat Brüschweiler	Federal Department of Home Affairs (FDHA) & Federal Office of Public Health (FOPH), Switzerland
Christa Burger	Centre Européen des Silicones
Eugenio Cavallini	CEPI
Francois Chastellain	CT Packaging & Design- Nestec
Wendie Claeys	Belgian Food Agency
Guy Dohogne	Pack4Food
Karl Ehlert	Keller and Heckman
Ralf Eisert	BASF
Leonor Garcia	Coca-Cola
Françoise Godts	DuPont de Nemours
Edwin Hensema	Arizona Chemical (AZC)
Klaus Hunger	Decernis
Sandro Leuenberger	Siegwerk
Perfecto Paseiro Losada	University of Santiago de Compostela
Francesca Mostardini	Pack Co s
Peter Oldring	CEPE
Hermann Onusseit	Henkel AG
Luigi Rossi	Keller & Heckman
Cecile Saint-Gerard	Rohm and Hass
Phillippe Saillard	CTCPA (Technical Centre for Food Preservation)
Koster Sander	TNO.NL
Massimo Sirotti	ETRMA
Llionel Spack	Netslé Research Centre
Mark Vints	Amcor Flexibles Europe & Americas (AFEA)
Lorenzo Zullo	European Tyre and Rubber Manufacturer's Association

GLOSSARY

2D-GC	Multidimensional Gas Chromatography
BADGE	Bisphenol A diglycidyl ether
CoE	Council of Europe
Coll	Collection of the Czech legislative as Acts, Decrees – Official Journal for EU legislation
ESCO	EFSA Scientific Cooperation
FCM	Food Contact Materials
GC-MS	Gas Chromatography- Mass Spectrometry
GC-TOF-MS	Gas Chromatography-Time of Flight- Mass Spectrometry
HPLC-UV	High Performance Liquid Chromatography –UV detection
HPTLC	High Performance Thin Layer Chromatography
HS-SPME-GC-MS	Head-Space Solid-Phase Microextraction- Gas Chromatography- Mass Spectrometry
H-NMR	Proton Nuclear Magnetic Resonance
LC-MS	Liquid Chromatography- Mass Spectrometry
LC-APcI-MS	Liquid Chromatography-Atmospheric Pressure Chemical Ionization-Mass Spectroscopy
NIAS	Non-Intentionally Added Substances
NODGE	Novolacs glycidyl ether
NPLC	Number of Power Line Cycles
SEC	Size Exclusion Chromatography
SCF	Scientific Committee of Food
TTC	Threshold of Toxicological Concern
UPLC-TOF-MS	Ultra Performance Liquid Chromatography- Time of Flight - Mass Spectrometry
UPLC-HDMS	Ultra Performance Liquid Chromatography-High Definition Mass Spectroscopy
QSAR	Quantitative Structure Activity Relationship