Scientific Network of the food ingredients and food packaging (FIP) Unit on food contact materials (FCM), the 'EFSA FCM Network'

Minutes of the 6th meeting

Held on 10-11 July 2018, Parma

(Agreed on 27 July 2018)[1]

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	Name
Austria	Thomas Schwartz
Belgium	Birgit Mertens
Bulgaria	Snezhana Todorova
Croatia	Nino Dimitrov
Cyprus	Antigoni Achilleos
Czech Republic	Jitka Sosnovcova
Estonia	Katrin Kempi
Finland	Merja Virtanen
France	Gilles Rivière
Germany	Stefan Merkel
Greece	Stella Kontou
Hungary	Banka Szilvassy
Ireland	Joseph Hannon
Italy	Riccardo Crebelli Maria Rosaria Milana
Lithuania	Skirmante Ambraziene
Netherlands	Dirk van Aken
Poland	Marzena Pawlicka
Portugal	Maria de Fatima Tavares Poças
Slovakia	Milada Sycova

[1] The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.

Spain	Perfecto Paseiro Losada Juana Bustos Garcia De Castro
United Kingdom	Tim Chandler
Iceland	Grimur Olafsson
Norway	Inger-Lise Steffensen
Switzerland	Stefan Kucsera

- **Intergovernmental organisation Council of Europe:**

Eugenia Dessipri as a substitute of Susanne Bahrke

- **European Commission:**

Jonathan Briggs (DG SANTE)

Eddo Hoekstra (DG JRC)

- **Member of Committee and Panels invited as speakers:**

Laurence Castle (member of EFSA Panel on Food additives and flavourings (FAF Panel))

- **EFSA:**

Food Ingredients and Packaging (FIP) Unit:

Claudia Roncancio Peña, Head of the FIP Unit

Eric Barthélémy, FCM Network Coordinator, Chair

Anna Federica Castoldi, FCM Team Leader

Julia Cara Carmona, FCM Team

Cristina Croera, FCM Team

Alexandros Lioupis, FCM Team

Ellen Van Haver, FCM Team

Katharina Volk, FCM Team

Pesticides Risk Assessment (PRAS) Unit:

Stefania Barmaz and Andrea Terron on behalf of Domenica Auteri, participated in agenda item 13

1. Welcome and apologies for absence

Claudia Roncancio Peña, Head of FIP Unit, opened the meeting.

She underlined that the EFSA Strategy 2020, with one of its strategic objectives being the building capacity in the area of scientific risk assessment also at the level of the Member States, is a main pillar for the Network. She stressed the importance of sharing knowledge and expertise on methodologies and challenges in the safety assessment of chemicals, as well as information on related ongoing projects, and Guidance documents to support harmonisation in risk assessment.

Besides the direct exchange between Member States during this meeting, further knowledge on risk assessment can also be gained through the a series of 2-day specialised training courses and 2-hour webinars on certain aspects of food safety risk assessment offered by EFSA (see email sent on 2 July).

The members of the Network were also informed about the reduction of the meeting duration to one day which is linked to general budget restrictions. As the Network is considered an important platform for collaboration, it was decided to guarantee the continuation of this work for improving harmonisation of risk assessment of non-EU regulated food contact materials (FCM).

Following the recommendations made at the last review of the general operating framework Networks across EFSA in 2012, an external evaluation is being performed to assess Networks' functioning, format, frequency, and to identify points for improvement and commonalities.

The Chair welcomed the participants, thanking them for their presence and spirit of collaboration and for sharing knowledge which is essential to achieve practical outcomes in terms of better harmonisation of safety assessment of non-EU regulated FCM.

The Chair informed about changes as regards new MS representatives and alternates as well as substitutes for the meeting. New participants introduced themselves.

Apologies were received from the following Member States: Denmark, Luxembourg, Malta, Romania, Slovenia and Sweden.

2. Adoption of agenda

The agenda was adopted with the addition, after agenda item 16, of a presentation from Belgium on a prioritisation strategy based on non-animal methods for genotoxic substances in printed paper and board food contact materials (see section 5.9.4).

3. Agreement of the minutes of the 5th meeting of the EFSA FCM Network, held on 10-11 July 2017, Parma.

The minutes were agreed by written procedure on 22 July 2017 and published on the EFSA website on 1 August 2017. An updated version of the minutes was published on 18 August 2017.

4. Declaration of interests and statement of confidentiality

All Network representatives signed a statement of confidentiality through the submission of their Annual Declaration of Interests.

5. Topics for discussion

5.1. European Commission SANTE activities

Jonathan Briggs presented ongoing and future activities of the European Commission DG SANTE. The summary provided by the speaker is reported below.

"The European Commission is undertaking an evaluation on the EU legislation on Food Contact Materials (FCMs). The purpose of the evaluation is to assess the overall effectiveness, efficiency, relevance, coherence and EU added value of the FCM legislation and in particular the rules and tools provided for by this legislation. It will also examine the situation concerning materials for which there are no EU specific measures and which may be subject to national measures. The evaluation will result in a Staff Working Document, which will provide a basis for the Commission to consider what, if any, possible steps need to be taken in the future concerning the regulation of FCMs in the EU.
The Commission is also working to fully implement Commission Regulation (EC) No 282/2008 and authorise approximately 140 decisions on the recycling of plastic for FCMs. The decisions will be complemented by monitoring to centralise data on occurrence of recurring contaminants, given the relatively limited knowledge on incidental contamination. This will provide knowledge on contaminant levels in view of a changing market, to inform risk assessment and to enforce and eventually improve and standardise waste collection. Work on recycling should continue in the future in light of the EU wide strategy on plastics.
Other on-going work by the Commission includes the development of new legislation to lower limits for lead and cadmium from ceramic FCMs, with the possibility to include other metals as well as glass materials within the scope; work to clarify rules on biocides in FCMs; coordinate monitoring of FCMs; updates and improvements to the online database of substances as well as further amendments to Regulation (EU) No 10/2011."

During the discussion following the presentation, it was questioned what the current status of the draft EU specific measure for printing inks was. During the 5th Network meeting of 2017, DG SANTE informed on the intention to develop such a measure in the near future to notably address the notification of a German draft ordinance. DG SANTE answered that an important and first step in this process is to define an approach for how to best regulate this complex and diverse group of chemicals. DG SANTE stressed the importance of the currently on-going evaluation of the general FCM legislation, which aims at answering questions about e.g. effectiveness and efficiency of the system currently in place. The outcome of this evaluation study will help to inform the decision-making process for possible future draft regulations which are not yet harmonised at EU level. Until its finalisation no concrete work on specific measures is foreseen.
With respect to the information provided on monitoring under Regulation (EC) No 284/2011, it was stressed that this is not strictly linked to certain substances, but that – pending a more concrete control plan – Member States could decide to monitor further substances of interest in the area of FCM.

As regards the area of plastic recycling, it was questioned how the authorisation of decisions on recycling processes (foreseen for early 2019) would articulate with the planned amendment of Regulation (EC) No 282/2008. DG SANTE clarified that changes notably aim to make the adoption and handling of decisions simpler and more manageable. It is planned to adopt the amended Regulation before or at the same time as the decisions on the recycling processes. The Member States will have the possibility to comment on the draft amendment through the Working Group on EC level.

5.2. EFSA activities

Katharina Volk presented ongoing and future EFSA activities. The summary provided by the speaker is reported below.

"The Network was informed about the renewal of the EFSA Panels, which had their inaugural meetings on 5-7 July. For the Panels that fall within the working area of the FIP Unit there have been changes in the mandate, i.e. the assessment of flavourings will be taken up by the FAF Panel (former ANS) that will now deal with flavourings and food additives, while the CEP Panel (formerly CEF) will deal with food contact materials, enzymes and processing aids. As a consequence of the renewal of the Panels, also new Working Groups are being established.
The launch of a call for the tasking grant "Entrusting support tasks in the area of Food Ingredients and Packaging" was advertised to the participants. Until 3 September Article 36 competent authorities can submit their proposals for scientific advice and assistance in the area of e.g. implementation of evidence-based risk assessment for the re-evaluation of BPA and substances for use in Food Contact Materials. For further information the following website can be consulted: https://www.efsa.europa.eu/en/art36grants/article36/180502.
The Network was also informed about on-going activities as regards the re-evaluations of phthalates and BPA. While for the re-assessment of phthalates the established Working Group is already operational and the opinion is expected by the end of the year, the re-evaluation of BPA is just about to start. A protocol that defines a priori the approach and methodology for performing the BPA hazard characterisation was published in December 2017. Currently, there is a call for data on-going that aims at gathering human and animal hazard studies/data (published, unpublished or newly generated) relevant to BPA safety evaluation. Relevant data can be submitted to EFSA until 31 August 2018. Additional information on the call for data can be found at the following website: https://www.efsa.europa.eu/en/consultations/call/180309-0."

A follow-up question to the presentation was related to the use of biomonitoring data, such as the on-going biomonitoring European study (HBM4EU), in the assessment of phthalates and BPA. As regards the re-evaluation of BPA it was clarified that the focus will be on the assessment of hazard data. For the re-evaluation of phthalates instead EFSA will mainly use the dataset that was also used by the ECHA RAC in their assessment of phthalates published in March 2017 and which includes information on hazard and exposure, among others also a biomonitoring study. Additionally, it has to be considered that the urinary biomonitoring data will inform about exposure from all sources, i.e. dietary and

non-dietary, whereas the assessment from EFSA would rather focus on the contribution of plastic FCM to the overall dietary exposure.

5.3. European Commission JRC activities

Eddo Hoekstra presented ongoing and future activities of the European Commission DG JRC. The summary provided by the speaker is reported below.

"The presentation gave an overview of relevant issues performed by the European Union Reference Laboratory for Food Contact Materials (EURL-FCM), established within the EC DG JRC. It addressed a project carried out together with the European Plastics Converters (EuPC). This concerns the migration of non-intentionally added substances (NIAS) from 70 articles that are representative for the EU market. This project aims to set up a procedure to prioritise the migrating NIAS for potential concern.
Another topic was the monitoring of mineral oil residues in food. The EURL-FCM is in charge of writing monitoring guidelines. The part on sampling and reporting of results to EFSA is in its final stage.
The "Guidelines on Testing Conditions for Articles In Contact With Foodstuffs (With A Focus on Kitchenware)" is under revision. It aims to harmonise test conditions. It will cover test conditions for all food contact materials. On request of DG SANTE the EURL-FCM will work in the near future on the development of testing conditions for cookware and bakeware and on the development of a monitoring and reporting approach for recycling processes. Results and progress of two proficiency tests were presented."

During the discussion on the prioritisation exercise on NIAS, and especially the criteria for the scoring, it was proposed to investigate the possibility for a differentiation between genotoxic and non-genotoxic substances. JRC will forward the proposal to EuPC which conducted the NIAS scoring. With regards to the substances included in the raw data set and for which no CAS could be identified, it was suggested to investigate in the future the frequency of occurrence to draw possible conclusions about material-specific NIAS and prioritisation.
Timeline for finalising the work on developing the testing conditions for ceramic cookware and bakeware was communicated to be the end of 2018. This may be quite challenging and the effective finalisation might affect the timeline for revising the directive on ceramics.

5.4. Council of Europe activities

Eugenia Dessipri presented ongoing and future activities of the Council of Europe. The summary provided by the speaker is reported below.

"Council of Europe activities in the area of Food Contact Materials (FCM) started under the former Council of Europe Partial Agreement (18 Member States) in the Social and Public Health Field and in 2009 were transferred to the European Directorate for the Quality of Medicines and Health Care (EDQM – 38 Member States) .

Thereafter, the Committee of Experts P-SC-EMB (Committee of Experts on Food Contact Materials) began a review of the existing resolutions and technical documents (https://www.edqm.eu/en/resolutions-policy-statements). Initial priority was given to the work on metals and alloys that are used in food contact materials and articles and in June 2013, Council of Europe member states adopted Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles. A Technical Guide that presents this Resolution and practical guidelines for its implementation can be downloaded (https://www.edqm.eu/en/food-contact-materials). The second edition of this Resolution is currently being prepared.
Activities are steered since 2018 by the Committee for food contact materials and articles (Partial Agreement – 38 Member States) (CD-P-MCA). Current priority is the elaboration of a Resolution for all FCM (under the scope of Regulation EC no. 1935/2004) that are not covered by specific harmonised legislation at a European level. The aim is to provide general principles and best practices to ensure the quality and safety of these materials. Material specific technical guides would complement this Resolution. Work is in progress for the elaboration of Technical Guides for FCM from paper and board, coatings, cork and ion exchange resins as well as guidelines relevant to the analysis of contaminants from printing inks."

With regards to the elaboration of a framework resolution for all FCM, it was clarified that this will not contain any list of evaluated substances, but will make reference to material specific technical guides in which the lists of evaluated substances, whenever included, are presented. The lists would be based on existing European and national evaluations. To this purpose, the mutual recognition of evaluations undertaken by other Member States, and mainly based on the SCF guidelines, is of high importance as this will further help to increase the level of harmonisation. It was questioned how different restrictions for the same substance would be considered and reported in the lists. It was proposed to make clear how the list was built and to address this question in the technical guides. For the sake of transparency it was proposed that the source of the restriction applied was referenced in the lists. It was identified the need to clarify the meaning of "not CMR". Likely, it is misconsidered as "not present in EU list of CMR". In such a case, the fact that a substance is not known to be a CMR does not necessarily mean that the substance was proven not to be a CMR based on toxicological data. It was stressed that the "10 ppb + no CMR" is often misused. The question of addressing the potential genotoxicity for any intentionally added substance, including those that do not migrate (LoD of 10 µg/kg food), was raised.

5.5. Report back from the EFSA partnering Grant on coatings

Dirk van Aken, Perfecto Paseiro and Riccardo Crebelli reported back on the EFSA partnering grant on coatings. The summaries provided by the speakers are reported below.

NL: "The issue of national regulations for coatings was discussed already in previous meetings of the EFSA FCM scientific Network. More recently the JRC study on non-harmonised FCM made clear that convergence between national

provisions is very limited. In a dedicated FCM Network teleconference in February 2017 with Member States (NL, SP, IT, BE, CR, SL) having expressed interest in cooperating on coatings within the FCM Network, it was agreed that a task force should investigate the possibilities for more harmonisation. Later that year, an application for an EFSA Partnering Grant was submitted to facilitate this work. The Grant has been awarded, the Grant Agreement has been signed and a kick-off meeting was held in January 2018. The project is planned to be finalised by mid July 2019.
The timeline, methodology and planned deliverables were briefly explained and the FCM Network members; invited to give input, both during the meeting and later."

SP: "A part of the planned deliverables of the task force on varnishes and coatings for food contact materials is to establish a list of essential terms and definitions used in the evaluation of coatings for Food Contact Materials.
The aim is to clarify the meaning of some scientific, technical or legal terms, which are frequently used by operators and agencies involved in risk assessment of chemical substances in the Food Contact Material (FCM)/coatings field. Through that, solutions could be proposed to the problems that have been identified: a) Ambiguous terms, the meanings of which should be inferred from the context; b) Disagreements in the definitions used by recognised organisations, institutions, agencies and legal texts, both on EU and international or national levels and c) Lack of definitions and/or appropriate references for the terms used in the legal texts, generating uncertainties about which substances are authorised and whether or not they should be subject to risk assessment.
The task force concluded that the terminology used in the field of coatings (coating, polymer, oligomer, pre-polymer, resin, etc.) is ambiguous and it may generate confusion to stakeholders (incl. risk assessors), when the term is not inferred rightly from the context; b) regardless the meaning of the terms, it should be considered the risk assessment of substances with molecular weight less than 1000 Da (polymers or pre-polymer, or oligomers or differently named), that remain in the coating and can potentially migrate into the food; and c) it should be considered if it is appropriate, from a food safety point of view, to apply the generic authorisation for pre-polymers of the plastics Regulation (EU) No 10/2011 also into the field of coatings, since pre-polymers are broadly used in their manufacturing."

IT: "In the framework of the activities finalised to the harmonization of national approaches for the safety assessment of substances used in food contact materials not falling under European legislation, a grant has been issued by the EFSA for a Task Force specifically devoted to varnishes and coatings for food contact materials (EFSA/AFSCO/2017/01). One of the early deliverables of the Task Force will be the development of a template suitable to collect and compare national approaches, for the comparative assessment of methods and criteria in view of the development of a common, harmonised approach.
To this aim, the Italian delegation is proposing a template in which the evaluation process of a coating substance is dissected in a work-flow, with consideration of critical non-toxicological data requirements and of the approaches for the safety assessment of all migrants from the finished product to food from the application of the coating substance, including its impurities and reaction products. As a practical example, the case of a cross-linking agent was

presented and discussed, displaying different risk assessment tools (e.g. MoS, MoE, TTC and SAR considerations) deployed on a case-by-case basis depending on the nature of migrants (e.g. the coating substance, its oligomers, impurities and other NIAS). The approaches to safety assessment of coatings presented here, and recently applied by the Italian authorities, are largely consistent with the currently applied principles in the European Regulation (EU) No 10/2011 on plastic food contact materials, and its recent scientific developments as envisaged in the relevant EFSA Opinion (EFSA Journal 2016; 14(1)4357)."

As a follow-up request from the Dutch presentation and to get a better overview of the different evaluation approaches in Europe, the Member States CZ, DE, EL, FR, SK (not members of this task force but with national provisions on coatings) agreed to provide more details on their specific provisions and the evaluation methodology by the end of August 2018.
NL underlined that the taskforce will particularly consider the assessment of migrating substances as they are ultimately relevant for the considerations on exposure and toxicology.
As regards the terminology and definitions in the area of coatings, it was proposed to harmonise the different categorisations/classes among the Member States and the related requirements. It was e.g. also questioned whether it would be worthwhile to distinguish thermoset and thermoplastic materials. Another point for further elaboration is the term "pre-polymer". For instance, do pre-polymers need to be assessed when they are the reaction product of evaluated monomers? Even if the genotoxicity of a pre-polymer may be derived from its monomers, this assumption cannot be applied for other pathways/effects like general toxicity, hence the migration potential may be a criteria. Similar questions apply to the reaction products of a pre-polymer. Can their toxicity be predicted from the pre-polymer? The migration potential should also be taken into account. In addition, it has to be considered that even if the toxicological profile is assumed/confirmed to be the same, those pre-polymers are not covered by the specific migration limit set for the monomer, but only through the overall migration limit.
The Network members were informed that the currently on-going joint evaluation by Italy and the Netherlands of a coating substance will be shared as soon as a proposal is finalized in order to also gather input from other experienced Member States in the assessment of coating substances.

5.6. Feedback on the EFSA "Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age"

Laurence Castle presented the EFSA Guidance on risk assessment for infants below 16 weeks of age. The summary provided by the speaker is reported below.

"The cross-cutting guidance document (GD) on Infants [Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age (EFSA Scientific Committee, 2017)] has direct relevance to the risk assessment of substances migrating from food contact materials. The GD considers the differences between infants, children and adults with regards to

both the susceptibility (i.e. hazard identification and characterisation) and the food intake (i.e. exposure) of infants. How this fits in with the normal (for FCM) tiered approach for toxicity data requirements (toxicity data depending on exposure or migration level) and on the default exposure scenario(s) used for FCM, was explored briefly in this presentation and will be further elaborated in the coming months by the new EFSA CEP Panel (Panel on Food Contact Materials, Enzymes and Processing Aids, 2018-21)."

Due to the tiered approach for toxicity data requirements in the area of FCM, only genotoxicity studies are submitted when migration is below 50 µg/kg food. On the other hand, the guidance takes for granted the availability of the overall toxicological profile through the standard (full) toxicological tests and recommends in addition either an EOGRTS or a neonatal study. Thus, the question raises as to whether additional (and what) tests should be requested when the migration of substances to be used in materials in contact with food intended for infants below 16 weeks of age is below 50 µg/kg food (and between 50 µg/kg food and 5 mg/kg food). A practical implementation needs to be decided by the CEP Panel.
It was questioned whether during the drafting of the guidance the European Medicines Agency (EMA) was consulted as regards information from paediatric investigation plans (PIP) submitted by pharmaceutical industries for applications prior to authorisation. EMA might have also considered the specificities and higher sensitivity of infants (below 16 weeks). The question was forwarded, after the meeting, to the coordinator of the Guidance who answered that all topic related documents from EMA were consulted and that EMA approach is case by case.
With regards to the exposure scenario suggested in the guidance (260 mL/kg bw per day), Belgium reported that the results from a national study with baby bottles show a similar consumption level (230 mL/kg bw per day). This new information should be taken into account when 'updating' the EFSA opinion of 2016 on recent developments in the risk assessment of FCM, reporting a consumption of 150 g/kg bw per day for the food category including water and baby bottle contents such as reconstituted milk formula.
Besides, it was suggested to request applicants to declare in their application whether the substance under evaluation is intended to be used in a FCM for contact with infant formula or water such as kettles, bottles for water, baby bottles, teats. This could help to decide whether additional toxicological studies should be requested or a restriction should be given.

5.7. Compilation of Member States projects/researches

Gilles Rivière presented the compilation of Member States "forthcoming risk assessment activities" reported in the area of FCM. The summary provided by the speaker is reported below.

"Starting in 2015, in the context of closer collaboration between Member States, a database of different research projects has been built. It is fed, on a confidential basis, by the Member States and comprises information on more than 600 MS risk assessments for all areas falling within the interest of EFSA. In the context of the EFSA FCM Network, it was decided to identify the projects

relevant for the area of FCM and to also keep them updated, with the purpose of promoting awareness and stimulating cooperation between MS."

France was thanked for leading this task in the interest of the whole Network. In the discussion following the presentation, it was noted that the projects listed and extracted from the database do not seem to represent all the projects on-going in the area of FCM in the Member States. The Network members were therefore invited to double check the entries and include any current activity related to safety assessment, e.g. research projects, development of guidance documents, etc. An updated database will help to raise awareness, avoid duplication, and find synergies among the Member States, thus providing a solid basis for collaboration.

5.8. Joint ECHA/EFSA Guidance for the identification of endocrine disruptor

Stefania Barmaz and Andrea Terron presented, on behalf of Domenica Auteri, the Joint ECHA/EFSA Guidance for the identification of endocrine disruptors. The summary provided by Domenica Auteri is reported below.

"The European Commission (EC) asked the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) to develop a guidance document for the implementation of the scientific criteria for the determination of endocrine-disrupting properties for Biocidal Products and the Plant Protection Products. The guidance document was developed jointly by ECHA and EFSA with the support of the JRC. It describes how to perform hazard identification for endocrine-disrupting properties by following the scientific criteria adopted in the EU in 2017 (for biocides) and 2018 (for pesticides). Like the criteria to identify endocrine disruptors, this guidance document is based on the WHO/IPCS definition of an endocrine disruptor (WHO/IPCS, 2002). Although the ED criteria cover all endocrine disrupting modes of action, i.e. adverse effects which may be caused by any endocrine modality, this guidance document mainly addresses the effects caused by estrogenic, androgenic, thyroidal and steroidogenic (EATS) modalities, because for these modalities there is currently the most knowledge available. However, the general principles outlined in the assessment strategy are also applicable to other endocrine (non-EATS) modalities."

Following the presentation, it was discussed which studies should be considered for the assessment of possible endocrine activity of a substance. This is *per se* highly dependent on the standard requirements for data sets which differ according to the various safety assessment areas and reference was made to the different levels of studies from OECD Work Related to Endocrine Disrupters. In the risk assessment of pesticides, a generally rich data set has to be provided, while in the area of FCM a tiered approach is applied, a reduced or limited set of toxicological data is submitted. Therefore, if and how the potential for endocrine disruption should be assessed for migration below 50 µg/kg food and between 50 µg/kg food and 5 mg/kg food needs to be addressed.
It was noted there are some *in silico* tools available, e.g. QSAR, that have a quite good level of prediction and can be indicative of endocrine properties, especially for interactions with the oestrogen or thyroid receptors. Nevertheless,

for other modes of actions, the prediction might be less good, and negative results should therefore be assessed critically.

5.9. Printing inks

5.9.1. Council of Europe activities

Eugenia Dessipri presented the Council of Europe activities in the area of printing inks. The summary provided by the speaker is reported below.

"The last policy statement concerning printing inks was elaborated by the Council of Europe in 2007. Current activities by the ad hoc working group on printing inks focus on analytical issues related to the examination of compliance of printed food contact materials with Regulation (EC) No. 1935/2004. Experts from 11 Member States participate in the group. Based on information from published surveys (UK and Germany), RASFF notifications and communication with Member State official control laboratories, printed FCMs are frequently assessed by testing for the migration of photoinitiators. A comprehensive list of commercial photoinitiators (115 substances so far - consolidation of German lists, Swiss lists and the EuPIA suitability list) is being compiled. Additional information on the physicochemical properties (for example, functional family, molecular weight, vapour pressure, melting point, boiling point, polarity, etc.) is available for most of these photoinitiators. Literature relevant to the analysis of such compounds is being shared in the EDQM sharepoint site and regularly updated. Following expression of interest from 14 laboratories (9 National Reference Laboratories, 3 Official Control, 2 Universities) the peer-review of methods for the determination of photoinitiators in simulants and dry food is being organised. The working group is currently elaborating the method details allowing the use of both GC-MS and LC-MS/MS instrumentation. While based on the in-house methods used by official control laboratories, the details of the analysis were agreed among the group members and will be further optimized until the end of 2018."

The on-going work of the CoE Working Group on printing inks was acknowledged to benefit from a wide collaboration between Member States.
The literature search covers publications from approx. 2005 onwards. As regards the planned inter-laboratory study on photoinitiators, it was identified as a challenge to cover this group of substances by testing only 6 photoinitiators using one or a few analytical methods, as photoinitiators are likely to have very different chemical structures. This should be considered in the design of the study. The speaker answered that the substances were currently chosen to represent different structural families and that, depending on resources, more studies could be organised in the future.
The limit of detection was considered to be another challenging point. The LODs could be set in relation to the SMLs, e.g. as defined in the CH/DE lists for printing inks. It was mentioned that according to the JRC Guidelines for performance criteria and validation procedures of analytical methods used in controls of FCM, the LOD should be 1/5th of the SML. It was also discussed how to handle substances that are listed as "non-detectable" (at a LOD of 10 ppb) and represent the majority of photoinitiator lists A and B (see 5.9.2).

It was stated that monitoring by coordinated national control plans could complement information received through the RASFF and would be useful in order to get a clearer idea of the EU market and imports on printing inks. This could also help in prioritizing the evaluation of substances from the Swiss list B.
It was concluded that it is essential to coordinate and plan research projects on a long-term basis also for the area of printing inks, and that the compilation of Member States projects (see 5.7) could present a good basis for that purpose. A long term planning could help in finding funds from European Institutions such as the 8th European Union's Framework Programme for Research and Innovation (2014-2020) called "Horizon 2020".

5.9.2. Swiss and German ongoing activities

Stefan Kucsera and Stefan Merkel jointly presented the activities on printing inks on-going in Switzerland and Germany since the last meeting in 2017. The summary provided by the speakers is reported below.

"In this presentation an overview on the joint safety evaluation of printing inks for food contact materials by German (BfR) and Swiss (FSOV) authorities was given. Procedures of safety evaluations according to the SCF guidelines as used by the EFSA for their assessment of food contact materials are also in place for the joint safety evaluations by the BfR and FSOV. Except for minor differences in the assessment of exposure, SCF guidelines are followed and petitions are submitted to German and Swiss authorities based on the templates found in the EFSA Note for Guidance. In a bi-annual joint panel, a critical discussion of separate, agency-specific toxicological assessments takes place and a mutual consensus on a dossier is reached. In case of need, analytical data are discussed in an analogous fashion.
An overview of recently evaluated substances was also included with a short summary of the toxicological assessment for the substance 4-Methyl-2-pentanol (MIBC). Furthermore, analytical challenges in the safety evaluations were highlighted with example of the substances 4-Methoxyphenol (MEHQ) and 4-nonylphenol."

After the presentation, the good cooperation between Germany and Switzerland was again acknowledged. It was clarified that the exposure assessment is mainly based on worst-case migration. Nevertheless, if applicants have to provide analytical methods suitable for enforcement when submitting the request for evaluation, the analytical characterisation was reported to be often challenging for the evaluation, the compliance testing and the enforcement. The information on the availability of analytical methods and on the method itself would be of interest to ensure compliance and enforceability at the EU level. It was clarified that substances that are authorised to be used in plastics have been evaluated hence are included in list A[2]. Therefore the list B contains only substances that have not been evaluated by EFSA/SCF or national Authorities. Along the lines already expressed on the misuse of the "10 ppb + no CMR" in 5.4 and 5.9.1, and considering the high number of chemicals in list B, the question was raised to

[2] This information was clarified after the meeting during the agreement of the Minutes.

address genotoxicity potential and prioritise. EuPIA could also be consulted to identify substances that are not used.
In the spirit of sharing information, it was asked whether the summary of the assessment reports/opinions from BfR could be translated in English and the full assessment reports be made available in their entirety to other Member States. This could apply to all Member States assessments.
The example of an evaluated stabiliser, which is added to the raw materials of printing inks in order to avoid oxidation and which within that process degrades, showed that it is essential to consider in the assessment not only the starting substance, but also the respective degradation/reaction products. As regards the toxicological assessment, two main points were discussed:
1) the importance to perform a suitable *in vivo* follow-up for substances tested positive in *in vitro* genotoxicity tests: in particular, it was recommended to follow the recommendations from the ESFA Scientific Committee (EFSA Scientific Committee, 2017; EFSA Scientific Committee, 2011);
2) the careful and critical consideration of inhalation studies in terms of their relevance to the area of food contact materials where the main route of exposure is oral ingestion.
There was also a discussion on how to deal with substances that are considered to be SHVC based on their endocrine activity. Reference was made to the presentation and the subsequent discussion on the ECHA/EFSA Guidance on ED (see 5.8).

5.9.3. Review of EuPIA guidance on migration tests methods and IP guidance on conformity of indirect FMCs

Stefan Merkel presented the scope of EuPIA (European Printing Ink Association) guidance on migration test methods and IP (Imaging & Printing Association) on conformity of indirect FCMs. The summary provided by the speaker is reported below.

"BfR is preparing a guideline for the application of adding new substances to the German Ordinance on Printing Inks. This guideline will provide explanations for the application process with specific regard to printing inks. The I & P Guidance Document "Conformity of Indirect Food Contact" and the "EuPIA Guidance on Migration Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials" provide information on conformity work."

The Network acknowledged that the BfR guidelines could represent a useful document for the evaluation of substances used to manufacture printing inks. The BfR guidelines would be based on the SCF guidelines and the EFSA Note for Guidance, plus would take into consideration specific aspects for printing inks which are not included in the EFSA Note for Guidance (e.g. on the manufacturing process). This could have an added value for future developments with respect to harmonisation at EU level. It was suggested to include this activity in the table of compilation of Member States projects related to safety assessment (see 5.7) and to share the draft with the Network members to allow them to provide comments and input, especially if active in the evaluation of printing inks.

5.9.4. Genotoxic substances in printed paper and board food contact materials: A prioritisation strategy based on non-animal methods

Birgit Mertens presented a project on a prioritization strategy for genotoxic substances in printed paper and board, based on non-animal methods. The summary provided by the speaker is reported below.

"Printing inks and paper(board), two FCM types that are often used in combination, have already been the subject of multiple food contamination issues. Nevertheless, as for the majority of FCM types, no specific harmonised European regulation is in place for printed paper and board. Since thousands of printed paper and board substances have not been officially evaluated for their safe use, identification of those of highest concern is required. In the present work, a prioritisation strategy based on the substances' genotoxic potential was developed as this toxicological endpoint is related to serious adverse human health effects, including cancer. The developed strategy was solely based on non-animal test methods including *in silico* tools, literature consultation and *in vitro* experiments. Importantly, within the strategy, most emphasis was put on the substances' potential to induce gene mutations as for this endpoint, *in silico* models are most advanced. By using a battery of 4 *in silico* models, a first selection was obtained consisting of 106 non-evaluated single substances that were predicted to induce gene mutations in all 4 models. For these substances, publicly available experimental genotoxicity data (including information on the induction of gene mutations) were collected. For the substances lacking (adequate) genotoxicity data, a bacterial reverse gene mutation test was performed. Ultimately, the prioritisation strategy identified a large number of substances of concern, out of which nineteen are of very high concern based on their confirmed *in vivo* genotoxicity, current use, high migration and bioavailability potential and inclusion in European lists with substances of concern. Interestingly, the developed strategy can also be applied in numerous other domains with a high need for substance prioritization."

It was noted that the available *in silico* (QSAR) models are mainly directed towards the prediction of mutagenicity in gene mutation assays *in vitro* (mainly the Ames test), which focus on the DNA reactivity of the compound and/or its metabolites. On the other hand, other mechanisms beyond DNA reactivity contribute to genotoxic hazard, especially for what concerns chromosome integrity and segregation, and these are not adequately addressed in QSAR analyses. A future refinement of prioritization strategies should consider the implementation of a larger set of QSAR profiles, once that validated tools for the prediction of other relevant end-points (e.g. interaction with topoisomerases, mitotic spindle, etc.) become available. It was questioned how these prioritization studies and the deducted hierarchies could be kept updated in the light of new developments in the area.
Another important question to be addressed are the criteria on which such a prioritization is generally developed, e.g. on endocrine activity, genotoxic potential, uses, exposure/migration, IAS/NIAS etc. Again, are the listed substances still used and do they deserve to be considered? This is of importance both for those authorised further to Institutional evaluation (List A) and those authorised on the basis of the "10 ppb + no CMR" (list B). Industry data on the actual use of substances were therefore considered to be relevant in

conducting prioritisation exercises. Enforcement Authorities could also collect information on the substances used through control/audit. Those substances should be reported in the declaration of conformity.
The issue of the misuse of the so called "10 ppb + no CMR" was raised again (see 5.4 and 5.9.2).

5.10. Paper and board

5.10.1. Italian, Dutch and German on-going activities

Maria Rosaria Milana, Dirk van Aken and Stefan Merkel presented the on-going activities in the area of paper and board in Italy, the Netherlands and Germany, respectively. The summaries provided by the speakers are reported below.

IT: "In Italy, paper and board are regulated via the Ministerial Decree, 21 March 1973 and its amendments. In this decree the main points are: positive listing, compositional requirements and purity criteria. Recycled paper and board are admitted only under strict conditions of purity and only for non-extractive foods. A monitoring study is on-going, under a research plan agreed with the Italian Ministry of Health (Competent Authority) to highlight which type of contaminants are currently recurring in recycled paper and boards, to map their frequency and their amount. The possibility to add new purity parameters (mainly organic molecules, such as residues of glues, inks, solvents, etc.) is under discussion."

NL: "In 2014, the Dutch regulation on FCM - the 'Warenwetregeling verpakkingen en gebruiksartikelen (WVG)' (Packagings and Consumer Articles Regulation) – had already been presented. Two types of paper are distinguished: 'for general use' and 'cooking packaging and filtering of beverages > 80 °C'. The WVG contains positive lists for starting materials and additives (IAS) and restrictions for IAS and possible contaminants; the use of recycled fibres is allowed. Since the last update in 2014, one substance was added to the positive list on P&B in 2016, and at the moment, one substance is under evaluation. This substance was also submitted for evaluation to Germany, and as a pilot project, a co-evaluation of NL and DE is performed, aiming to result in one joined SDS. From the Positive List for paper and board for general use, 2 categories of substances will be deleted: 'macromolecular compounds' and 'preservatives for coatings'. Instead, a reference to the (revised) chapter on coatings will be made. This revision is foreseen for this year. Main findings of a RIVM report on mineral oil were also highlighted."

DE: "The BfR recommendations XXXVI are valid for paper and board for food contact, for hot filter papers, for paper for baking purposes and for absorber pads based on cellulosic fibres for food packaging. Approximately 900 substances, monomers and polymers are listed in the recommendations. Applications to add new substances should follow the EFSA Note for Guidance along with special requirements. Depending on the type and use of paper, different migration methods from theoretical calculations to measurement into foodstuffs are proposed. Thermostability tests are also required under certain circumstances. The evaluation of oligomers from polymeric additives is currently one of the most challenging topics."

As regards the monitoring study conducted by IT on recycled paper and board, it was clarified that the analysis conducted on the packaging itself was of compositional nature (i.e. no migration test), and that it was a non-targeted screening. For instance, MOSH is used as an indicator for MOA. According to the Italian decree recycled P&B is allowed, among others, for contact with foods (non-fatty, non-liquid) where no migration test is required according to Regulation (EU) No 10/2011. Given the recent amendments of that Regulation where also requirements for migration testing were changed, it was reminded to take that also into consideration when interpreting the restrictions in place in IT.
From a Dutch report on mineral oils in food, whose main findings were presented by NL, it was clarified that the contribution of paperboard packaging to the intake of MOSH/MOAH was found to be limited (2%) and that the food was analysed as consumed.
Following the presentation by DE on the BfR recommendations on paper and board, it was suggested to possibly investigate whether the substances listed therein overlap with the plastics positive list of Regulation (EU) No 10/2011. It was clarified that the conventional 40 g paper in contact with 1 kg food (DIN EN 645 and 647 for cold and hot water paper extract) was verified by BfR. The issue of analytical identification of migrating substances, especially for oligomers derived from polymeric additives was raised again, and should deserve attention. Following the entry into force of the Biocide Regulation (EU) No 528/2012 and the removal of slimicides and preservatives from the BfR Recommendations, several applications for evaluation were received in BfR and consequently substantial work has been done at Member State level on process biocides. It was clarified by EC that the current priority as regards the EU regulation on biocides is to establish migration limits for biocides with antimicrobial function in the final articles (also called 'surface biocides'), although the format of an authorisation/positive list is still under discussion. As regards 'process biocides', it was suggested to take advantage of evaluations already done by Member States and to also consider them for a possible database of IAS in paperboard.

5.10.2. Council of Europe activities

Thomas Schwartz presented the activities of the Council of Europe Working Group on paper and board. The summary provided by the speaker is reported below.

"This presentation laid out the current status of the CoE draft technical guide on paper and board. It was supposed to give an overview over the structure of the document and give insight into what parts are still works in progress and up for debate in the working group.
The draft shall supplement the Draft Resolution on the Safety and Quality of Materials and Articles by laying out additional requirements for materials and articles made of paper or board. This includes restrictions for well-known contaminants as well as a list of evaluated substances for the use in FCMs (that will later be published separately). Substances may intentionally be used if risk assessed by EU national authorities or EFSA, otherwise they have to be risk assessed by the manufacturer and included in the DoC. The main focus of the

document is the summarisation of applicable methods for compliance testing in order to meet the requirements of Article 3 of Regulation (EC) No. 1935/2004."

Following the presentation, there was a discussion on the use of recycled paper and board behind a functional barrier layer. IT clarified the special derogation in place in their decree on paper and board: the layer in contact with the food needs to be of virgin nature and the purity requirements for lead need to be respected, whereas the layers behind can contain recycled material as long as the food is not extractive. It was noted that even virgin material might be contaminated and that volatile migrants could still cross the layer of virgin material and consequently end up in the food.
In the proposed approach for compliance testing in the CoE draft technical guide, four indicators for the use of recycled paper and board are listed (i.e. UV light, light microscopy, DIPN and BPA). It was questioned whether an additional indicator such as lead should be considered, bearing in mind that lead can be present in coated virgin paper and board.
Although there is a strong focus on IAS, for paper and board NIAS are also a challenging topic. It was reported that a list of well-known contaminants has been generated, this being a good starting point. The restrictions on these "contaminants" are mainly based on limits defined in Regulation (EU) No 10/2011 (as amended and in use) and Regulation (EC) No 1881/2006. It should also be clearly communicated that the user/business operator has the responsibility for NIAS. It was suggested to include this principle in the FCM framework resolution that is also currently under preparation by the CoE.
The topic of mineral oils was raised again. It was mentioned under 5.10.1 that RIVM had conducted work on MOSH/MOAH and had not found significant contribution from paper and board either recycled or virgin. As concerns the CoE draft technical guide, consideration is given to MOAH being included in Table 1, i.e. the restrictions for known contaminants. Discussion on possible limits is still ongoing. A consultation period would proceed adoption of the Technical Guide.
The importance of consultation with industry was reiterated. Useful information could be gained e.g. on sorting and characterisation of input material.

5.10.3. Analytical strategy to obtain information on less-studied compounds

Gilles Rivière presented results from a PhD thesis on the analytical strategy to obtain information on less-studied compounds. The summary provided by the speaker is reported below.

"Production of FCM involves a large number of substances; some of them are intentionally added (IAS) whereas others are non-intentionally added (NIAS). IAS are well known substances, authorised and limited in number. NIAS are mostly unknown, non-listed in positive lists and virtually unlimited in number. Since these substances are able to migrate into the food, it is essential to characterize them. IAS characterization is generally based on targeted principle but this approach is not adapted for NIAS. In this context, DTU and Anses developed an analytical strategy based on semi-quantification and tentative identification. FCM were extracted with ethanol and the extracts were analysed by LC-MS. Compounds were semi quantified with the use of marker.

Identifications were based on MS spectra fragments collection and compared to database of known substances. A risk prioritization approach that classified chemical compounds according to expected risks was developed in the case of paper and board."

During the discussion, it was clarified that in a currently ongoing activity it is checked whether the substances identified in the prioritisation exercise have already been evaluated. The list of samples used for the prioritisation included both IAS and NIAS.
The issue of analytical characterisation was reiterated, the identification being considered as a major uncertainty.
It was stressed that, in addition to the toxicological properties, another criterion for prioritisation could be whether substances/masses are found regularly in more than one sample and therefore represent recurring migrants.
For the example presented, it has to be considered that the list of substances was generated based on extraction of the packaging samples, which is a worst case compared to the real migration.
With regards to the approach for CMR classification, it was clarified that this is an automated process based on QSAR in which several databases are consulted and consequently a final scoring is produced. Validation of these databases and prediction models were considered to be essential but not always available. Therefore there is the clear need to combine these tools with expert judgment follow-up. In addition, it was suggested to always use a combination of tools in order to balance the differences and shortcomings.

5.11. Next FCM Network meeting: proposal for possible follow-up in terms of scientific cooperation and activities

Laurence Castle summarised some of the points raised during the discussions of the FIP FCM Network meeting and the participants were asked to express their views on any topics of their interest.

There are ongoing activities in the Member States on common themes, e.g. printing inks, paper and board, coatings. It was praised that topic-specific sessions were organised because this allows a more focused discussion and a better identification of common interests and challenges/commonalities identified by the different Member States. In the area of printing inks for example there is already a joint evaluation established between Switzerland and Germany. As regards coatings, the task force composed of several Member States is currently undertaking work aiming at a more harmonised approach for the safety evaluation and migration testing. Although covering different types of food contact materials, common challenges have been identified:

Prioritisation was identified to be a topic of high interest. On-going activities in that area were presented by France and Belgium, and this need was also underlined all along the presentations (e.g. Swiss list B for printing inks). It was proposed to establish, similar to the task force on coatings, a closer collaboration between Member States in the area of prioritisation, possibly led by an already experienced Member State. This would help to find commonalities, discuss difficulties encountered and define approaches for future exercises. Amongst other, the following criteria should be discussed: CMR in particular genotoxicity

and reprotoxicity potential, used chemicals (see below), exposure, recurrence in migrats. The criteria may differ at some points when addressing IAS and NIAS due to the different degree of knowledge (e.g. on the identity) and substance availability. Prioritisation is not only discussed in the area of FCM, but e.g. also for contaminants, REACH, etc. Thus taking a look at approaches applied in other fields, e.g. at ECHA, may be helpful. In this respect, a webinar on prioritisation/screening by ECHA would be appreciated. Another possible option for defining priorities could be to consider a risk-based market surveillance approach (incl. risk occurring throughout the food chain). Indeed, the question as to whether all listed **substances are still used** is recurrently raised at each meeting, and an update of the existing lists with the information on the actual uses/use levels would be welcome. The contribution from industry and control Authorities is key in this area. It would be useful to define a process to obtain and keep this information updated for any evaluated and/or authorised FCM substances.

Another point that was mentioned and discussed various times throughout the meeting(s) was the use of substances not 'officially evaluated' on the basis of the so called **"10 ppb + no CMR"** which should relate to a "Not detectable" migration for which a limit of detection of 10 µg/kg food was set a long time ago. As said, a substance not listed as a CMR does not mean that it has been proven as a 'non CMR'. The 10 ppb limit is often misused as a cut-off value assuming that no toxicological data have to be provided, sometimes even if migration is detected below 10 µg/kg food. The need was identified to provide more clarity on this aspect, to ensure the safety of intentionally added substances, because in line with the SCF guidelines, in the area of (plastic) FCM data on genotoxicity must always be provided.

Analytical characterisation was reiterated to be a challenge particularly for NIAS. The Danish and French joint research project presented at the meeting brought some contribution. The issue deserves interest and involvement, for instance in the area of printing inks and coatings. It was proposed to build a **shared European database of mass spectra**. This could be difficult due to the need of a universal use with the various devices available on the market, but it would really support the evaluation of NIAS. This work could start with the upcoming list of evaluated NIAS in the area of coating and even be linked/included in an already existing database such as the so called "Belgium database".

The **assessment of pre-polymers and oligomers** also deserves further attention and support. The context may differ with regards to material types and uses (e.g. monomer, polymeric additives, pre-polymers) but the questions on analysis (identification and quantification) and toxicological testing are common. The work of the partnering grant on coating is expected to provide some responses with regards to pre-polymers and the need for assessing them when manufactured from evaluated monomers and other starting substances. Evaluations made by EFSA on polymeric additives (see e.g. the presentation given at 3rd network meeting in 2016) and recommendations on the assessment of polymeric additive in the EFSA Note for guidance may provide some hints. The ongoing work of the EFSA Scientific Committee on a guidance for assessing mixture could help too, hence it should be followed.

An important topic to be further discussed is the identification and assessment of **substances with endocrine properties**. The EFSA/ECHA guidance presented mainly refers to the context of biocides and plant protection products. For the latter group of substances, usually a rich toxicological dataset is available. When it comes to the area of FCM, mainly a reduced or limited set of toxicological studies is submitted, according to the tiered approach. Improvements of already available and/or development of new *in silico* QSAR tools would certainly help in addressing the challenge of how to evaluate ED compounds. Overall, it was identified that this is a topic of mixed responsibilities between risk assessment and risk management because a common approach needs to be defined for if and how to consider EDs in FCM.

Another area where the exact approach for data requirements and evaluation still needs to be defined is the risk assessment of substances for **infants below 16 weeks of age**. Especially for this population group, the need for a more refined exposure assessment has become apparent, and was already suggested in EFSA's opinion of 2016 on recent developments in the safety assessment of FCMs. Discussion on how to assess the risks for infants from substances used in FCM, and based on which dataset, have to be continued at the level of the CEP Panel.

The importance of sharing information of relevance for safety assessment the whole Network was stressed. The Network represents an interesting and highly constructive platform for enhancing cooperation and promoting synergies. The, compiled list of Member States **"forthcoming risk assessment activities"** in the area of FCM could be helpful in this respect, but as it stands now it appears incomplete. All the members are then invited to actively support this by adding all relevant researches, projects, draft guidance documents, etc. in the area of FCM. This compilation represents a basis for identifying common interests, possible grounds for collaboration which will eventually benefit further the aim of a better harmonisation of risk assessment of non EU regulated FCM.

In the light of the foreseen EU measure on printed FCMs, of the ongoing work on coatings from the partnering grant task force that should end next July 2019, and interest and activities in other materials such as paper and board and rubber, the activities on those materials should be followed up.

Finally, the need for a **European database of evaluated chemicals** (IAS and NIAS) is obvious to avoid duplication and to benefit from the work of all Member States. Member States are thus strongly invited to systematically update Belgium on any new safety assessment to support the constant updating of the so called "Belgium database".

It would be useful if in any of the area/topic mentioned above, a **Member State could take the lead** to exchange views with other interested and/or experienced Member States and make proposals for discussion.

6. Date for next meeting

The next meeting of the FIP FCM network will be organised in 2019. EFSA took note of the proposals for possible follow-ups and will submit a draft agenda to the Network members.

7. Concluding remarks and closure of the meeting

The FIP FCM network coordinator Eric Barthélémy reminded about important aspects for fostering and strengthening the Network: collaboration and exchange of knowledge between EFSA and the Member States are key to ensure a better harmonisation of risk assessment approaches. With only limited resources available, the principle of working together and consequently of sharing workload, expertise and avoiding duplication of work, becomes even more important.

The Minutes of the meeting and public versions of the given presentations will be published on the EFSA website within 15 working days.

The Coordinator of the Network closed the meeting by thanking the speakers and all the participants for their contributions to the discussions and the colleagues from EFSA who participated in and supported the meeting.