FOOD INGREDIENTS AND PACKAGING UNIT

Network on Food Contact Materials Minutes of the 7th meeting

Held on 6-7 November 2019, Parma

(Agreed on 11 December 2019)

Participants

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

Country	Name
Austria	Christa Hametner
Belgium	Els Van Hoeck
Cyprus	Antigoni Achilleos
Czech Republic	Jitka Sosnovcová
Denmark	Gitte Alsing Pedersen
Estonia	Katrin Jõgi
Finland	Merja Virtanen
France	Gilles Rivière
Germany	Stefan Merkel
Greece	Stella Kontou
Ireland	Karl McDonald
Italy	Riccardo Crebelli Maria Rosaria Milana
Lithuania	Skirmante Ambraziene
Netherlands	Krista Bouma Bianca van de Ven
Poland	Marzena Pawlicka
Portugal	Maria Fatima Poças
Slovakia	Milada Sycova
Slovenia	Viviana Golja
Spain	Perfecto Paseiro Juana Bustos Garcia de Castro
Sweden	Kettil Svensson Marie-Louise Nilsson
Norway	Inger-Lise Steffensen
Switzerland	Beat Brüschweiler

- **Intergovernmental organisation Council of Europe:**

Eugenia Dessipri

- **Hearing Experts**

Elina Karhu, Andreas Ahrens (ECHA)

- **European Commission:**

Jonathan Briggs (DG SANTE)

Eddo Hoekstra (DG JRC)

- **EFSA:**

REPRO Department: Guilhem de Seze (Head of REPRO Department)

FIP (Food Ingredients and Packaging) Unit: Claudia Roncancio Peña (Head of the FIP Unit), Eric Barthélémy (FCM Network Coordinator, Chair), Anna Federica Castoldi (FCM Team Leader), Mary Carfí (Flavourings Team), Consuelo Civitella (FCM Team), Cristina Croera (FCM Team), Alexandros Lioupis (FCM Team), Carla Martino (Flavourings Team), Foteini Pantazi (FCM Team), Ellen Van Haver (FCM Team), Katharina Volk (FCM Team)

BIOCONTAM (Biological hazards and contaminants) Unit: Katleen Baert

ENCO (Engagement and Cooperation) Unit: Sergio Potier Rodeia

FEED Unit: Paola Manini

SCER (Scientific Committee and Emerging Risks) Unit: Hans Verhagen

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

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

1. Welcome and apologies for absence

Guilhem de Seze, Head of EFSA's REPRO Department, opened the meeting. He highlighted the participation from European Commission and the European Chemicals Agency (ECHA) and underlined his appreciation for the high number of attendances from representatives of the Member States. One of the strategic objectives of EFSA is building the EU's scientific risk assessment capacity and knowledge community, and the Network meeting was acknowledged as an important platform for Member States to come together, share expertise and find opportunities for collaboration through the different topics outlined in the agenda and beyond. As one of the recent practical outcomes of the Network, the taskforce on varnishes and coatings for food contact materials was mentioned in which a joint effort between several Member States was made towards a harmonised approach for safety assessment of coatings. Especially in the area of FCM, with fragmentation and limited harmonised legislations at EU level, the work towards more harmonisation is of high importance. The Network was also informed that this meeting was the last of the three-year-mandate which finishes by the end of 2019. For the future collaboration with Member States, aspects of the recently

adopted Transparency Regulation[1] which will impact EFSA's way of working, were presented to the Network: emphasis is put on collaboration between different institutions and EFSA's role in facilitating collaboration with Member States, also by looking at EFSA's system of governance. Discussions are currently undertaken to define through which tools/processes these regulatory requirements can be achieved by EFSA. Once finalised, a more concrete idea could be provided on the future of the Network after the end of its current mandate.

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 in composition of the Network and role of members as regards Member State representatives, alternates and substitutes for the meeting. New participants introduced themselves.

Apologies were received from the following Member States: Bulgaria, Croatia, Hungary, Iceland, Luxembourg, Romania.

2. Adoption of the agenda

The agenda was adopted with the following changes: agenda item 7 was replaced by any other business (AOB) introduced as last discussion point on the first day. Agenda item 17 was moved after agenda item 21.

It was reminded that the minutes of the 6th meeting of the Network on Food Contact Materials held on 10-11 July 2018, Parma were agreed by written procedure on 27 July 2018 and published on the EFSA website[2] on 02 August 2018.

3. Declaration of interests and statement of confidentiality

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

4. European Commission DG SANTE activities

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

"The European Commission is preparing a Staff Working Document, due in the first part of 2020, to communicate the results and conclusions of the evaluation of food contact materials (FCMs) legislation. This will include an analysis of the effectiveness, efficiency, relevance, coherence and EU-added value of the current EU legislation. It will be used to inform decision making, priority setting and justify any possible changes to the current EU legislation on FCMs.
The Commission is also working to fully implement Commission Regulation (EC) No 282/2008 and to authorise approximately 130 decisions on the recycling of PET plastic for FCMs. An amendment to the Regulation is first being drafted to introduce a transition period, clarify obligations and responsibilities as well as a

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1381&from=EN
[2] https://www.efsa.europa.eu/sites/default/files/event/180710-m.pdf

Compliance Monitoring Summary Sheet, after which the Decisions will be introduced. Future work will focus on all recycled plastics and will seek to address chemical recycling.
As regards heavy metals, the Commission published an inception impact assessment in 2019 to describe the current situation for reducing limits for lead and cadmium in ceramics, with the possibility to include other metals as well as vitreous materials within the scope. An impact assessment will be consulted on in 2020. Other current issues include a planned EU measure on epoxysilanes, coordination of monitoring of FCM substances and new EFSA mandates as well as an ongoing amendment to Regulation (EU) No 10/2011."

The evaluation of the FCM legislation was identified as an important opportunity for building the future, for risk assessors as well as for risk managers, in the area of FCM, both in terms of further harmonisation and coherence with other interrelated regulations, e.g. REACH.
A question was raised concerning the concept of "non-detectable" for certain substances, set out in Regulation (EU) No 10/2011 via a detection limit of 10 µg/kg food. It was highlighted that this limit is often misused as a cut-off value under which the migration would be tolerable. The decrease of this detection limit to 2 µg/kg food for primary aromatic amines (PAA) as planned in the next 14th amendment of the Regulation was welcomed. It was questioned whether the detection limit of 10 µg/kg food set for other chemicals with such a restriction is still valid in view of the current analytical capabilities and safety criteria. DG SANTE highlighted that the possibility for lowering the limit in this specific case is clearly linked to the analytical capabilities and that further refinements of "non-detectable" values for compliance purposes may be possible for other substances that are currently included in the positive list with a "non-detectable" restriction, depending on analytical capabilities.

5. Council of Europe activities

Eugenia Dessipri presented the ongoing Council of Europe activities. 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[3]. 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[4].
Activities are steered since 2018 by the Committee for food contact materials and articles (Partial Agreement – 38 Member States) (CD-P-MCA). The second edition of the guidelines on metals and alloys is being prepared. Work for the adoption of a Resolution for all FCM (under the scope of Regulation (EC) No 1935/2004) that

[3] https://www.edqm.eu/en/resolutions-policy-statements
[4] https://register.edqm.eu/freepub

are not covered by specific legislation at a European level aims at formulating commonly agreed principles that ensure the quality and safety of these materials. Technical guides prepared to supplement the Resolution elaborate on specific issues. Work is in progress for a Technical Guide for FCM from paper and board, the peer-review of a multianalyte method for the analysis of contaminants from printing inks and a technical guide with instructions for the compliance documentation and declaration of compliance."

With regards to the guidelines on metals and alloys, explanations were provided on how the specific release limits (SRLs) are derived. In principle, SRLs are based either on a point of departure or a health-based guidance value usually set by a national, European or international Institution. A factor to consider other sources of exposure is allocated either based on the relevant exposure or fixed at 20% when relevant exposure data are not available. If toxicological reference values are not available and oral intake data are available (food, drinking water, other), SRLs are based on oral intake data without the application of allocation factor. In two cases (Al, Fe), the ALARA (As Low As Reasonably Achievable) approach is considered. Detailed explanations are provided in Article 4 of Chapter 1 of the Council of Europe guide.
Regarding Chapter 3 of the guide, it was clarified that the 2nd Edition will refer to the testing conditions (time, temperature) from the JRC guidance Part 2: Testing conditions for metal kitchenware (under preparation). The JRC guidance should also refer to the Council of Europe technical guide with regards to the scope, the simulants (0.5% citric acid and artificial tap water) and surface to volume conversion (envelop volume approach).
Besides, EFSA informed about the ongoing EFSA mandate on Nickel[5] (EFSA-Q-2019-00214, see EFSA Register of Question[6]) and the setting by ECHA of a TDI for silver ions (not published yet) in the context of the Biocidal Products Regulation. Whilst the use of the NOAEL on silver ions reported in the EFSA's 2016 Opinion on E174[7] for setting the SRL was questioned, the need to ensure coherence and harmonisation was underlined.

6. European Commission DG JRC activities

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

"The JRC "Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials" was published (S. Bratinova, E. Hoekstra (Editors), 2019, ISBN 978-92-76-00172-0, doi:10.2760/208879[8]). Hands-on training was given to national reference laboratories (NRLs) for food contact materials (FCM) and to official food control laboratories. The implementation of the mineral oil analysis in food and FCM by official control laboratories will be checked by two proficiency tests to be organised in 2020 and 2021.

[5] Request for an update of the EFSA scientific opinion on the risks to public health related to the presence of nickel in food and drinking water.
[6] https://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?4
[7] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4364
[8] https://ec.europa.eu/jrc/en/eurl/food-contact-materials/technical-guidelines

Another JRC guidance on "Testing conditions for kitchenware articles in contact with foodstuffs – Part 1: Plastics" was published (G. Beldi et al., 2019). A JRC Task Force is now working on testing conditions for metallic kitchenware.
Progress related to work on monitoring of recycling processes, development of test conditions for bakeware of ceramics, glass and enamels, development of multi-analyte methods by the EURL-NRL-FCM network and development of several guidance's for official control were also reported."

It was clarified that technical guidance on compliance testing of plastic FCM would consist of several parts. Aspects of sampling are currently being developed, while further considerations on testing when the FCM is already in contact with food, on verification of compliance and other issues are still needed. JRC clarified that the monitoring of recycling processes is first deemed to inform DG SANTE (see slide 13 of the presentation) who will consider what follow up should be given.

7. EFSA opinion on phthalates / Any Other Business

As indicated under section 2. on the adoption of the agenda, item 7 was replaced by an item on AOB introduced as last discussion point on the first day. Under this item, three topics were presented by ECHA, EFSA and BfR, dealing respectively with the drinking water directive, migration of nickel and migration of polyamide oligomers.

7.1 Drinking Water Directive (DWD)

A short update was provided by ECHA on the DWD in the context of its ongoing revision and particularly regarding the harmonisation of requirements for materials in contact with drinking water. On request by the Commission ECHA has provided technical support in further developing i) how to translate the existing national lists into the first EU positive list and ii) how to update the EU positive list (add new substances, remove substances, update the existing entries).

7.2 Data on migration of nickel from Food Contact Materials

EFSA's ongoing work on nickel was presented. An opinion on the risks to public health related to the presence of nickel in food and drinking water was published in 2015[9]. The opinion covered several exposure scenarios but not the one on exposure from FCM. The EFSA CONTAM Panel was now requested to update this scientific opinion, also with respect to migration of nickel from FCM (see EFSA Register of Questions, question EFSA-Q-2019-00214). The Member States are invited to send any relevant data/study reports on migration from FCM to contam@efsa.europa.eu by 9 December 2019.

7.3 Migration of oligomers from polyamide kitchenware

Germany presented the recently published BfR statement[10] on migration of oligomers from polyamide kitchenware. PA 6 (dimer to octamer) and PA 6,6 (monomer to tetramer) "have been assessed as non-genotoxic. However, high doses cause adverse effects in the liver and thyroid which are due to metabolism.

[9] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4002
[10] https://www.bfr.bund.de/cm/349/polyamide-kitchen-utensils-keep-contact-with-hot-food-as-brief-as-possible.pdf

Based on the available data, the value of 5 mg/kg of food was considered as being toxicologically acceptable as a group migration value for the compounds mentioned". The assessment was acknowledged, and it was particularly noted that a grouping approach was chosen for assessing a group of cyclic oligomers and that a SML(T) was established. The principles for evaluation of NIAS including oligomers outlined in the EFSA 2016 opinion on recent developments in the risk assessment and the impact on FCM[11] were reminded. "Safety assessment should focus on the low-molecular mass fraction and follow the tiered approach …". In case the migration exceeds 50 µg/kg food, the same requirements for the toxicological assessment as for the IAS apply. If the migration is below 50 µg/kg food, "…experimental testing may not be necessary". Non-testing methods like read across and QSAR could be applied in order to address the question of potential for genotoxicity.

8. VKM's ranking of substances for monitoring in foods

Inger-Lise Steffensen presented VKM's ranking of substances for monitoring in foods. The summary provided by the speaker is reported below.

"The Norwegian Food Safety Authority requested the Norwegian Scientific Committee for Food and Environment (VKM) to provide a ranked list of substances in foods, drinks and dietary supplements that may constitute a potential health risk for humans, based on the VKM members' expert judgements. Additionally, VKM should give an overview of the foods, drinks and dietary supplements most relevant for monitoring of the substances, as well as describe adequate sampling procedures, to ensure monitoring representative for the food intake in the Norwegian population[12].

The following groups and subgroups of substances were ranked:

- Natural toxins; with the subgroups mycotoxins, plant toxins, marine and freshwater algae toxins
- Metals and metalloids
- Persistent organic pollutants (POPs); with the subgroups brominated flame retardants, dechloranes, dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs), non-dioxin-like polychlorinated biphenyls (NDL-PCBs), perfluorinated and polyfluorinated alkyl substances (PFAS) and siloxanes
- Substances in food contact materials; with the subgroups bisphenols and phthalates
- Flavourings
- Additives; with the subgroups nitrites and nitrates, phosphates, sweeteners and synthetic antioxidants
- Process-induced contaminants; with the subgroups acrylamide, esterified 3- and 2- monochloropropane-1,2-diol (MCPD), glycidyl fatty esters (GEs), furans, heterocyclic aromatic amines (HAAs) and polycyclic aromatic hydrocarbons (PAHs)
- "Other substances"
- Trace elements

Veterinary medicine residues, illegal pharmaceuticals and pesticide residues were not included since they are already monitored. The ranking of the substances was

[11] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4357

[12] https://vkm.no/download/18.6d89b87d16d5ceab77710d3/1569227303176/Ranking%20of%20substances%20for%20monitoring%20in%20foods,%20drinks%20and%20dietary%20supplements%20-%20based%20on%20risk%20and%20knowledge%20gaps.pdf

based on toxicity (hazard) and level of exposure (both occurrence and intake). In addition, knowledge of vulnerable groups, adequacy of toxicity data and exposure data were considered. A simple methodology was used. More advanced methodology may be used in later updates of this ranking, if found useful."

The consideration of data gaps as a criterion was discussed. In the VKM prioritisation exercise, substances or group of substances with very little data on toxicity and/or on exposure, got a relative high score. Monitoring such substances can provide a better knowledge and understanding of possible issues around these substances in the future and help decide whether they need further prioritisation. Data on the actual use/occurrence of substances would be a valuable information. The outcome of this exercise, which was based on expert judgement, now needs to be put in practice and will possibly be updated in the future. Looking at the ranking and related scores, it was questioned why bisphenols S, F and AF have a score of 6.5 whereas BPA has a score of 3. This was said to be due to less available data for these substitute bisphenols compared to BPA. A comment was made that high BPF exposure could occur through consumption of mild mustard that contains high concentrations of naturally occurring BPF[13].

9. Prioritisation of substances for further regulatory action

Elina Karhu presented ECHA's prioritisation of substances for further regulatory action. The summary provided by the speaker is reported below.

"Prioritisation enables authorities to focus on (groups of) substances that have highest potential to cause risks to human health or the environment. ECHA makes use of all available data – primarily REACH registrations and classification and labelling inventory but also information from other sources – to select substances for further scrutiny. Prioritisation is also used to identify optimal combination of the regulatory actions. Where possible based on available data, substances are progressed to hazard confirmation (harmonised classification and for persistent, bioaccumulative, toxic (PBT)/ very persistent and very bioaccumulative (vPvB) and endocrine disrupting (ED) substances inclusion in the candidate list) or regulatory risk management measures (restrictions or authorisation under REACH or measures under another EU legislation). This said, as most of the substances with sufficient information are already under work, currently in many cases further information generation via REACH evaluation processes is the first step. ECHA has moved from substance-by-substance work to address substances as groups based on structural similarity. This supports prioritisation, ensures that we use all available hazard information and enhances consistency of the regulatory action on similar substances. Grouping and integrated implementation of the REACH/CLP processes are key to shorten the time from the identification of the (potential) concern until the appropriate regulatory measures are in place or it can be concluded that the substance is of low priority for further work by authorities. Prioritisation can also be used to increase predictability of the authorities work towards industry and other stakeholders. Furthermore, it provides a better basis for aligning actions under different EU legislation."

The Network acknowledged the participation of ECHA and the benefit of presenting an integrated regulatory strategy. It is important to better understand the

[13] http://dx.doi.org/10.1080/19440049.2015.1110623

processes under REACH, what data and how data are used, what criteria and with what outcome in order to facilitate the use of the work made. It was noted that prioritisation is also an opportunity to group chemicals and that it should be "fit for purpose" especially with regards to the next steps and work to be done. The discussion clarified that polymers are not included under the ECHA prioritisation scheme as there is no need for registration for these group of substances. They are indirectly dealt with via the registration of the respective monomers. Additionally, it was explained that a grouping based on the nano character of certain substances has not been conducted, as the primary focus of the prioritisation under REACH is on putting together groups of structurally related compounds. However, it should be noted that chemicals in nanosize such as fibres are considered under CLP. Interest in the actual composition of groups of structurally similar substances was raised as it could help also in other on-going prioritisation exercises. The Network was informed that an updated version of the "Mapping the chemical universe to address substances of concern - Integrated Regulatory Strategy Annual Report 2019"[14], will become available by the end of the year.

10. Prioritisation strategy for non-harmonised FCMs

Els Van Hoek presented the Belgian prioritisation strategy for non-harmonised FCMs. The summary provided by the speaker is reported below.

"Humans can be exposed to a large variety of substances coming from (non)-harmonized FCMs. However, not all these substances have (recently) been evaluated for their safety. A detailed characterisation of the complete toxicological profile of all these substances is not feasible. Therefore, prioritisation strategies need to be developed. *In silico* models have shown to be useful tools to assign priority to those substances for which a comprehensive safety evaluation is most urgently needed. A strategy, combining these *in silico* tools with literature data and *in vitro* experiments was developed and applied for the priority setting of substances that can be present in different types of non-harmonized FCMs such as coatings and printed paper and board. In addition, the strategy was also applied to assign priority to non-intentionally added substances (NIAS) migrating from plastic baby bottles since guidance on how their assessment (e.g. impurities, oligomers, degradation products and newly formed compounds) should be conducted is currently missing. Finally, the advantages and limitations of the approach are briefly discussed."

For evaluating substances that can be present in non-harmonised FCMs and for which no safety evaluation has been performed, as well as NIAS, BE proposes that the main criteria should be the genotoxicity potential. It was questioned whether the list of substances used for prioritisation was established based on analysis of samples or on information regarding the production of the different articles. It was clarified that for the exercise on baby bottles the substances were those identified from migration experiments, whereas for the study on paper and board and coatings, the existing list with potentially used substances was considered. When based on the migration, the identification of migrating chemicals is critical and

[14] https://www.echa.europa.eu/documents/10162/27467748/irs_annual_report_2018_en.pdf/69988046-25cc-b39e-9d43-6bbd4c164425

requires a proper analytical strategy. The need for screening methods will be touched upon under 17.

11. REACH Plastic additive initiative

Andreas Ahrens presented the REACH Plastic additive initiative. The summary provided by the speaker is reported below.

"In late 2016, ECHA and 21 industry sector organisations launched a joint project to characterise the uses of plastic additives and the extent to which the additives may be released from plastic articles. The project, which lasted for two years until December 2018, generated an overview of over 400 additives in plastics used in high volumes in the EU, and looked at how use and exposure information could be used to focus the regulatory work by authorities under REACH. The work included the development of a method for comparing the release potential of different additives. The presentation by ECHA provided on overview and analysis of the data obtained, as well as the learnings drawn so far from the project."

A common discussion was held on items 11. and 12., and the main points are summarised under item 12.

12. Prioritisation for evaluation of authorised substances with no restriction

Alexandros Lioupis presented EFSA's prioritisation for evaluation of authorised substances with no restriction. The summary provided by the speaker is reported below.

"An on-going prioritisation exercise on substances used in plastic FCM, requested by a mandate from the European Commission, was described. The substances have not been evaluated by EFSA Panels working on FCM, and their inclusion in the Union list of Regulation (EU) No. 10/2011 is mainly based on earlier risk assessments, conducted by the Scientific Committee on Food (SCF). They are included in the Union list without a specific migration limit (SML). EFSA is asked to review the substances without an SML and to identify those substances for which an SML would be necessary, grouping them in high, medium and low priority, which will serve as the basis for future re-evaluations of individual substances. The use of existing knowledge on the chemistry and toxicology of these substances is needed for the priority setting and therefore the task includes searches in relevant public databases, Union lists and the use of predictive tools. The sources of information and the lack thereof, along with some preliminary results, were presented."

Comparing the figures reported in ECHA and EFSA prioritisation exercises, only 85 substances appear to be present both in the Union list of Regulation (EU) No 10/2011 and in the list developed through the REACH plastic additive initiative. The discussion firstly focussed on the identification of potential reasons. Monomers and other starting substances are not included in the initiative. The latter covers additives that are registered with a production volume of more than 100 tons and may exclude those produced at a lower volume. Additives are used for all kinds of plastics hence are not restricted to food contact plastics only. Besides, the information such as the intended uses may be not well reported in the REACH

registration dossier. The naming convention of substances may contribute to differences in the figures. A common naming with CAS number and/or other EC names would facilitate cooperation and identification of substances of common interest.
In addition to concerns for toxicity, another component of prioritisation is the migration potential of a substance. In the absence of migration data and information on substance identity and function, it was suggested that a worst-case calculation could be undertaken based on typical concentration ranges associated to the function of the additive. Together with information on the physical and chemical properties, this could inform the migration potential and the prioritisation.
As a general remark for all the prioritisation exercises presented, it was stressed that it is important to understand the criteria for prioritisation. In order for the different prioritisation exercises to represent a benefit for all parties involved and/or interested, the strategy and criteria should be coherent for exercises with a similar scope. In the case of the prioritisation exercise carried out by Belgium for substances not evaluated yet at the European or national level (NIAS and non-EU harmonised IAS), the main criterion is the potential genotoxicity of substances (a non-threshold principle being applied to genotoxic carcinogen). Acknowledging the methodology and the experience gained, it was questioned whether other criteria, e.g. ED, PBT, used in the ECHA's integrated regulatory strategy should or should not be included.
Overall it was identified that ECHA has a lot of experience in different prioritisation strategies, and their knowledge could be of help for other institutions that face similar challenges.

13. Welcome and practical information of the second day

The chair welcomed the participants and updated them on the agenda and the unfolding of the day reminding the move of item 17 after agenda item 21.

14. Compilation of Member States projects/researches

Gilles Rivière presented the compilation of Member States projects/researches. 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 several hundred 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 Member States. Currently, 29 projects related to the area of FCM from 12 Member States have been identified from the compilation of researches."

France was thanked for leading this task in the interest of the whole Network, as it is an important tool for building collaborations by raising awareness and consequently avoiding duplication.
Several Member States informed about a few non-reported projects. Further to the discussion, it was agreed to include any project types related to the safety assessment of FCM and related substances (e.g. research projects, development

of guidance documents, desk research, etc). For instance, the BfR's assessment of polyamide oligomers should be added as it provides support to the assessment of oligomers in general. To avoid duplication in areas of common interest to several Member States, timely information on future projects is key, when it is still feasible to start a collaboration. Thus, it was agreed to include future projects planned to start in 2020 and beyond. It was also commented that the context, objectives and possible follow-ups of the various researches would be a valuable information.
Network members were invited to double check the entries and to include any missing current and future activities related to the safety assessment of FCM. The working file will be further refined, by establishing groups related to chemicals, plastics, etc, which can facilitate the identification of areas of common interest.

15. EFSA activities on microplastics

Hans Verhagen presented the EFSA activities on microplastics. The summary provided by the speaker is reported below.

"The environmental and human health risks posed by micro and nanoplastics have recently been subject to increasing regulatory and scientific scrutiny. Micro and nanoplastics (synthetic polymer-containing particles <5mm) can be formed through the wear and tear of larger objects, including synthetic textiles and tyres. They can also be manufactured and intentionally added to products, e.g. cosmetics, fertilisers, detergents, paints. Once released into the environment, they are persistent and may be accumulated by animals, including fish and shellfish, and consequently consumed in food by consumers. EFSA has been addressing nanoscience and nanotechnologies in the food chain for some years, producing guidance on risk assessment in 2011, and updating this for human and animal health in 2018[15]. Microplastic and nanoplastic particles in food were first flagged as a potential future food safety issue by EFSA's Emerging Risks Exchange Network. In reaction to this and as a first step towards a future assessment of the potential risks to consumers from microplastics and nanoplastics in food, especially seafood, EFSA reviewed the current state of knowledge in 2016[16], concluding that:

- Methods are available for identification and quantification of microplastics in food, but occurrence data are limited; for nanoplastics, no methods or occurrence data in food are available.
- Research on the toxicokinetics and toxicity, including studies on local effects in the gastrointestinal (GI) tract, are needed as is research on the degradation of microplastics and potential formation of nanoplastics in the human GI tract.

Given the interest in the topic of microplastics and nanoplastics, EFSA (with the help of EU Sister Agencies) is planning to host a Scientific Colloquium[17] in spring 2020, with the aim to identify questions relevant for research and risk assessment of this contemporary emerging issue."

The discussion was held together with the next item 16. on Member States' activities on micro/nano-plastics.

[15] http://www.efsa.europa.eu/en/efsajournal/pub/5327
[16] https://www.efsa.europa.eu/en/efsajournal/pub/4501
[17] http://www.efsa.europa.eu/en/events/event/scientific-colloquium-25-microplastics-and-nanoplastics-food-and-feed

16. Member States' activities on microplastics

The participants were asked to inform on any planned, ongoing and past activities in their Members States about micro- and nano-plastics related to FCMs. Germany, Norway and Sweden provided feedback as follows:

Norway reported about the recent Opinion of the Norwegian Scientific Committee for Food and Environment on "Microplastics; occurrence, levels and implications for environment and human health related to food" (VKM Report 2019: 16[18]). In this Opinion, based on literature searches, evidence and type of data related to microplastic were mapped. With regards to the human risk characterisation, the available information did not provide sufficient basis to characterise potential toxicity, based on oral exposure solely, and the occurrence data in food is not sufficient to estimate the exposure. Therefore, the risk for humans from micro- and nanoplastics exposure could not be characterised. With regards to the environmental risks posed by micro-/nanoplastics, the available information did not provide a sufficient basis to perform a high-quality characterisation. Due to large data gaps, the environmental risk characterisation has to be considered provisional. Moreover, it was only performed for aquatic ecosystems (surface water and the water column). For marine ecosystems relevant to Norway, the overall risk is low. For the most heavily polluted locations in the North Sea and Sweden, a potential risk exists.

Sweden made a presentation and reported on an ongoing national survey on micro- and nano-plastics in drinking water. The Swedish Food Agency (Livsmedelsverket) was asked to provide advice on the health risks posed by the presence of microparticles and nanomaterials of plastics in drinking water, mapping the presence of such contaminants in drinking water in Sweden and proposing measures to reduce the exposure, if needed. At present drinking water from 10 water works located all over Sweden are surveyed for levels of microplastics. Several analytical challenges for lower filter pore sizes lead to the reduction of sampling places and to fewer results from lower filter pore sizes. The report is expected to be delivered to the government in April 2019.

BfR reported on their review of several published studies[19]. Due to the use of different analytical methods a comparative assessment of the cited study results

[18] https://vkm.no/download/18.345f76de16df2bc85a513b4e/1571823698421/20191023%20Microplastics;%20occurrence,%20levels%20and%20implications%20for%20environment%20and%20human%20health%20related%20to%20food.pdf

[19] [1] Schymanski, D., C. Goldbeck, H.-U. Humpf, and P. Fürst (2018). Analysis of microplastics by micro-Raman spectroscopy: Release of plastic particles from different packaging into mineral water. Water Research, 129, 154-162.

[2] https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cvua-mel.de%2Findex.php%2Faktuell%2F138-untersuchung-von-mikroplastik-in-lebensmitteln-und-kosmetika&data=02%7C01%7C%7Cbc7a881905544962ad8308d7732c9a4f%7C406a174be31548bdaa0acdaddc44250b%7C1%7C0%7C637104507719298090&sdata=tP6Dj4mNRT%2BNhSSFUC7BBniVA5APaqNdSkH1K75Uhrc%3D&reserved=0, downloaded 26.10.2018

[3] Oßmann, B. E., Sarau, G., Holtmannspötter, H., Pischetsrieder, M., Christiansen, S. H., Dicke, W. (2018).

[4] Small-sized microplastics and pigmented particles in bottled mineral water. Water Research, 141, 307-316. sciencedirect.com/science/article/pii/S0043135418303956

could not be done. Nonetheless, studies [1-4] highlighted the presence of particles including microplastics in bottled mineral water. Possible sources could be found throughout the entire production process. On the basis of the cited publications, the BfR came to the conclusion that the release of microplastic particles from the packaging material could not be proven. The source of microplastic in mineral water, including packaging material, should be traced along the production process.

The recent publication "Plastic Teabags Release Billions of Microparticles and Nanoparticles into Tea" (L.M. Hernandez *et al.*[20]) was mentioned. This adds to the concern on exposure to micro/nano-plastics from foods.

The environmental concern related to plastic wastes is well recognised. However, the possible contribution from FCMs during their uses in contact with foods may need to be addressed.

The Network was invited to register to the EFSA Scientific Colloquium at scientific.colloquia@efsa.europa.eu and to submit abstracts/proposals for oral presentations and/or posters.

17. EFSA partnering Grant on Coatings

Maria Rosaria Milana, Riccardo Crebelli and Viviana Golja presented the work of the EFSA partnering Grant on Coatings. The summary provided by the speakers is reported below.

"A harmonised approach for the safety assessment of migrants from coatings is proposed by the Task Force on varnishes and coatings for FCM under the EFSA Partnering grant AFSCO/2017/01-GA07. The approach is largely compliant with basic principles underpinning the safety assessment of plastic FCM, with special consideration of the possible health risk posed by non-intentionally added substances (NIAS) generated during coating manufacture. To this aim a stepwise approach is proposed, which distinguishes intentionally added substance (IAS) (e.g. coating substances intentionally used as starting substances), for which a standard toxicological data package is required, from NIAS (degradation and reaction product, including prepolymers), for which non-testing methods (QSAR, read-across, TTC) are applied for a preliminary safety assessment when toxicological data are not available. The Task Force noted that the application of non-testing methods requires information on chemical identity, which may be inadequate in case of NIAS. In order to circumvent this limitation, either expert judgement to rule out the exclusion criteria, or a genotoxicity testing strategy optimised for complex mixtures according to the EFSA guidance (2019)[21] are recommended for the application of the TTC to NIAS migrating from coatings."

"With regards to nanotechnology-derived food contact coatings, the Task force recommends thorough characterisation of nanotechnology-derived food contact coatings, nanoparticles incorporated in coatings and nanoparticles that are

Mason, S. A., Welch, V. G., & Neratko, J. (2018). Synthetic Polymer Contamination in Bottled Water. Frontiers in chemistry, 6, 407.
[5] Pivokonsky, M., Cermakova, L., Novotna, K., Peer, P., Cajthaml, T., Janda, V. (2018). Occurrence of microplastics in raw and treated drinking water. Sci. Total Environ. 643, 1644–1651.
[20] https://pubs.acs.org/doi/10.1021/acs.est.9b02540
[21] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5519

released into foods. New applications should consider not only diffusion, but also other mechanisms of possible nanoparticle release from the coatings, especially different matrix degradation caused by mechanical abrasion, thermal decomposition, UV light or hydrolysis/dissolution of the matrix. Harmonisation of nanoparticle release testing from novel food contact materials is needed as well."

It was clarified that the list of evaluated NIAS was based on information from the literature, hence it is not confidential. It would be benefitial to include the NIAS evaluated by Member States in the context of applications. Since this information is often confidential, Member States should agree to share such information under confidentiality.

The need to consider more specifically the production process of coatings to assess their safety in use was discussed. It was questioned if a list of substances evaluated for use in coatings - similarly to the Union list - would be sufficient, or it should consider the production process to cover the migrating chemicals/mixture. Applying the whole mixture approach for testing the genotoxicity of migrating chemicals would cover the substances used, the NIAS, and would link the evaluation to the production process.

The need for guidance on migration simulants and testing conditions was underlined.

The development of a standardised approach for untargeted screening/analysis would be useful both for risk assessors and producers. A method developed by FERA[22] was mentioned for consideration. The Network was also reminded about the JRC taskforce on kitchenware which investigates migration from various articles, e.g. metals, by using multi-analyte-methods which could also be applied to non-targeted screening for NIAS. A workshop on untargeted screening/analysis will be organised by the JRC-EURL in 2021.

The clear need for implementation of the approach suggested by the task force was identified in order to increase the level of harmonisation and to reduce data gaps. The report of the taskforce is expected to be published by January 2020. Member States especially from the Task Force and more generally carrying out safety assessment of coatings were invited to report back on their experience with implementing/using the document and the proposed approach. This will help in improving and harmonising the evaluation of varnishes and coatings at EU level.

18. BfR activities on rubber

Stefan Merkel presented the BfR activities on rubber. The summary provided by the speaker is reported below.

"BfR Recommendation XXI 'Commodities based on Natural and Synthetic Rubber' applies to elastomer articles for contact with food and with mucous membranes. This recommendation was first established in 1962 and generally revised in 1978. There were only few petitions for new substances after 1990. As the evaluation of many substances listed in recommendation XXI is not in accordance with the current state of risk evaluation on FCM a revision including an editorial update is

[22] https://www.fera.co.uk/media/wysiwyg/food_safety/M._Driffield_Fresenius_NIAS_presentation.pdf

necessary. The revised BfR recommendation XXI will be structured in four recommendations:

- XXI. Commodities based on elastomers, manufactured from natural and synthetic rubber,
  - XXI/1: Commodities manufactured from natural and synthetic rubber for food contact
  - XXI/2: Special commodities manufactured from Natural and Synthetic Rubber.
  - XXI/3: Commodities for food contact manufactured from thermoplastic elastomers (TPE-V) (will be added later).

Restrictions for use amounts will be replaced by specific guidance values for migration into food (SMR) as far as available. All substances will be subdivided into two lists. List A will contain substances evaluated according to the state of the art with SMRs. List B will be a provisional list of substances not evaluated according to the state of the art maintaining the current types of restrictions. All substances will be listed in tabular format with CAS No., FCM No., and limits."

It was noted that the same migration testing conditions and simulants are proposed for rubber articles as for plastic FCM under Regulation (EU) No 10/2011. It was questioned whether the application of the simulants for plastic FCM for migration testing of other FCM materials was straightforward and reliable. It was indeed acknowledged that for some simulants (e.g. 50% ethanol to simulate milk), further considerations/improvements may be needed in order to establish a representative testing method.
Circa 120 substances are in List A and circa 80 substances are in List B. It was stressed that the substances contained in list B may not have been evaluated, or have been evaluated decades ago, therefore not according to the current risk assessment principles. It was however also highlighted that industry, as producer and user of these substances, is obliged to evaluate the substances' safe uses according to the general provisions set out in the FCM Framework Regulation. It is desirable for the substances in list B to conduct up-to-date evaluations in order to guarantee their safe use, and this will be triggered by dossiers submitted by industry, with data supporting the move of substances from List B to List A. After a transitional period, substances for which no dossier has been submitted will be withdrawn from List B.

19. ANSES activities on rubber

Gilles Rivière presented the ANSES activities on rubber. The summary provided by the speaker is reported below.

"Rubber is a non-harmonised FCM. A rubber material is made of natural or synthetic polymer with a high stretching rate obtained through vulcanization process.
The main uses of rubber in the context of FCM are the following: seals, pipes, gloves, dummies, conveyor belts, etc. At French level, a decree was published in 1994 and is composed of two lists: authorised substances and temporarily authorised substances. The temporarily authorised substances were permitted for the use until 31/12/1998. In the time frame imposed to ANSES, it was not possible to perform a risk assessment for all substances listed in the decree.

In this context, ANSES published a methodology in order to establish different lists of substances to integrate in the revised French decree. Since plastic and rubber have similar composition, the Union List from the EU plastic regulation was used in the evaluation process. The working group established different criteria and specifications and three lists of substances were proposed: authorised substances, temporarily authorised substances and non-authorised substances."

The French list appears to contain more substances than the German list. Germany commented that the rubber Industry indicated that export outside Germany is somehow limited.
Italy informed that they also have activities on rubber with the preparation of a list of authorised substances (outcome expected in 2020). In first instance, the Union list for plastics is compared with the Italian 'list' for rubber. Substances not authorised for use in plastics would be removed from the rubber list.
It was reminded that the JRC Baseline study compiled national measures on non-EU-harmonised FCM and that a list of substances authorised for rubber at a national level was established. JRC proposed to circulate this list to the Member States for them to check if the correct information is reported and update it as needed. The updated version could then serve as a database of substances regulated in Europe. The use of the so-called "Belgium database" of known FCM substances may help.

Some restrictions reported in the Union plastic list and in the national rubber lists may be different for instance due to the different conditions in which plastic and rubber articles are produced and/or used.

Like for other existing lists, and in the light of the technological evolvements of the past years, the need to inform on whether substances are still used was highlighted to avoid unnecessary work. The principle of the provisional lists for a transitional period along with deadline to submit an application may answer the question.

Clear synergies between the work undertaken by Germany and France in the area of rubber were identified with this providing a good basis for a closer collaboration. Both Member States have developed a system based on different lists of substances (authorised vs. temporarily authorised) that could help to clear the current list and to start (re-)evaluations. It was suggested to start as soon as possible by comparing the respective lists in order to identify commonalities and discuss differences with respect to the included substances and respective restrictions. Some substances may not be present in the two lists and that's fine if this is supported. It is of high importance to also have a harmonised approach for carrying out the (re-)evaluation of the substances including for testing the migration (categories and related testing conditions). This would benefit the mutual recognition, could bring synergies by finally sharing rather than duplicating the evaluations. Overall, this could harmonise the evaluations and safety use of rubbers in Europe.

Most advanced Member States with expertise in rubber, i.e. France, Germany and Italy could organise a joint Group to which the Netherlands may wish to join too.

20. Assessment of untreated wood flour and fibres as additive

Katharina Volk presented the EFSA assessment of untreated wood flour and fibres as additive. The summary provided by the speaker is reported below.

"The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) was asked by the European Commission to review whether the authorisation of 'wood flour and fibres, untreated' (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004. The additive was included in the list of additives for use in plastic FCM based on the assumption of its inertness. No toxicological evaluation underlying the inclusion of this entry in the positive list is available. In a literature search, general information on the chemical composition of wood was retrieved showing that wood may contain toxic components and contaminants. The information on migration of substances from wood was found to be limited to its use in the production of wine. Data on migration of substances resulting from the use of wood (flour, fibres) as plastic additive were not available. As a second step, as requested by the mandate, criteria for future evaluations of wood and similar materials from plant origin as additives for plastic for food contact applications were proposed. It was noted that due to the chemical differences in composition of plant materials, the safety of migrants from these materials must be evaluated on a case-by-case basis, considering beyond species also origin, processing, treatment for compatibilization with the host polymer and assessment of the low molecular weight constituents migrating into food. Migration of substances resulting from using wood or other plant materials should be tested comparatively in samples made with and without the additive. Toxicological data should cover the substances detected in this analysis."

The participants were informed that the opinion was adopted by the CEP Panel in October and is expected to be published by end November 2019[23].

21. BfR activities on printing inks and Paper and boards

Stefan Merkel presented the BfR activities on printing inks and Paper and boards. The summary provided by the speaker is reported below.

"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. Recycled fibres made from paper and board can be used as raw material for the production of paper and board for food contact which is intended to be used at temperatures up to 90°C according to BfR recommendation XXXVI. Finished articles have to comply with the requirements of the Annex to recommendation XXXVI for the use of recycled fibres as raw materials. Recycled fibres may contain bisphenol A due to recycling of thermal paper. The overall exposure should not exceed the t-TDI of 4 µg/kg bw per day derived by EFSA. There are sources for bisphenol A other than FCM. This is why an allocation factor of 20% should be used. For that reason, the migration guidance value for bisphenol A in the annex of BfR recommendation XXXVI will be lowered from 0.24 mg/kg food to 0.05 mg/food.
For the production of substances such as sizing agents, retention agents and wet-strength agents epichlorhydrin is used. This substance may hydrolyse to chloropropanols for which maximum migration guidance values in BfR recommendations XXXVI are set. New experimental results showed that the hot water extract does not represent the worst case. Therefore, the cold water extract is to be used despite intended use of the paper.
In paper production different substances contain aluminium. EFSA derived a tolerable weekly intake for aluminium of 1 mg/kg bw per day and noted that the

[23] https://www.efsa.europa.eu/en/efsajournal/pub/5902.

current dietary exposure of a significant part of the European Union's population likely exceeds this level. Therefore, an allocation factor of 10% to the conventionally derived migration value should be used. For that reason, a maximum migration guidance value of 1 mg/L in the cold water extract of the finished article and will be added to BfR recommendations XXXVI.
These changes will be published in December 2019."

CoE reminded their ongoing activities on the Draft technical guide on paper and board materials and referred to their discussion on limits for metals. CoE questioned the release of aluminium in water and suggested acetic acid extraction. Germany also tested the release by using 3% acetic acid, which was expectedly higher than in water.

With regards to the higher release of chloropropanols in cold water than in hot water, JRC questioned on whether the chloropropanols reacted with other chemicals when extracted with hot water and whether other substances were detected in the extracts. The fact that substances are not detected may also be due to their transformation to break-down products during contact with simulants. JRC recommended to verify the stability of the compounds under the testing conditions. It was recommended that JRC, Germany and CoE liaise together on the testing conditions and interpretation of the results.

22. Evaluation of an additive with a nano-size fraction

Laurence Castle presented the evaluation of an additive with a nano-size fraction. The summary provided by the speaker is reported below.

"This presentation covered the safety assessment conducted by the EFSA CEP Panel on two additives that have a fraction of nano-sized particles and are intended for plastic FCM. They are FCM substance No 1075 (montmorillonite clay modified with hexadecyltrimethylammonium bromide)[24] and No 1077 (titanium dioxide surface treated with fluoride-modified alumina)[25] and the opinions were published in 2019. Of particular interest for the evaluations were:

- the particle size distribution of the additive as such and after incorporation into plastics;
- the polymers, the level of addition, and the food contact (types and conditions) intended;
- migration potential of the particles, including under conditions of polymer swelling and/or abrasion if relevant;
- migration of any inorganic or organic materials released in solubilised form from the additive.

The rationale for these points of focus and some of the methods and approaches used by the applicants to address them, were described and discussed by reference to the two opinions on the above substances."

The diffusion model applied was discussed. It was notably clarified that the substances evaluated were assumed to have a good solubility.

[24] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5552
[25] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5737

Also, the particles were embedded in the polymer matrix. This was confirmed by surface analysis and migration testing, and led to the conclusion that no migration of nanoparticles was expected.

The most recent opinion on titanium dioxide surface treated with fluoride-modified alumina[14] provides a good reference for the methodology to be applied for the assessment of the use and/or presence of nanoparticles in plastic FCMs.

Overall, the topic of nano-sized additives was identified as an area of inter-disciplinary collaboration for analytical chemistry, material sciences and microscopy.

23. Assessment of the potential toxicity of mixtures

Paola Manini presented the assessment of the potential toxicity of mixtures. The summary provided by the speaker is reported below.

"The EFSA Scientific Committee (SC) has recently issued a guidance document, which describes harmonised risk assessment methodologies for combined exposure to multiple chemicals for all relevant areas within EFSA's remit, i.e. human health, animal health and ecological areas (EFSA SC, 2019[26]). The overarching framework described in the guidance is based on the four risk assessment steps (problem formulation, exposure assessment, hazard characterisation and risk characterisation including uncertainty analysis) with tiered and stepwise approaches for both the whole mixture approaches and component-based approaches. In the guidance, specific considerations are given to component-based approaches, including the grouping of chemicals into common assessment groups, the use of dose addition as a default assumption, approaches to integrate evidence of interactions and the refinement of assessment groups. The guidance also includes three case studies to explore the feasibility and spectrum of applications of the proposed methods and approaches for human and animal health and ecological risk assessment.
The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has started applying the principles of the guidance in the risk assessment of botanical preparations when used as feed additives. The experience of the FEEDAP Panel with the risk assessment of two essential oils was presented and discussed, highlighting how the overarching framework has been tailored to address the specific needs of the Panel."

The presentation illustrated the application of the whole mixture and component-based approaches to two well characterised mixtures (essential oils). For FCM, the guidance and mixture approaches could be useful for the evaluation of additives (such as process mixtures) and migrats (especially for migrated NIAS). A main difference is the level of characterisation, migrats being often not fully/well characterised and containing a significant number of unidentified substances.

With regards to the component-based approach applied to the very well characterised cardamom oil (48 identified compounds counting for 99.4%), it was noted that the unidentified components (<0.1%) were treated as Cramer class III. Since the presence of DNA reactive substances in cardamom oil was excluded, the lowest applicable threshold of toxicological concern (TTC) value was applied

[26] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5634

to them. In the case of a substantial fraction of unidentified components, a mixed component-based and whole mixture approaches could be used. The Cramer class assessment of the unidentified substances could then be supported by testing genotoxicity.

24. Assessment of the potential genotoxicity of mixtures

Mary Carfí and Carla Martino presented the assessment of the potential genotoxicity of mixtures. The summary provided by the speakers is reported below.

"In 2019, the EFSA Scientific Committee addressed the peculiarities related to hazard identification of genotoxicity of mixtures and provided a general framework for the assessment of the genotoxic hazard of chemical mixtures present in food and feed. The EFSA Scientific Committee proposal starts with the chemical characterization of the mixture as far as possible and follows by the genotoxicity assessment of the substances in the mixture. Different approaches are proposed for fully chemically defined mixture and for mixture containing a substantial fraction of unidentified components. Each identified substance is considered individually and if one or more of them are assessed to be genotoxic *in vivo* via a relevant route of administration, the mixture raises concern for genotoxicity. For mixtures containing a substantial fraction of substances that have not been chemically identified, experimental testing of the unidentified fraction should be considered as the first option or, if this is not feasible, testing of the whole mixture is recommended. If testing of the fraction(s) or of the whole mixture in *in vitro* assays provides clearly negative results, the mixture does not raise concern for genotoxicity. If *in vitro* testing provides one or more positive results, an *in vivo* follow-up study should be considered. For negative results in the *in vivo* follow-up test(s), the possible limitations of *in vivo* testing should be weighed in an uncertainty analysis before reaching a conclusion of no concern with respect to genotoxicity. For positive results in the *in vivo* follow-up test(s), it can be concluded that the mixture does raise a concern about genotoxicity."

The presentation illustrated the application of the whole mixture and component-based approaches to a flavouring mixture containing a substantial fraction of unidentified components. This case presents similarities with the evaluation e.g. of migrats and migrated NIAS.

The Scientific Committee guidance recommends starting with the highest level of characterisation of the different components/fractions; this even if it is technically not feasible to fractionate the mixture.

The evaluation should start with the assessment of the identified chemicals (e.g. QSAR, literature, testing, etc.). If it can be demonstrated that the identified components are not genotoxic, then the unidentified fraction should be tested. If it is not possible to isolate the fraction of unidentified components, the testing of the whole mixture should be conducted. By "known *in vivo* genotoxic substance" in the presentation, it is meant "demonstrated to be genotoxic *in vivo*".

The robustness of the whole mixture approach was discussed. In the example presented, the testing (Ames and *in vitro* micronucleus tests) of the whole mixture showed negative results, whereas there is an indication for genotoxicity for 6 substances that require to be further evaluated (i.e. for these substances positive

results were observed in *in vitro* genotoxicity testing). The publication on "Value and limitation of *in vitro* bioassays to support the application of the threshold of toxicological concern to prioritise unidentified chemicals in food contact materials"[27] was also mentioned with regards to the limited sensitivity of available bioassays. Finally, it was underlined that the conclusions on tests conducted under the whole mixture approach should be carefully evaluated considering the possible limitations, e.g. the possible dilution of effects and potential false negative results.

25. EFSA Partnering and other grants

Sergio Potier Rodeia presented the EFSA partnering and other grants. The summary provided by the speaker is reported below.

"EFSA regularly awards grants or subsidies for projects and activities that contribute to EFSA's mission in the following areas: data collection, preparatory work for scientific opinions, other scientific and technical assistance. Only competent organisations, based on designations by Member States, are eligible to apply for grant calls (named calls for proposals). A brief introduction is provided to the concept of grants, including its six underlying principles, as opposed to procurement. A brief broad overview on the different types of EFSA grants, with particular focus on those where beneficiaries set the specificities of project activities. Particular attention is provided to the concept of Partnering Grants, which focus in promoting the transfer or exchange of knowledge and expertise in risk assessment between organisations in different Member States and, in this way, further build risk assessment capacity at EU level. It is important to note that, in order to best align the subject matter of submitted proposals with the strategic priorities established by EFSA and Member States, these calls will favour (through the award criteria) proposals that focus on priorities set under the EFSA strategy 2020; and/or focus on agreed EFSA/Member States priorities, as identified in the final report on the identification of food safety priorities using the Delphi technique."

The taskforce on varnishes and coatings was mentioned as a practical example and outcome of the opportunities offered by EFSA in the context of grants. The Member States were invited to follow closely the calls for grants as they represent a valuable opportunity for EFSA and Member States in terms of collaboration for risk assessment and specifically harmonisation in the area of FCM. Each applying consortium should include at least two organisations from two different countries. Bearing in mind that the upcoming call will be launched in mid-2020, interested Member States will have time to familiarise with the key priority areas of work noted in the technical specifications of the call prior to submitting a project on FCM.

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

Laurence Castle summarised some of the points recurrently raised during the discussions of the meeting.

The encouraging work of the partnering Grant taskforce on **varnishes and coatings** was recognised as an important step towards harmonisation of risk

[27] https://doi.org/10.1080/19440049.2019.1664772

assessment approaches. The proposed approach should be used and refined as needed by the Member States carrying out the assessment of coatings. Identified gaps and recommendations should be addressed, particularly the need for a guidance on migration simulants and testing conditions and the development of a standardised approach for untargeted screening/analysis. On those matters, the key role of the JRC was highlighted.

There are clear needs and opportunities for a similar work also in other FCM areas such as rubber, as identified during the respective presentations of France and Germany during the meeting. As for coatings, **Rubber** is high priority due to the well advanced work. The clear recommendation was expressed to continue bilateral exchanges on this topic after the Network meeting. Ideally, most experienced Member States in the rubber field such as France, Germany, Italy and possibly the Netherlands should organise a joint Group with the aim to harmonise as much as possible the approach of assessing and regulating substances for use in rubber materials.

As presented by the European Commission, the results and conclusions of the **evaluation of the FCM Framework regulation** will be released in the first part of 2020, and this will play an important role in defining the future work FCM, also with respect to their risk assessment. Priorities as well as a policy follow-up need to be defined, and certainly these activities and decisions can benefit from the Member States' experience on so far non-harmonised groups of FCMs.

Prioritisation was confirmed to be a topic of high interest due to the numerous non-EU-harmonised FCM types and to the possibly out-of-date evaluations of some authorised substances present on the existing lists. Interesting insights into the different prioritisation exercises under REACH were provided by ECHA. Due to the vast experience of ECHA on this topic, a webinar on prioritisation/screening could be useful to train all interested parties. Also, Belgium, Norway and EFSA presented their recent activities on prioritisation in the area of FCM. It was commonly acknowledged that it is important to share and agree on methodologies not only in the area of risk assessment, but also for prioritisation strategies. Only in this way can the outcome be applicable to all interested parties. As mentioned above, there are two main areas where prioritisation could be very useful and would imply the use of different methodologies: i) the prioritisation for substances never evaluated at European or national level and ii) the prioritisation of the substances to be re-evaluated that are currently on the European or national lists of authorised substances. This corresponds to the work currently led by Belgium (i) and EFSA (ii), respectively. Similarly to the task force on coatings, a closer collaboration between Member States, possibly led by an already experienced Member State, could help avoid duplication and harmonise the methodologies across all interested parties.

As in previous meetings, the wish for one single **European database of evaluated substances** for all different types of FCM was expressed. This would prevent work duplication and divergences and would benefit from the work of all the Member States. To build such a database, it is essential to understand which methodologies have been applied in the respective assessments. The substances should be attributed clear identifiers in order to ease comparison with evaluation under other frameworks, e.g. REACH. Such a database could also serve as a starting point for investigating whether the substances are still used in practice or whether they could be removed from the various lists existing at EU and national level.

The importance of sharing information of relevance for safety assessment was clearly highlighted. One should acknowledge the willingness from all participants to share and discuss their activities, methodologies and challenges in a constructive manner at the meetings. The compiled list of **Member States** "**forthcoming risk assessment activities**" in the area of FCM is another useful tool to identify common interest and possible area of synergies. It has been completed and it needs to be kept up to date by adding all relevant researches, projects, draft guidance documents, etc. in the area of FCM. The Network considered it necessary to inform on future projects at the earliest, in order to make it still feasible to build synergies. It was thus agreed to include future projects planned to start in 2020 and beyond, and the Member States were invited to populate the list accordingly.

27. Date for next meeting

This meeting was the last one for this three-year-mandate which ends in 2019. A new mandate needs to be proposed to the EFSA Advisory Forum for the FCM Network to be renewed and for the next meeting to be organised. In view of the ongoing discussions on new approaches for holding EFSA Scientific Networks, the FIP Unit will wait until a new approach is agreed by the Management board before submitting a new mandate and organising the next meeting.

28. Concluding remarks and closure of the meeting

The FIP FCM Network coordinator 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. In the light of the limited resources available, working together, sharing workload, expertise and avoiding duplication of work become even more important.

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

The chair 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.