Scientific Network of the food ingredients and food packaging (FIP) Unit "FIP Network"

Subgroup on food contact materials (FCM)

Minutes of the 3rd meeting

Held on 24-26 May 2016, Parma

(Agreed on 5 August 2016)[1]

Participants

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

Country	Name
Austria	Christa Hametner
Belgium	Fabien Bolle
Bulgaria	Snezhana Todorova
Croatia	Nino Dimitrov
Czech Republic	Jitka Sosnovcova
Denmark	Gitte Alsing Pedersen
Estonia	Katrin Argus
Finland	Jari Vartiainen
France	Bruno Teste
Germany	Stefan Merkel
Greece	Zoe Mousia
Hungary	Anita Maczó
Italy	Riccardo Crebelli
Lithuania	Skirmante Ambraziene
Netherlands	Dirk van Aken
Poland	Marzena Pawlicka
Portugal	Ana Sanches Silva

[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.

Slovakia	Milada Sycova
Slovenia	Viviana Golja
Spain	Perfecto Paseiro Juana Bustos Garcia De Castro
Sweden	Kettil Svensson
United Kingdom	Richard Burden
Iceland	Katrin Gudjonsdottir
Norway	Inger-Lise Steffensen
Switzerland	Beat Brüschweiler

- **Hearing Experts**

Peter Oldring (Industry platform for non-EU harmonised food contact materials (FCM)), participated in agenda point 15

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

Laurence Castle (member of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) and Chair of the Standing Working Group on Food Contact Materials)

Vittorio Silano (Chair of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel))

- **European Commission:**

Jonathan Briggs (DG SANTE)

Eddo Hoekstra (Joint Research Centre- JRC), participated in agenda points 9-18

Catherine Simoneau (JRC)

- **EFSA:**

Juliane Kleiner, Head of REPRO Department, participated in agenda point 1

FIP Unit:

Claudia Roncancio Peña, Head of FIP Unit

Eric Barthélémy, FIP Network Coordinator, Chair for Agenda points 11-15 and 19-28

Anna Federica Castoldi, Food Contact Materials Team Leader, Chair for Agenda points 1-10 and 16-18

Cristina Croera, FCM Team

Alexandros Lioupis, FCM Team

Ellen Van Haver, FCM Team

Katharina Volk, FCM Team

Marco Lannutti, Administration Team, participated in agenda point 9

AFSCO Unit:

Julia Finger, AFSCO Unit, participated in agenda point 4

DATA Unit:

Davide Arcella, Exposure assessment Team leader, participated in agenda point 18

EXREL Unit:

Lucia De Luca, External Relations Unit, participated in agenda point 19

1. Welcome and apologies for absence

Juliane Kleiner, Head of the REPRO Department, opened the meeting.

She underlined that the Network represents an important initiative for collaboration and harmonisation. This is reflected by the agreement of the Advisory Forum on prolonging the mandate of the network and the increase of the Network membership. Also the Committee of the European Parliament on the Environment, Public Health and Food Safety (ENVI Committee) is currently calling for more harmonisation at EU level in its draft report dated April 2016[2] on the implementation of the FCM Regulation (Regulation (EC) No 1935/2004)[3].

As regards harmonisation of risk assessment methodologies, it was underlined that the EFSA CEF Panel opinion on "Recent development in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in FCM" applies, in principle, for the safety assessment of any substances that migrates from any FCM types. This opinion will serve as basis for a new EFSA guidance on the safety assessment of plastics. Also in the context of its strategy 2020 under which EFSA is enhancing cooperation with Member States, the Network should be involved in the preparation of this new guidance before the public consultation.

The Chair of the first day session, Anna Federica Castoldi, welcomed the participants and asked them to shortly introduce themselves in a tour de table.

Apologies were received from 5 Member States (Cyprus, Luxembourg, Malta, Romania and Ireland) and from 12 Member State representatives/alternates Georgi Baldjiev (BG), Evgenia Paraskeva Vatyliotou, Antigoni Achilleos, Nektaria Varnava (CY), Külli Suurvarik (Estonia), Marja Pitkänen (FI), Gilles Rivière (FR), Karla Pfaff (DE), Vassiliki Avramopoulou (GR), Katalin Frecskáné Csáki (HU), Paulius Pavelas Danilovas (LT), Sandy Nosbusch (LU), Flavia Zammit (MT), Bianca van de Ven (NL), Maria Fatima Pocas (PT), Irina Moldoveanu, Gina Popovici (RO), Susanne Ekroth (SE), Mark Willis (UK), Ireland.

[2] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-575.317+01+DOC+PDF+V0//EN&language=EN

[3] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

2. Adoption of agenda

The agenda was adopted with the following changes: agenda point 19 (EFSA project on Transparency and Engagement in Risk Assessment, TERA) was moved after agenda point 26.

3. Agreement of the minutes of the 2nd meeting of the Network on risk assessment of regulated food ingredients and food packaging "FIP Network" – subgroup on food contact materials, held on 1-2 July 2015, Parma.

The minutes were agreed by written procedure on 14 September 2015 and published on the EFSA website on 16 September 2015.

4. Declaration of interests and statement of confidentiality

All Network representatives signed a statement of confidentiality either through the submission of Annual Declaration of Interest or at the beginning of the meeting.

Julia Finger, coordinator for the harmonisation of EFSA Scientific Network activities, gave a presentation on the new "EFSA guidelines for Network Representatives". She presented the key aspects of the information flow between EFSA and the Member States through Scientific Networks. She gave an overview on the framework of the operation of EFSA's Scientific Networks and explained the nomination procedure through the Advisory Forum. Particular importance was given to the role of the Network Representatives as representing the designated national Network member organisation and in a broader sense the Member State. She underlined the importance of national networking and the role of national Focal Points in facilitating the information flow between Network and Advisory Forum. The recently published Guidelines for Network Representatives, giving more detailed information on the role of the Representative and his interaction with Advisory Forum and Focal Points were distributed to all participants.

5. Topics for discussion

5.1. CEF Panel opinion on "Recent development in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in FCM"

As an update from the last Network meeting, Laurence Castle presented the EFSA CEF Panel opinion on "Recent development in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in FCM"[4].

[4] EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016. Scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Journal 2016;14(1):4357, 28 pp. doi:10.2903/j.efsa.2016.4357 - https://www.efsa.europa.eu/en/efsajournal/pub/4357).

This Opinion is an outcome of a self-tasking activity by the EFSA CEF Panel. It describes the recent developments in the risk assessment of chemicals in food and explores their potential impact on EFSA evaluation of FCM substances. The draft version of this opinion was published in summer 2015 for a 3-month public consultation. EFSA received 205 comments and 4 data sets from 21 interested parties, including governmental and non-governmental organisations, industry organisations and consultants. This draft opinion was then modified by addressing the relevant scientific comments received. It was published on 28 January 2016 together with the EFSA technical report on the consultation process which lists all the comments received and provides a response to the relevant comments.

Following the suggestions received, the introduction now clearly states that the scientific opinion applies to substances in plastics that are regulated and evaluated by EFSA, and also reports the view of the CEF Panel about the safety assessment of any substance that migrates from any FCM. Regarding the identification and evaluation of migrating substances, experience has shown that more focus is needed on the finished materials and articles.

One major area to revisit is the estimation of consumer exposure. Four food consumption categories could be set. They are approximately 9, 5, 3 and 1.2 times higher than the current SCF default scenario, i.e. 17 g/kg bw/day, and so using them would give a higher level of protection, particularly for infants and toddlers. By combining migration with the food consumption category figures, the exposure could be calculated.

The amount of toxicity data needed should be related to the expected human exposure level, in accordance with the principle that the higher the exposure, the greater the amount of data is required. For the tiered approach of the SCF an update is proposed. For substances used in FCM, genotoxicity testing is always required, even if their migration leads to a low exposure. Beyond this, three threshold levels of human exposure, namely 1.5, 30 and 80 µg/kg bw/day, are proposed as triggers for the requirement of additional toxicity data. For specific endpoints additional studies may be needed.

Considering the non-intentionally added substances (NIAS), such as impurities of the substance along with reaction and degradation products including oligomers, the same approach as is used for authorised substances could, in principle, be applied for their toxicological assessment, as the same degree of safety should be warranted for all migrating substances. However, non-testing methods (read-across, computational methods, TTC) could have increased importance for the assessment of genotoxicity of NIAS.

The introduction of an additional food consumption group and refinements in the toxicological data requirements were welcomed by the participants. It was questioned whether endocrine activity should be tested for any tier and not only in case of existing data indicating such activity or high exposure. Also the possible consideration of cocktail effects/additivity was discussed in the context of the evaluation of regulated substances and of migrats (i.e. mixture of substances migrating from finished articles). It was noted that when a substance shows similarities with other evaluated and authorised substances, the substance under evaluation may be included in the existing specific migration limit applying to already authorised substances upon scientific evidence. When the "substance" that is evaluated prior to authorisation is a mixture (e.g. process mixture), it is characterised, considered as a whole and the restriction applies to

the whole mixture. In the case of migrat, the lack of characterisation and variability of its composition are a limiting factor. Direct analysis and testing of migrats instead of individual substances might provide some insight.

5.2. French draft Guidance on non-harmonised FCM

Bruno Teste presented the French draft Guidance on non-harmonised FCM. The summary provided by the speaker is reported below.

"Food contact materials (FCM) are regulated by the framework Regulation (EU) No 1935/2004. Nevertheless non-harmonized regulations are in place for many FCM such as: paper and board, wood, inks, metals… Different member states national agencies have initiated work related to non-harmonized FCM. ANSES' objective is to establish some guidelines for the assessment of non-harmonized materials. These guidelines will indicate all needed information for ANSES to perform risk assessment. Two decision trees for the specific case of non-intentional added substances (NIAS) will be proposed. The first tree will be used for substances that belong to the threshold of toxicological concern (TTC) approach, the second to the substances excluded from the TTC approach. These trees will be used only for the administrative admissibility of the technical dossier and do not condition marketing authorization. These guidelines should be published by the end of 2016."

The discussion focused mainly on the exclusion criteria shown in the different decision trees intended to be used for the acceptance of dossiers (i.e. their validity). How and if additivity or endocrine disrupting activity are to be considered in the decision trees is not decided yet. For the risk assessment of substances, once dossier are accepted, the revised toxicological thresholds as proposed in the recent EFSA opinion on safety assessment of substances used in FCM could be taken into account instead of the current theoretical exposure level (TEL) approach. This was considered as a valuable step for EU-harmonisation.

5.3. EFSA's activities

In the light of the minutes[5] of the European Commission Standing committee on Plants, Animals, Food and Feed where a proposal for deletion of Article 11(2) of Regulation (EU) No 10/2011[6] (leading to the removal of the generic specific migration limit of 60 mg/kg) was discussed, Alexandros Lioupis presented preliminary work on possible implications for EFSA activities.

5.4. EFSA's training on Benchmark Dose (BMD) modelling and computational toxicology and modelling tools

During the year EFSA offers the possibility to the members of the Network to attend training courses on advanced risk assessment, i.e. on Benchmark Dose (BMD) modelling and computational toxicology and modelling tools. A feedback on these trainings was given to the audience by Christa Hametner on behalf of

[5] http://ec.europa.eu/food/safety/docs/reg-com_toxic_20160419_sum.pdf

[6] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1–89.

Roland Grossgut who attended these courses last year. She acknowledged their good preparation, their usefulness and made proposals for future developments.

5.5. Use of the EFSA Document Management System (DMS)

Marco Lannutti trained the participants on the use of the EFSA Document Management System (DMS). It was shown how to 1) log in the EFSA DMS, 2) access documents, folders, communities, and 3) collaborate on documents.

5.6. Training on the Belgium database of substances known by Member States of the Council of Europe to be used: presentation, access and use

Fabien Bolle presented and gave a training on the so called "Belgium database" of substances known to be used by Member States of the Council of Europe. The summary provided by the speaker is reported below.

"As part of his work in the delegation to the Council of Europe, the Institute of Public health has created and developed a database of substances known to be used in materials and articles in contact with foodstuffs and currently provides its management. This database contains all known substances used in FCM in the Member States of the Council of Europe. It is based on national legislation, regulations and guidelines of the Commission or the resolutions of the Council of Europe. It contains approximately 10,000 substances, with their CAS number (if available) and their presence in different lists. For these substances, results from several existing toxicological prediction software (e.g. Toxtree, VEGA, OECD) can be found. The database project has the potential to have a permanent structure that can finally address this problem in the long term, constantly providing answers to questions raised by Member States. It also helps Belgium to have rapid information on the level of health concern related to the presence of non-evaluated substances."

Following the introductory presentation, exercises were provided to the Network. During the subsequent discussion, possibilities for further improvements and developments were discussed, e.g. the practicality to search within reports processed by the database, the report of the accurate mass of listed substances and its use as a search function.
It was noted that the same substance could have different restrictions depending on the FCM type and the Member State carrying out the evaluation. This does not represent *per se* an inconsistency. The evaluated uses can be different, the conclusion can be limited to the requested uses or extended to wider uses, the restriction can be expressed in different ways, etc.
It was clarified that the toxicological data included in the database are mostly based on computational methods (sometimes from ECHA) and do not originate from the literature. These data could be used for prioritisation purposes, but do not replace the risk assessment process.
Whereas the database reports on single substances, the access to list of substances could be made available to Member States under confidentiality and upon request.

5.7. EC DG SANTE activities: update on EC food contact materials baseline study

Jonathan Briggs gave an update on the EC food contact materials baseline study. The summary provided by the speaker is reported below.

"The purpose of the framework Regulation (EC) No 1935/2004 on food contact materials (FCMs) is to ensure the effective functioning of the internal market for FCMs and secure a high level of protection of human health and the interests of consumers. The Regulation sets out general safety requirements for all FCMs although specific measures for groups of materials and articles may also be introduced, such as is the case for plastic FCMs. In the absence of such specific measures, Member States may maintain or adopt their own national provisions. However, these national provisions cover different materials and substances, differing in scope, approach and with different specific requirements from one Member State to another. The divergent national measures and lack of sufficiently harmonised measures at EU are seen by some stakeholders as a barrier to trade and may impede the functioning of the internal market.

The European Commission's Joint Research Centre (JRC) was entrusted by DG SANTE to carrying out a baseline study in order to provide a comprehensive description of the current situation concerning FCMs for which there are no specific measures at EU level. The objectives of the baseline study were to a) collect and organise information on the current national measures or other measures in place for these materials, b) collect information from different material supply chain and c) analyse the efficiency and effectiveness of the existing national measures as regards safety and compliance as well as the associated burden for Member States and industry, including possible barriers to trade. Preliminary findings indicate that as regards different risk assessment petitions, although in theory they are based on the principles of EFSA, they may require additional specific requirement and on different templates for different Member States with difficulties also in the flow of information.

The information from the report will allow the European Commission to assess the efficiency and effectiveness of the current situation, including the benefits as well as the administrative burdens and costs of the existing situation on businesses."

During the discussion, it was underlined that the awareness of national legislations could support mutual recognition between Member States. Therefore the finalisation of the report along with the translation of the main national legislations is considered of high priority by the network members. It was pointed out that the number of substances identified through the baseline study as non EU-harmonised and the number of substances listed in the "Belgium database" (see 5.6) are in the same range of magnitude. As part of the exercise, the list of chemicals authorised under the "plastic" Regulation (EU) 10/2011 was also compared with the chemicals classified as substances of very high concern

(SVHC) under the REACH Regulation (EU) No 1907/2006[7]. According to the EC, the report of the "study" should be finalised in the coming weeks.

5.8. Update on the draft EC JRC guidelines on plastic migration testing including 6th amendment

Eddo Hoekstra gave an update on the draft EC JRC guidelines on plastic migration testing which takes into account the 6th amendment. The summary provided by the speaker is reported below.

"Regulation (EU) No 10/2011 sets some new rules and requirements for legislating plastic contact food materials and articles. In support of this Regulation a technical guideline on compliance testing is foreseen. A joint Task Force of the Joint Research Centre (JRC) and Directorate General Health and Consumer Protection (DG SANTE) of the European Commission prepared these guidelines using input from various experts and stakeholders.
The discussions in the Task Force resulted in proposals to improve the legal text of Regulation (EU) No 10/2011 on several aspects. Most of these proposals will be incorporated into the 6th amendment of the Regulation. This presentation provided an update of the current situation."

The 6th amendment should be adopted and published by the end of 2016. Clarifications on a possible transitional phase for the on-going applications were deemed necessary.

5.9. Update on the German research project on migration from elastomer

Stefan Merkel gave an update on the German research project "Migration from elastomers for food contact". The summary provided by the speaker is reported below.

"The objective of the research project is to survey the nature and quantity of migration of additives, impurities and reaction products from elastomers for food contact.
For the research project different kinds of elastomers like natural and synthetic rubber as well as thermoplastic elastomers were used as samples. These materials are used in many different applications for food contact. For the project 50 different elastomer samples were extracted and 164 substances could be identified. In addition to GC-MS and HPLC-MS methods GCxGC-ToF was used for non-target analytic. Using this method for extracts of ethylene propylene diene monomer (EPDM) rubber and natural rubber, substance groups like n-alkanes, mineral oil saturated hydrocarbons (MOSH), and mineral oil aromatic hydrocarbons (MOAH) were detected. Additionally, a HPLC-APCI-MS/MS method for quantification of 14 different N-nitrosamines in acetic acid and 50% ethanol migrates of elastomers was validated. The validation of multi analyte methods

[7] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

has not yet been completed. An assessment of the results and a consideration of the results in BfR Recommendation XXI are planned."

During the discussion following the presentation, it was underlined that the 164 substances identified refer to substances extracted from the materials. Migration experiments are in progress and no risk assessment is available yet. This is an example where, if necessary, the Belgium database (see 5.6) could provide a first hint on their possible effects. Interest in dynamic migration testing (elastomer-tubing) was expressed. It was reported that dynamic systems are also used for testing physical ageing of water pipes in technical centre for building and may give some insight for developing migration testing under dynamic conditions.

5.10. French research project on the determination of rubber specific simulant(s)

Bruno Teste presented the on-going French research project on the determination of rubber specific simulant(s). The summary provided by the speaker is reported below.

"FCM risk assessment is based on substances identification, quantification and migration from the material into the food using standardised protocols. These protocols have been standardised in the case of plastic materials assessment for which established simulants and contact conditions to apply exist. These conditions were then transposed to rubber materials but were not specifically adapted. In this context, ANSES started a research project in collaboration with the national laboratory of metrology to establish rubber specific simulants. The first results highlight that the current simulants and testing conditions for fatty food and milk products are not adapted for rubber materials. Indeed, these conditions could lead to structural modifications of rubber materials and thus leading to biased migrations. Preliminary results for the establishment of new simulants and testing conditions for milk simulants were obtained."

The discussion following the presentation focused on the choice of the food simulants, the testing conditions and related overestimation. As for plastics migration testing, it is important to assess first the migration and kinetics into food simulants and into foods to set appropriate food simulant(s). The determination of rubber specific simulants was identified as an area of common interest, as shown by the presentation of a German research project on migration from elastomer (see 5.9). Collaboration between ANSES (FR) and BfR (DE) would be very valuable for all Member States and for harmonisation.

5.11. Industry view on the application of plastics testing conditions / methodology to non-plastic FCMs

Peter Oldring presented the view of the Industry platform for non-EU harmonized FCM on the application of plastics testing conditions to non-plastic FCMs. The summary provided by the speaker is reported below.

"The lack of EU harmonised legislation for many FCMs can create misunderstanding and confusion, particularly where migrants and conditions for

testing for migration are concerned. In the absence of guidelines, the rules for plastic FCMs in Regulation (EU) No 10/2011 are frequently applied and sometimes mis-applied. The impending publication of 'Technical guidelines for compliance testing - In the framework of Regulation (EU) No 10/2011 on plastic food contact materials' raised concerns amongst the wider FCM community. Consequently 18 professional associations are participating in an initiative to propose testing conditions for their classes of FCMs. Not all conditions in Regulation (EU) No 10/2011 are inappropriate but in cases where they are, alternatives are being proposed.

Each association will host their own guidelines in order that they can be referenced by whomever. The overall format is similar for all. There is an introductory 2 page document available showing where to find individual associations guidelines. Some guidelines have already been published and others will be in the next few months. Different FCMs will, in some cases, need different testing protocols. As knowledge increases, guidelines will be updated."

In the discussion following the presentation, the Network welcomed the work of industry panels on migration testing for the non-plastics. This is one of the areas of interest of the Network and some Member States also reported that plastic migration testing does not apply to any FCMs under any circumstances. This is considered to be very important for safety assessment, control and compliance with Article 3 of Regulation (EC) No 1935/2004. The Network took note that link(s) to Industry guidelines will be put on the JRC website, even though this does not mean that they have been endorsed by JRC. The Network especially acknowledged that the proposed migration testing conditions should be based on scientific evidence, and that the latter should be made available in order to further discuss and consider Industry proposals. Commonly agreed proposals could be implemented into possible future EU-wide guidelines. National Reference Laboratories (NRL) and JRC as the European Reference Laboratory (EURL) should be involved in such validation.

5.12. Examples and discussion of evaluation of NIAS including oligomers

Examples of evaluation of NIAS including oligomers were presented by Beat Brüschweiler (CH), Bruno Teste (FR), Stefan Merkel (DE) and Laurence Castle (EFSA CEF Panel). The summaries provided by the speakers are reported below.

CH: "According to the Commission Regulation (EU) No 10/2011, any potential health risk from non-intentionally added substances (NIAS) in food contact materials (FCM) should be assessed in accordance with internationally recognized principles in risk assessment. Some guidance documents have been recently published regarding the toxicological evaluation of NIAS (e.g. ILSI, 2015[8]; EFSA CEF Panel, 2016[4]). Within this presentation toxicological assessment of NIAS was demonstrated by means of five real cases that occurred in the last years. Application of methods and tools supportive of creating the toxicological profiles, deriving adequate thresholds and fixing migration limits

[8] International Life Sciences Institute (ILSI), 2015. Guidance on best practices on the risk assessment of non-intentional added substances (NIAS) in food contact materials and articles. ILSI Europe Report Series 2015, ISBN: 9789078637424. DOI: D/2015/10.996/39.

were shown and conclusions and recommendations for future NIAS evaluations were given."

FR: "The risk assessment of non-intentionally added substances (NIAS) appears challenging since unknown NIAS can be present at very low concentrations. NIAS are not explicitly mentioned in EU legislative text other than Regulation (EU) No 10/2011. Their risk assessment is based on the same approach as established for IAS. France has formulated regulation concerning materials exposed to ionizing radiations (> 10 kGy) that clearly mentions NIAS screening for substances evaluation prior to marketing authorisation. In this context an example of NIAS risk assessment was presented for multilayer plastic films submitted to ionizing radiations. These radiations led to NIAS (in this case degradation products) formation from an antioxidant intentionally added in the material. Degradation products identification and quantitation were based on a large analytical screening using GC-MS combined with knowledge on degradation pathways from the starting substances. Two degradation products were identified and the determination of their specific migration led to toxicological studies."
In the discussion following the presentation, it was clarified that the genotoxicity tests required refer to the identified NIAS, not to the antioxidant from which they are formed. According to the French guidelines on ionizing treatments of plastic FCM, genotoxicity tests are required when the theoretical exposure level (TEL) to products formed due to the treatment is above 0.5 µg/person/day. Below this level, scientific argumentation is acceptable if well supported.

DE: "Official control laboratories have tested the migration of oligomers from epoxy can coatings, polystyrene and polyamide 6 and 66. BfR was asked to evaluate the results.
The migration of cyclo-di-BADGE from epoxy coatings into fish in oil preserves was determined to be up to 2 mg/kg. The exposure resulting from an average consumption of canned fish does not pose health concerns. For high consumers, the acceptable intake of 90 µg/person/day for substances classified into Cramer structural class III may be exceeded.
Up to 51 µg/kg as sum of styrene di- and trimers was measured in migration solutions of polystyrene articles. At this level negative health effects on consumer are not expected. Higher migration rates as measured from foamed PS articles cannot be evaluated to the lack of appropriate toxicological data.
Dimers migrating from kitchen utensils made of polyamide 6 have been found up to 1.5 mg/dm². For sausage casings made of polyamide 66, the migration of dimers was up to 0.43 mg/kg. Furthers oligomers up to 1000 Da are migrating simultaneously. Assuming that one meal per day is prepared with kitchen utensils made of PA6 with a contact surface of 1 dm², the resulting exposure exceeds the exposure not expected to pose a health risk by far. The migration from the artificial casings analysed is not expected to endanger consumers assuming mean sausage consumption for children and adults.
In most cases data which would allow to derive toxicological thresholds for migrating oligomers are not available. The application of the TTC concept (Cramer classification) and of *in silico* assessment tools in connection with a specific exposure assessment can be helpful."

EFSA/CEF Panel: "Examples for the evaluation of oligomers in the context of the safety evaluation of monomers, cross-linkers and polymeric additives were presented. The low molecular weight fraction (LMWF) can be analysed in the polymer itself and/or in food simulants, using e.g. gel permeation chromatography (GPC), size exclusion chromatography (SEC), GC/MS, LC/MS. The LMWF of the polymers or migrating from the polymers made with and without the applied substance (e.g. for crosslinker) can be compared to analyse the extent in which the oligomeric fraction is affected by the use of the applied substance. When migration in food simulants is not available, migration can in first instance be evaluated using modelling or based on the assumption of total mass transfer of the oligomers characterised in the polymer. Concerning the toxicological evaluation of the oligomers, different approaches were reported such as the evaluation of toxicological data on the oligomers, the read across with e.g. monomers or related substances, hydrolysis of the oligomers into evaluated substances, loss of the functional group. As part of the restriction on the applied substance, migration of oligomers can be limited by a specific migration limit or through the restriction in use of the applied substance which ensures the migration of oligomers stays with the range of the evaluation."

One point of discussion following the presentation was risk assessment of pre-polymers. According to Regulation (EU) No 10/2011, pre-polymers can be used without being evaluated and further authorised if the monomers or starting substances required to synthesise them are already included in the Union list. It was questioned whether, in this case, pre-polymers do need to be evaluated as starting substances. On one hand, monomers are expected to be more reactive than the pre-polymers and may represent a worse case as regards genotoxicity potential. On the other hand, it was stressed that, in general, the risk assessment approach should focus more on the final FCM than on the starting substances, as this is what the consumer is exposed to. This approach was also proposed in the EFSA opinion on "Recent development in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in FCM" (see 5.1).

In a general discussion on the evaluation of NIAS, the development of a common stepwise approach of methods was questioned. A range of approaches were illustrated in the Swiss presentation such as the use of available experimental data for the substance or through read across, TTC, toxicological profiling (TTC plus (Q)SAR plus molecular modelling). Those approaches can be used alone or combined. Pieces of information are provided in the EFSA opinion on "Recent development in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in FCM" (see 5.1). Also the French guidelines on ionizing treatments of plastic FCM provide guidance for evaluating NIAS. It was underlined that, in line with the assessment of intentional used substances, the extent of the required toxicological data or information set should be related to the exposure along the lines that the higher the exposure, the greater the amount of toxicological data is required.
The use of *in silico* methods was discussed. They are useful tools in the prediction of possible effects, but the results should be interpreted carefully. It was noted that no guidance is available for the use of multiple software, whereas different softwares may provide different responses.

It was mentioned that evaluated NIAS (e.g. by EFSA, National Agencies) could be referenced, listed with the outcome of their evaluation. This could avoid repeating evaluations and being also useful for compliance to be performed by Industry and controlled by Member States.
In the general context of sharing and making use of existing information and data for safety assessment, the Network referred to the ECHA database from which summaries are available, but not the raw data necessary to carry out a safety assessment.

5.13. Training on EFSA Comprehensive database: presentation, access and use; Information on Food label database

Food group categories set in the EFSA opinion on "Recent development in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in FCM" (see 5.1) are based on the food consumption data from the EFSA Comprehensive database[9] (with the exception of consumption of water by infants that comes from WHO).

Davide Arcella provided training on the information available in the EFSA Comprehensive database and in the Global New Products Database (GNPD) ("Food label database"). The summary provided by the speaker is reported below.

"The Comprehensive Food Consumption Database is a source of information on food consumption across the European Union (EU). It contains detailed data for a number of EU countries. The database plays a key role in the evaluation of the risks related to possible hazards in food in the EU and allows estimates of consumers' exposure to such hazards, a fundamental step in EFSA's risk assessment work. The database is also relevant to other fields of EFSA's work, such as the assessment of nutrient intakes of the EU population. EFSA used its food classification system 'FoodEx' to categorise all foods and beverages included in the Comprehensive Database. Summary statistics from the database enable quick screening for chronic and acute exposure to substances and organisms that may be found in the food chain. In the database, dietary surveys and food consumption data for each country are divided by category. These include: age, from infants to adults aged 75 years or older; food group (over 1,500) and type of consumption, covering both regular and high consumption thus allowing calculations to be tailored to each category of consumer. These food consumption statistics are stored and presented in the EFSA Data Warehouse. The statistics on food consumption are reported in grams per day (g/day) and grams per day per kg of body weight (g/kg bw per day). The statistics for chronic food consumption are available for the total population ('all subjects') and for consumers of respective food categories. The statistics for acute consumption are available for all days and for the consuming days.
A long term objective of EFSA is the acquisition of a harmonised pan-European Food Consumption database within the framework of the EU Menu process "What's on the Menu in Europe?" (EU Menu). In December 2014, EFSA published the guidance on the EU Menu methodology. This guidance was based on the 2009 EFSA guidance, two EU Menu feasibility pilot studies and two methodological projects, and its aim is to cover the EU Menu methodology and

[9] https://www.efsa.europa.eu/en/food-consumption/comprehensive-database

therefore facilitate the collection of more harmonised food consumption data from all European Union Member States by the year 2020. This guidance has been developed by the EFSA Evidence Management Unit (DATA) and the EU Menu Working Group with Advisory Function, and has been endorsed by the EFSA Network on Food Consumption Data.
In June 2015 EFSA signed a contract with MINTEL in order to have access to the Global New Products Database (GNPD). The GNPD monitors product innovation in consumer packaged goods markets worldwide and allows searching, multi-filtering, downloading and running analysis on a number of variables, e.g. packaging (types, materials, size, limited edition, decoration, ink, etc..), packaging claims (e.g. environmental friendly, product friendly, edible, etc.), food Ingredients including chemical substances, food additives, enzymes, nutrients. GNPD currently covers: 20 Europe members, 12 EU non-members, Middle East & Africa countries, 12 North and South American countries and 17 Asia Pacific countries."

In the discussion following the presentation of the two databases, it was clarified that the Food label database only gives an overview of the products newly placed on the market, also with information on the respective package, whereas consumption or market share of the foods are not reflected.

The EU Menu project is instead dedicated to food consumption and aims at, in the future, also including information on the food packaging material which will be retrieved from the Member States' national dietary survey.

5.14. Council of Europe (CoE) activities

As the Chairman of the scientific expert Committee on packaging of the Council of Europe and in the absence of Susanne Bahrke, Fabien Bolle presented the CoE activities. The summary provided by the speaker is reported below.

"The Council of Europe is preparing a "framework resolution" to summarise all the common concepts related to non-plastic materials in only one document. The Council also actively works on a resolution on paper and board. It began the revision of the resolution on cork and ion exchange resins. Review of the resolution on coatings is envisaged for 2017 and the resolution on metals and alloys is currently open for comments for a possible revision."

5.15. Joint Research Centre (JRC) scoping investigations on release of metals from ceramics ware, crystal ware and bake ware in foodstuffs and simulants

Catherine Simoneau presented scoping investigations of the JRC on release of metals from ceramics ware, crystal ware and bake ware in foodstuffs and simulants for which the provided summary is below.

"The European Commission has been considering a potential revision of Directive 84/500/EEC to introduce different limits and potential expansions of scope (metals, articles covered, tests). The work done by JRC was presented and included investigations on tests for testing metals migration from ceramic materials. The work aimed to provide a better understanding on the release of metals from ceramics into foods and food simulants, and to develop adequate

approaches for testing these articles including towards potential lower limits including for repeat use. In the present work, the release of metals from more than 100 ceramic, tableware and cookware samples as well as crystal articles were investigated. In a first phase previously presented, 3 different testing regimes were compared (conventional using acetic acid and room temperature, citric acid at 70°C as for metals and alloys guide, and an accelerated test). Repeat use was investigated. The release of metals was also studied into tomato sauce as an example of benchmark food. In this second phase, consecutive tests were evaluated and the results of multiple migrations with and without weekend time gap in between migrations were compared. A study of storage effect (to equate) occasional use and its impact on release of metals was also performed. Testing was investigated for tableware, bake ware and for crystal articles both in foods with kinetics an repeat testing, as well as with simulants. Precision criteria for different analytical quantification methods were also derived from 2 inter-laboratory comparison involving 55 laboratories. The results are presented and show in particular that analytical methods are equivalent for the quantification of various metals released. They also indicate that a gap between migrations tests due to a weekend had limited effects on migration to the extent that gap could be accepted for the demonstration of compliance. It also showed that for crystal ware, the testing regime currently in use for ceramics would not be representative of real use nor appropriate as conventional test."

In the discussion following the presentation, it was clarified that further work has to be done for glass. According to EC, the timeframe for a potential revision of the Directive 84/500/EEC on ceramic articles [10] and for addressing metals should be set out by the end of 2016.

5.16. German research project on metal (such as Al) release from metals and alloys

Stefan Merkel presented the German research project on metal release from metals and alloys ("Aluminium release from food packaging"). The summary provided by the speaker is reported below.

"The objective of the research project is to investigate the release of aluminium from uncoated aluminium utensils. For the research project aluminium espresso makers and foil dishes were used as samples. For the espresso makers the specific release limit (SRL) was reached at the 3rd test (relevant for multiple uses) when using artificial tap water. No relevant release was detected if coffee was used. An increase in release rates was observed after dishwasher cleaning, but the SRL was still within the limit. The release of aluminium from foil dishes was tested with different foods and simulants. Lactic and citric acid led to a higher and artificial tap water to a lower release of aluminium compared to foods (apple sauce, tomato purée, sauerkraut juice). Furthermore, thallium was accompanied with aluminium and was detected in every test made with foil dishes. For aluminium and thallium different test conditions were investigated and kinetic release tests were carried out."

[10] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs. OJ L 110, 30.4.2005, p. 36–39.

During the discussion following the presentation, it was clarified that sources other than food or FCM had not been yet considered for assessing exposure to aluminium. The extent to which dermal exposure (e.g. from cosmetics) could contribute to the overall intake of aluminium is not yet completely examined and needs further investigation, also in collaboration with industry. In addition, the origin of thallium released along with aluminium was discussed.

5.17. 1st step toward a Danish regulation on fluorinated substances in paper and board and test strategy of paper and board food contact materials

Gitte Alsing Pedersen presented the plan for a Danish regulation on fluorinated substances in paper and board as well as a test strategy of paper and board food contact materials. The summary provided by the speaker is reported below.

"FCM shall comply with Art. 3 of Regulation (EC) No 1935/2004 and Denmark requests compliance declaration for all types of FCM including paper and board. Since August 2015, a Danish national recommendation restricts the use of fluorinated substances to 0.35 µg total organic fluorine/dm^2 paper and board with the aim to reduce the potential human exposure of fluorinated substances intentionally used. Risk assessment is lacking for most of fluorinated substances and information on exposure to the substances from paper and board is either limited or not available. The Danish restriction was based on i) the assumption that several fluorinated substances are suspected to be carcinogenic, immunotoxic and endocrine disruptors, ii) their potential for accumulation in man and in the environment and iii) their potential to become a secondary source of human exposure.

A four year Danish project on mixture effect of chemical substances was finished in 2015. Part of the project aimed at developing a strategy to identify chemical substances in paper and board FCMs and evaluate their toxicological potentials. The approach involved a step wise process initially applying cost-effective quantitative structure activity relationship models (QSARs) to predict toxicities of compounds from an inventory list. Subsequently the strategy includes an extended effect-directed analysis panel of *in vitro* assays of sample extracts covering endocrine-related activities, oxidative stress, genotoxicity, mutagenicity and cytotoxicity combined with advanced state-of-the-art analytical chemistry to identify active chemicals. In continuation of the project, on-going work on quantification of unknown chemicals in paper and board is in progress (presented at the second FIP FCM Network meeting in July 2015)."

During the discussion, it was clarified that the restriction of total organic fluorine/dm^2 paper and board would include, *per se*, all fluorinated substances independently of their sources such as those authorised for inks. The restriction being hazard-based, data on exposure scenarios and occurrence in food would be needed to carry a risk assessment. Given the interest of Austria in further investigations in this area, a collaboration between Denmark and Austria could be built and be beneficial to achieve developments in the area of risk assessment of substances used in paper and board. The question of the identity and assessment of substitute(s) to fluorinated substances was also raised.

As a follow up of the EFSA Scientific opinion on perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts (EFSA, 2008[11]) and the EFSA Scientific report on perfluoroalkylated substances in food: occurrence and dietary exposure (EFSA, 2012[12]), EFSA is currently preparing a scientific opinion on the evaluation of perfluoroalkylated substances[13]. The deadline is July 2017. The outcome of this assessment could help achieve a broader understanding of possible effects from this class of substances.

5.18. Spanish research project on exposure to chemicals from food packaging. Study and evaluation of new emerging contaminants

Perfecto Paseiro presented a Spanish research project on exposure to chemicals from food packaging including study and evaluation of new emerging contaminants. The summary provided by the speaker is reported below.

"The project aims to:

- Study of the risk assessment by estimating exposure to certain chemicals transferred from food contact materials.
- Establish an analytical protocol for the identification of NIAS. At present there is no standard method for addressing this subject.

Study design includes: selection of the population of interest (e.g. infants, adults, elderly, specific groups): selection of target migrants (IAS, including prepolymers) packaging and foods; food sample collection (regarding possible variables affecting migration); selection and development of analytical methods, screening of packaging (identification of IAS and NIAS), food sample preparation (e.g. pools, cooking of foods) and food analysis; estimation of exposure.
Special focus was drawn on pre-polymers. Pre-polymers, when used as monomers or starting substances, are substances authorised if the monomers or starting substances required to synthesise them are included in the Union list (Regulation (EU) No 10/2011, Art. 6). Pre-polymers are not evaluated as such. They have not specific restrictions, only subject to overall migration limit. Not included in the Union list and excluded from assessment of substances in accordance with internationally recognized scientific principles on risk assessment (Regulation (EU) No 10/2011, Art. 19). It is in the interest of food safety to know the concept, nature and uses of these substances in the frame of food contact materials (coatings, adhesives, paper and board, etc.) as well as the migration levels in foods. FIP FCM Network was invited to collaborate in this research."

5.19. Compilation of Member States projects/researches (DMS)

As an initiative for facilitating the collaboration between Member States, Eric Barthélémy presented a template document to compile past, on-going and

[11] Opinion of the Scientific Panel on Contaminants in the Food chain on Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts, The EFSA Journal (2008) Journal number, 653, 1-131. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/653.pdf

[12] European Food Safety Authority; Perfluoroalkylated substances in food: occurrence and dietary exposure. EFSA Journal 2012; 10(6):2743. [55 pp.] doi:10.2903/j.efsa.2012.2743. https://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2743.pdf

[13] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00526

planned research projects. By filling in the respective information, awareness of the work done in other Member States should be strengthened and possibly lead to enhanced collaboration.

5.20. Lessons learnt on Member States cooperation on safety evaluation

Beat Brüschweiler and Stefan Merkel presented the Member States cooperation on safety evaluation of substances in printing inks between Switzerland (FSVO) and Germany (BfR) for which they provided the summary below.

"The Federal Food Safety and Veterinary Office (FSVO) of Switzerland and the Federal Institute of Risk Assessment (BfR) of Germany cooperate closely on safety evaluation of substances in printing inks. The joint evaluation started in 2012 and has successfully continued until today. In the last five years 60 petitions were received and approximately 30 substances were evaluated. Twice a year the petitions are discussed at the toxicology expert panel of the "BfR Committee for Consumer Products". This Committee serves as a joint panel for discussion and decision. The joint evaluation is well accepted by the industry and petitions are submitted to FSVO and BfR at the same time."

This approach of collaboration in risk assessment was considered as a good example for sharing methodologies leading to a higher level of harmonisation.

5.21. EFSA project on Transparency and Engagement in Risk Assessment (TERA)

Lucia de Luca presented the EFSA project on Transparency and Engagement in Risk Assessment (TERA). The summary provided by the speaker is reported below.

"EFSA believes that more meaningful engagement with a wider range of stakeholders will raise the quality of the Authority's work and help define the organisation as a trusted partner and as an active guardian of food safety in the EU. This is reflected in the first strategic objective of the EFSA Strategy 2020, which states that the Authority aims to prioritise public and stakeholder engagement in the process of scientific assessment. In 2012, EFSA initiated a review of the way in which it engages with its stakeholders and the new stakeholder engagement approach outlines the results of this review and offers a new approach for engaging with stakeholders. The new approach is only one of the components of a broader set of transparency and engagement policies at EFSA which see their practical implementations in the various initiatives headed by the Transparency and Engagement in Risk Assessment Initiative (TERA)."

5.22. Proposal for possible follow up in terms of scientific cooperation and future activities (including research)

Vittorio Silano summarised the most important points raised during the discussions of the FIP FCM Network meeting.

The Network represents an important opportunity to share methodologies and experiences between Member States and to build collaboration in the area of risk assessment in order to achieve a higher level of harmonisation. The importance of the Network was also confirmed by the Advisory Forum in its March meeting when it agreed to support a new mandate to continue the work undertaken under the current mandate that ends on 18th October 2016. Therefore proactive collaboration can further be enhanced in the following years.

An example of fruitful cooperation on the safety evaluation of substances in printing inks was shown by Switzerland and Germany. Further collaborative projects could be promoted by sharing information on research projects between Member States in an internal "database" updated by the representatives Member States (see 5.19). Sharing the database with National Reference Laboratories could be envisaged.

The EC activities in the context of the baseline study were considered essential to monitor the current situation on the non-harmonised FCM and for enhancing collaboration between Member States.

The migration testing for non-plastics was confirmed as a priority topic with already a considerable amount of on-going work for different kinds of materials. Collaboration between Member States, with scientific institutions (such as EC JRC and national laboratories) and industry representatives could be beneficial to promote and achieve harmonisation. An area for which expertise exists, researches are on-going and interests are shared by several Member States is that of rubber. Cooperation in this area that would benefit the harmonisation is the preparation of common proposals for researches, common position and common draft guidance for migration testing. This could be shared notably with the Network and could serve the development and the recognition of a harmonised guidance for migration testing in that area. This was mentioned as an example and there are other areas where some Member States share expertise and interest, e.g. coatings.

Some Member States also expressed interest on exposure to fluorinated substances. Cooperation could be built in that area as well.

NIAS remain an important and challenging area where collaboration is sought. The safety assessment of migrating NIAS would benefit from more guidance and experience from EFSA and Member States. Indications on the use of multiple software, on analytical methodologies and other approaches to evaluate human exposure to NIAS could help. A database of identified/evaluated NIAS migrating from different FCMs could be an added value for all.

As regards harmonisation of risk assessment methodologies, EFSA expresses the intention to involve the Network in the preparation of the new guidance for safety assessment of FCMs before it is submitted to public consultation.

Trainings in the area of safety assessment, such as those on advanced risk assessment (see 5.4), those given at the meeting (see 5.6 and 5.13), or on migration modelling, support the sharing of knowledge and cooperation in safety assessment. Hosting Member State scientists at EFSA, and participation in some FCM Working Group meetings were also mentioned.

To promote research initiatives aiming at a better harmonisation across Europe, Network members were reminded of the possibility to apply for thematic grants

to support these activities according to Article 36 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [14].

6. Concluding remarks

Claudia Roncancio Peña, Head of FIP Unit, commented on important aspects for enhancing the work of the Network: capability, transparency, awareness and communication. Combining these principles can be used to create a common programme and to share work in the several fields where research is still needed. The FIP FCM network coordinator Eric Barthélémy mentioned migration testing and harmonisation of guidelines as key elements to be addressed within the next mandate of the Network.

7. Date for next meeting

The next meeting of the FIP FCM network will fall under the new Network mandate, and will be organised in 2017. EFSA took note of the proposals for possible follow-ups and will submit a draft agenda to the Network members.

8. Closure of the meeting

The Head of FIP Unit and 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.

[14] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.