FOOD INGREDIENTS AND PACKAGING UNIT

Network on Food Contact Materials Minutes of the 8th meeting

Held on 22-24 November 2022, Parma

(Agreed on 2nd January 2023)

Participants

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

Country	Name
Austria	Christa Hametner Thomas Schwartz
Belgium	Els Van Hoeck
Cyprus	Nektaria Varnava
Croatia	Nino Dimitrov Ivona Vidic Strac
Denmark	Gitte Alsing Pedersen
Estonia	Margot Paavel
Finland	Merja Virtanen
France	Bruno Teste Fernando Aguilar
Germany	Stefan Merkel
Greece	Stella Kontou
Hungary	Gabriella Gaal
Iceland	Grimur Olafsson
Ireland	Karl McDonald
Lithuania	Skirmante Ambraziene
Luxembourg	Sandy Nosbusch
Netherlands	Krista Bouma
Poland	Marzena Pawlicka
Portugal	Maria de Fatima Tavares Pocas
Slovakia	Milada Sycova
Slovenia	Viviana Golja
Spain	Juana Bustos Perfecto Paseiro Losada
Sweden	Marie-Louise Nilsson
Switzerland	Beat Brüschweiler
Norway	Inger-Lise Steffensen

- **ECHA**

  Evelin Fabjan (Unit B3), Stefano Frattini (Unit B4), Niko Hellsten (Unit B4), Vessela Vitcheva (Unit C4), Panagiotis Zarogiannis (Unit B3)

- **Intergovernmental organisation Council of Europe (CoE):**

  Susanne Bahrke (EDQM)

- **European Commission (EC):**

  Jonathan Briggs (DG SANTE), Eddo Hoekstra (DG JRC), Bastiaan Schupp (DG SANTE)

- **Hearing Experts**

  Emilio Benfenati (Mario Negri IRCCS), Ronan Cariou (Oniris/INRAE)

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

  Laurence Castle (EFSA Panel on Food additives and flavourings, FAF Panel) and Gilles Rivière (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids, CEP Panel)

- **EFSA:**

  FIP (Food Ingredients and Packaging) Unit: Valeriu Curtui (Head of the FIP Unit), Eric Barthélémy (FCM Network Coordinator, Chair), Sandra Rainieri (FCM Team Leader), Gloria Lopez-Galvez (FCM team), Daniele Comandella (FCM Team), Cristina Croera (FCM Team) and Katharina Volk (FCM Team)

  ENREL (Engagement and External Relations) Unit: Drago Marojevic

  MESE (Methodology and Scientific Support) Unit: Maria Chiara Astuto, Irene Cattaneo

  RAL (Risk Assessment Logistics Unit): Maria Ciaula

1. Welcome and apologies for absence

Eric Barthélémy, Coordinator and Chair of the FCM Network, opened the meeting.

He welcomed the participants and underlined the importance of the FCM Network as a platform for cooperation on risk assessment activities and harmonisation of risk assessment methodologies. He emphasised that the FCM Network is an important platform for Member States to come together, share their expertise and find opportunities for collaboration through the different topics outlined in the agenda and beyond. Especially in FCM, with fragmentation and limited harmonised legislations at EU level of the so-called "non-plastics" FCM, the work towards more harmonisation is essential.

He highlighted the representation of 24 Member States, the Council of Europe (CoE), the European Chemicals Agency (ECHA) and the European Commission (SANTE and JRC). He thanked them all for attending the meeting fostering collaboration and sharing knowledge.

Apologies were received from representatives from Bulgaria, Latvia, Romania for the entire meeting. Italy did not join the meeting.

Participants introduced themselves in a tour de table.

2. Adoption of the agenda

The agenda was adopted with the following changes: B. Schupp was introduced as additional speaker of item 6 and M. Ciaula replaced A. Amodio for item 13.

The minutes of the 7th and last meeting of the Network on Food Contact Materials held on 6-7th November 2019, Parma, were agreed by written procedure on 11 November 2019 and published on the EFSA website[1].

3. Declaration of interests and statement of confidentiality

All participants signed a statement of confidentiality.

4. Terms of References of the FCM Network

Eric Barthélémy presented the terms of reference of the FCM Network[2] that was renewed in April 2022.

5. Council of Europe activities: work programme 2022-2025 & Resolution (2020)

Susanne Bahrke presented the ongoing CoE activities. The summary provided by the speaker is reported below.
"The Council of Europe adopted Resolution CM/Res(2020)9 on the safety and quality of food contact materials and articles (FCM). The detailed requirements had been endorsed by the European Committee for FCM (CD-P-MCA). Guiding principles are set out in the annex and apply to all materials in contact with food for which no specific European measures have been defined. The following technical guides supplement the Resolution and elaborate on specific issues:

- Technical guide for FCM made from paper and board (published in 2021)
- Technical guide on metals and alloys (2nd revised edition in preparation)
- Technical guide with instructions for the compliance documentation and declaration of compliance (in preparation)
- Technical guides on FCM made with coatings, cork, enamels as well as resins for adsorption and ion exchange (work scheduled 2023-25)

To check the contamination that occurs during food production, packaging, storage or transport, multi-analyte methods have been developed for the determination of substances migrating from printing inks to dry food or food simulants. Testing is performed by competent authority or private laboratories to assess the safety of food contact materials and articles. The above publications can be downloaded from the EDQM platform FREEPUB."

The importance of CoE activites in the field of FCM was highlighted. The Network was informed that the guidelines on metal and alloys will be incorporated into the national legislation of Benelux countries (BE, LU, NL).

The work programme of the CD-P-MCA committee on the implementation of the resolution was discussed. The activity on "*Officially evaluated substances* –

[1] https://www.efsa.europa.eu/sites/default/files/event/EFSA%20FCM%20Network_7th%20Meeting%206-7November2019_Minutes.pdf

[2] https://www.efsa.europa.eu/sites/default/files/assets/fipnonplasticsnetworktor.pdf

prepare procedures for national authorities (2022)" was subject of discussion. CoE clarified that the activity will be collecting and collating information to create lists of substances that are evaluated at national level for use in "non-plastic" FCM, including those authorised for use in plastic FCM (EC Union List). CoE is developing templates and operational procedures (agreed between member states) for creating and/or updating these list(s). It was clarified that CoE does not carry out risk assessment. It was noted that to improve harmonisation, the generation of a database would be beneficial.

The recommended principles for the use of substances in the manufacturing of FCM were questioned especially regarding the use of 'non-evaluated' substances that are not migrating or released (limit of detection LOD < 0.01 mg/kg if non-CMR, CMR suspect or nano form). The Chair reminded that in several previous Network meetings the "10 ppb + no CMR" principle was erroneously considered as "not present in EU list of CMR". The fact that a substance is not known to be a CMR does not necessarily mean that the substance was proven not to be a CMR, based on toxicological data. Also, it is quite questionable not to address the potential genotoxicity for any intentionally added substance, including those that do not migrate (LoD of 10 µg/kg food).

6. European Commission SANTE activities

Bastiaan Schupp and Jonathan Briggs presented the ongoing DG SANTE activities. The summary provided by the speakers is reported below.
"Current European Commission activities include the implementation of a new Commission Regulation (EU) 2022/1616 on plastic recycling, which entered into force on 10 October 2022. National legislation no longer applies and specific EU rules are directly applicable to the placing on the market of plastic with recycled content, including the use of a suitable recycling technology. However, the Regulation includes a procedure that establishes whether novel recycling technologies are suitable to recycle plastic FCM. It supports the development of innovative recycling technologies that are likely to allow in the future the recycling of plastics that cannot be recycled today into FCM, while it maintains a high level of safety of those recycled plastics. The Commission is in the process of authorising around 230 mechanical polyethylene terephthalate (PET) processes for which an application has been received. The 16th amendment to Commission Regulation (EU) No 10/2011 was voted on favourably on 19 October 2022. This includes updated rules for phthalates and extends use or authorisations for a number of other substances. Further, it revokes authorisation from FCM 96 (wood) and FCM 121 (salicylic acid). Two further amendments are planned (17th and 18th amendments); one to clarify rules in view of the new Regulation on plastic recycling, to clarify rules on natural materials, migration testing and rules for biocidal substances. A separate amendment will address substances only, in particular concerning restrictions on styrene and titanium dioxide."

The new Regulation on recycled plastic materials and articles intended to come into contact with foods was presented in depth. The differences and improvements compared to the previous regulations were stressed as essential to ensure a leaner evaluation/approval process while ensuring that recycled plastic is safe for consumers. In Commission Regulation (EU) 2022/1616, differentiation is made between technology (generic concept, principle and practices to recycle), process (sequence of operations using the technology) and installation (application of the process). Authorisation of recycling processes will be possible only for suitable

technologies; at the moment only PET mechanical recycling and recycling loops. For novel technologies, a specific evaluation/authorisation procedure will be put in place.

In addition to the main aspects of amendments No. 16, 17 and 18 of Regulation EU 10/2011, DG SANTE outlined other activities. In particular, DG SANTE informed the Network on its activities on potential new requirements for styrene migration, on the enforcement action regarding bamboo powder and other unauthorised plant-based additives in plastic FCM, and on the control and monitoring of plastic kitchenware.

7. European Commission JRC activities

Eddo Hoekstra presented the ongoing European Commission JRC activities. The summary provided by the speaker is reported below.
"JRC reports on the progress on relevant topics in the FCM area and the European Union Reference Laboratory (EURL). Three topics are highlighted. JRC is working on developing test conditions for kitchenware covering non-harmonised FCM. Currently test conditions for paper and board are tackled. The second topic is the issue on the implementation of the "stability rule" for repeated use articles as introduced by amendment Regulation (EU) 2020/1245 of regulation (EU) No 10/2011. The third topic is the status on the work of the general guidance of the determination of mineral oil saturated and aromatic hydrocarbons and specifically on the method validation of mineral oil in infant formula."

JRC informed the Network that in the coming years substantial efforts will be made to develop test conditions for measuring migration from paper and board. In order to check compliance of plastic FCM articles for repeated use implementing the stability rule, it is proposed to distinguish the cases of monomers and additives migrating into food/food simulant.

8. ECHA activities on drinking water materials

Panagiotis Zarogiannis presented the ongoing ECHA activities regarding materials in contact with drinking water (DW). The summary provided by the speaker is reported below.
"On 12 January 2021, a revised Directive of the European Parliament and of the Council on the quality of water intended for human consumption was adopted as Directive (EU) 2020/2184. This is known as the Drinking Water Directive (DWD) and is a revision of the previous DWD of 1998. Its overarching objective is to ensure a high level of protection of the environment and of human health from the adverse effects of contaminated drinking water. In its Article 11 DWD addresses materials in contact with drinking water with the aim of (a) setting minimum hygiene requirements for such materials and (b) harmonising their approval across the EU. Under Article 11 ECHA has received new responsibilities. These relate to the setting up and maintaining European positive lists of starting substances, compositions and constituents for four types of materials: (a) organic, (b) cementitious, (c) metallic, and (d) enamel, ceramic or other inorganic materials. The first European positive lists will be based on existing EU and national positive lists. All list entries will be subject to review during 2025-2040 according to expiry dates, which will be assigned on the basis of a proposal by ECHA. Parallel to setting up the first European positive lists, ECHA is working on

establishing a new, fully IT-based DWD application process which will be used by industry and Member State authorities to apply for the addition, renewal or removal of entries from the European positive lists. Such applications will be submitted to ECHA and will fulfil certain requirements on testing and acceptance. The first positive lists, the requirements on testing and acceptance and the application procedure will be described in Commission decisions which will be adopted in 2024-2025."

The Network appreciated the participation of ECHA. The importance of ensuring awareness and understanding on the assessment of substances used both in Drinking Water and Food Contact Materials was acknowledged. ECHA clarified that the positive lists will establish Maximum Tolerable Concentrations at the tap water (MTC_{tap}). Pending the review based on a prioritisation scheme (2025-2040), the MTC_{tap} will be based on the migration limits available in EU and national positive lists, such as the specific migration limits (SMLs) from Regulation (EU) 10/2011.

The differences in the data requirements between the draft guidance for the assessment of substances to be used in DW contact materials (DWCM) and the guidance for FCM were noted. For example, the DWD requires a reproductive toxicity screening study for substances migrating between 2.5 and 200 ug/L (tier 2, slide 14). For the same tier 2 in the assessment of plastic FCM there is no requirement for a reproductive toxicity study (EFSA Note for guidance, 2008[3]). This questioned the harmonisation of the MTC_{tap} during the review. ECHA clarified that, once all the substances will be reviewed, their restrictions including the MTC_{tap} will be harmonised as their assessment will be based on the same DWD guidance.

It was noted that the concentration levels of the three tiers set by the DWD for toxicity data requirements are based on those used by EFSA for plastic FCM, considering a consumption of 2 litres of water per person per day (compared to 1 kg food) and the application of a 10% allocation factor. The grounds for applying the 10% allocation factor is a conservative approach followed by the 4 Member States Initiative (4MSI, comprising DK, DE, FR, NL and UK), which in turn comes from the WHO guidelines on drinking water quality[4].

It was highlighted that cooperation and harmonisation efforts are ongoing between ECHA and EFSA (see for instance item 9) and should be strengthened to promote synergies rather than duplication and potential divergences.

9. Chemical Strategy and Sustainability (CSS) and the One Substance One Assessment (1S1A)

Gloria Lopez-Galvez presented the ongoing EFSA activities in the framework of CSS and 1S1A. The summary provided by the speaker is reported below.
"The Chemicals Strategy for Sustainability (CSS) is supported by five objectives; the one on "Simplifying and consolidating the legal frameworks concerning chemicals in the EU" conveys to the One Substance One Assessment (1S1A). Data and methodologies are two important pillars behind the 1S1A. EFSA is conducting several activities towards the implementation of the 1S1A. In particular four assessments from the area of FCM —for which collaboration with ECHA is being or has been attained— are being piloted. In the context of the Drinking Water

[3] https://www.efsa.europa.eu/en/efsajournal/pub/rn-21

[4] https://www.who.int/publications/i/item/9789241549950

Directive EFSA collaborates as observer since some of the substances are common with FCM; specific topics are being discussed regarding data requirements, methodologies and the technical dossier format under the two legal frameworks. The EC's mandate on phthalates and related substances already foresaw collaboration between EFSA and ECHA, owing to the use of these substances under REACH; the identification and prioritisation of these plasticisers and the protocols for risk assessment have been already developed. The work on Bisphenol A (BPA) performed by EFSA will be considered by the overarching strategy on bisphenols that ECHA is building under REACH in which 148 substances (including bisphenols and bisphenols derivatives) are being reviewed. In the scientific opinion on the 'Safety assessment of the substance silver nanoparticles for use in food contact materials' the collaboration with ECHA followed the application of the additive and of other silver-containing compounds as surface biocide. The CSS and the 1S1A may bring more challenges in the area of regulated products."

It was clarified that future implementation of the 1S1A should in principle apply to the assessment of any inter-agency "common substance" after the actions behind the 1S1A are finalised. The work is currently in progress and will be supported by various pieces of legislation which are not expected to be completed before 2024. For substances that have been already evaluated (like those in plastic FCM, Reg (EU) 10/2011), the principles of the 1S1A would apply at the time those substances are re-evaluated or identified to be in common with another Regulatory framework.

10. EFSA activities on phthalates

Katharina Volk presented the ongoing EFSA activities regarding phthalates, structurally similar substances and replacement substances. The summary provided by the speaker is reported below.

"EFSA was mandated by the EC to re-evaluate the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials. The mandate is divided into i) preparatory work and ii) actual risk assessments. The preparatory work is being finalised and includes the following tasks:

1) Identification and prioritisation for risk assessment of substances: the identification was done using Annex II of the mandate, ECHA's PLASI inventory, the Plastics Regulation and the Regenerated Cellulose Film Directive, the ECHA database and grouping approach, and consultation with Member States. Only substances authorised for FCM at EU or at national level were prioritised. Five substances classified either as carcinogenic, mutagenic, toxic to reproduction Cat. 1 (under CLP) or as endocrine disruptors, persistent, bioaccumulative and toxic, very persistent/very bioaccumulative (under REACH) were placed into an 'exclusion group'. Prioritisation was based on the date of the most recent risk assessment in the context of FCM.

2) Protocols for exposure and hazard assessment: the Draft framework for protocol development for EFSA's scientific assessments was used to develop the protocols. Total dietary exposure, exposure coming from FCM, and overall exposure (dietary and non-dietary) to the prioritised substances were considered for the exposure protocol. Hazard identification and hazard characterisation were considered for the hazard assessment protocol. The protocols describe the approach for identifying, selecting, extracting, appraising the evidence, analysing and integrating it and addressing the uncertainties, to perform exposure and hazard assessments that

will be used to risk assess the prioritised substances in the second part of the mandate.
3) Calls for data in support of the exposure assessment and literature review: two calls for data were launched: occurrence of prioritised substances in food and occurrence in/migration of prioritisation substances from FCM. A review of exposure related literature on the prioritised substances is being performed."

The Network acknowledged the progress made on the assessment of phthalates and structurally similar substances since the last communication given in 2019. The contribution of Member States to the prioritisation exercise (task 1) was discussed; it was highlighted that 17 Member States provided data.

11. EFSA activities on bisphenol A (BPA), RIVM research project on alternatives to BPA

Cristina Croera and Krista Bouma presented the ongoing EFSA activities regarding BPA and the ongoing RIVM project on alternatives for BPA used in Food Contact Materials, respectively. The summary provided by the speakers is reported below.

EFSA activities on BPA: "In 2015, EFSA established a temporary tolerable daily intake (t-TDI) for BPA risk assessment of 4 µg/kg bw per day. In 2016, the European Commission mandated EFSA to re-evaluate the risks to public health from the presence of BPA in foodstuffs and to establish a tolerable daily intake (TDI). For this re-evaluation, a pre-established protocol was used that had undergone public consultation. Taking into consideration the evidence from animal data and support from human observational studies, the immune system was identified as most sensitive to BPA exposure. An effect on Th17 cells in mice was identified as the critical effect; these cells are pivotal in cellular immune mechanisms and involved in the development of inflammatory conditions, including autoimmunity and lung inflammation. A reference point based on this effect was therefore selected and, applying an uncertainty factor to account for the uncertainties in the overall assessment, a new TDI was established"

Ongoing RIVM project on alternatives for BPA: "This research project is carried out by RIVM and commissioned by NVWA. In the EFSA draft opinion on BPA, the TDI is lowered by a factor of 100.000. This means that in practice BPA cannot be used anymore in FCM. There are indications that analogues of BPA may have similar or worse toxicological properties. This RIVM research project aims to identify functional BPA alternatives that are being used in FCM. The toxicological properties and migration of these alternatives are retrieved from EFSA assessments and ECHA's dissemination database, scientific literature and FCCmigex Database. Scientific publication of this research project is foreseen at the beginning of 2024."

Regarding EFSA's activities on BPA, EFSA mentioned that the TDI established in its draft opinion, is based on an observed immunotoxicity endpoint. It was noted that the proposed TDI is expected to be lower than the Threshold of Toxicological Concern (TTC). Since BPA is in the Candidate list of Substances of Very High Concern (SVHC) due to endocrine properties[5] and in view of the low value of the TDI, it was questioned whether endocrine properties were covered by the TTC

[5] https://echa.europa.eu/it/-/msc-unanimously-agrees-that-bisphenol-a-is-an-endocrine-disruptor; https://echa.europa.eu/en/substance-information/-/substanceinfo/100.001.133

since the endocrine activities is not mentioned in the 2019 guidance[6] but only in the 2012 opinion[7].

It was mentioned that in the EFSA 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 CEP Panel, 2016), EFSA CEP Panel proposed a tiered approach for toxicity testing with additional considerations on endocrine disruptors potential. Substances with immunotoxicity potential were not considered. It was concluded that this topic should be part of a wider discussion on the improved methodology used to risk assess non-intentionally added substances (NIAS).

Regarding the RIVM project on the alternatives to BPA, it was mentioned that major data gaps on toxicity still exist on substances used as BPA alternatives. The efforts of RIVM in screening the used alternatives to BPA were appreciated by the Network and deemed useful to monitor the use of potentially hazardous substances in FCM. It was noted that similar work was ongoing as part of the Partnership for the Assessment of Risks from Chemicals[8] (PARC partnership) and a collaboration with RIVM could be established on the topic of BPA alternatives.

12. Welcome and practical information

The chair welcomed the participants and updated them on the agenda and the unfolding of the day.

13. Guidelines for Network Representatives

Maria Ciaula, replacing Alessia Amodio, presented the EFSA's Guidelines for Network Representatives. The title of the presentation was updated to "EFSA's Guidelines for Network Representants". The summary provided by the speaker is reported below.
"The presentation will highlight the main provisions included in the EFSA Decision of the Management Board concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission. The aim of the Networks is to support EFSA and the Member States in carrying out the Authority's mission in accordance with the established standards of scientific excellence, transparency and responsiveness foreseen in the General Food Law Regulation. Each Network should meet its individual targets laid down in its Terms of Reference. EFSA informs the Management Board and the Advisory Forum of the activities of each Network through regular reports. EFSA will evaluate the work of each Network, based on this, the Advisory Forum shall recommend non-binding either the continuation or discontinuation of each Network and the Management Board shall decide whether a particular Network should be continued or discontinued. Network participants are required to ensure timely feedback on any discussions and outcomes of any meetings of the Network and/or online collaborative working, as well as the identification of possible future discussion topics. Considering the fundamental importance of the Focal Points in enhancing scientific cooperation and networking activities between and among

[6] https://www.efsa.europa.eu/en/efsajournal/pub/5708

[7] https://www.efsa.europa.eu/en/efsajournal/pub/2750

[8] https://www.era-learn.eu/network-information/networks/chemicals-risk-assessment

Member States and EFSA, all appointed Network participants and alternate participants taking part in Network meetings and/or providing any other contributions to the work of a Network shall collaborate with their national Focal Points. If a Network participant cannot take part in a Network meeting, they shall contact their alternate participant and their national Focal Point to ensure operational continuity."

14. Compilation of Member States projects/research and Member States' oral feedback

Gilles Rivière presented the compilation of Member States projects/research. 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 Member State's 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 that could be 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, 60 projects that could be related to the area of FCM from 15 Member States have been identified from the compilation of research."

The importance of this list of projects of interest for FCM was acknowledged and considered essential for promoting cooperation, avoiding duplication, and creating synergies on topics of mutual interest. To achieve this, it was remarked that it is essential to: i) report in advance the future projects and ii) check the list before starting a new project.

It was clarified that the list was extracted from the EFSA "R4EU database on Member States risk assessment plans". This database is filled by the national Focal Points with the information on the relevant national research projects. Only members of national Focal Points and of the Advisory Forum have access to the database. The Network representants were invited to liaise with their national Focal Points as recommended in the EFSA's Guidelines on Network Representants to exchange information on the activities related to FCM.

The Network representants were also invited to double check the entries from the FCM list extracted from the R4EU database and to include any missing activity (past, current and future) related to the safety assessment of FCM. The final project reports or publications of interest can be requested either to the national Focal Point or to the identified contact point of the project, if reported.

Two projects from BE were described due to for their topic, the fact they dealt with emerging risks related to FCM, and their interest for the assessment of materials and articles made with/of natural compounds (item 16). The first project named 'TREFCOM - Risks of new trends concerning materials and objects in contact with food' was launched in Belgium in 2021. This project aims at investigating the new trends related to FCM and their potential health risks for the consumers. First, an in-depth market survey was performed to identify new articles on the market (e.g. as replacement and/or labelled as *green* or *recyclable*). The results were compiled in a matrix to select the FCM samples. Next, the (potential) migrants were identified using targeted and untargeted analytical methodologies, and the corresponding risks will be assessed. Finally, a consumer survey will investigate consumer practices (e.g. buying or storing

articles) regarding food sold in bulk and their potential risks. The survey is expected to be launched in January 2023. A similar project, MIGRACARTO, started in September 2022. This project uses the same methodology, but the envisaged samples are straws and takeaway products made of paper and board. The results of both projects will be merged to obtain a comprehensive overview of the potential risks related to the new trends. The analytical methods that will be used in the second project and its target substances were discussed. The analytical methodology will be based on the updated JRC validated methods, reference methods and measurement report "Testing conditions for kitchenware articles in contact with foodstuffs: Plastics, Metals, Silicone & Rubber" (2021[9]). Targeted analyses will focus on, among others, bisphenols, polyfluorinated alkyl substances (PFAS), primary amines, phthalates. Non-targeted analyses will deal with substances having high response factor.

The Network was also informed of other activities dealing with analysis of paper and board such as activity of the Greek National Reference Laboratory (NRL, see item 21) and a research project carried out in PT, as part of a COST action. In the latter, samples will be collected from several Member States (PT, ES, DK, AT were mentioned) and analysed for potential new migrants in applications where plastic is currently more used than paper and board (for its moisture-resistant properties).

15. RIVM project on alternatives to single uses materials: focus on biobased materials

Krista Bouma presented the ongoing RIVM project investigating biobased materials as an alternative to single use materials. The summary provided by the speaker is reported below.

"The Single Use Plastic (SUP) directive came into force in July 2021. The directive is driven by environmental impact, as single-use plastics do not fit into a circular economy. Also part of these plastics wind up as marine litter. This directive causes a shift to other materials, but also promotes re-use and recycling of plastics. These changes may involve health risks. In 2022 the RIVM started a research project, commissioned by NVWA, to investigate which alternative materials are begin used. A second step is to prepare an inventory of potential migrants present in these materials, to direct enforcement projects. In 2023, the RIVM will carry out a research project on the microbiological, physical and chemical risks of re-using food-utensils, such as coffee-to-go cups, straws, and take-away food packaging. Biobased materials are upcoming and are party replacing single-use plastics. There is no specific EU legislation for these biobased materials. The NVWA therefore is carrying out a market study on the chemical safety of these biobased food utensils, by analysing the presence of plant protection chemicals, PFAS, metals and metalloids, and a general GC-MS screening. The Dutch FCM legislation on wood and cork will be extended to all natural materials as a national measure. Plastic straws have been partly replaced by paper straws. The NVWA received several consumer complaints, that part of the paper straw was bitten of and got stuck in the back of the throat of a child. The NVWA is currently

[9]Beldi G., Senaldi C., Robouch P. and Hoekstra E. Testing conditions for kitchenware articles in contact with foodstuffs: Plastics, Metals, Silicone and Rubber. European Commission, Ispra, 2021, JRC125894.

investigating the chemical safety of these straws, by analysing for PFAS, metals and metalloids and performing a general GC-MS screening."

The details of the project were discussed. The speaker specified that the project will investigate not only chemical or microbiological risks, but also physical risks for which many incident reports were collected by NVWA – especially regarding choking incidents with paper straws. Regarding the analytical methodology used for the screening, the method will use solvent extraction with identification of mass fragments after GC separation. It was pointed out that for the time being, the project will not assess whether different types of additives are used for single use *vs* repeated uses or conventional materials *vs* biobased materials. DE informed the Network that during control checks of articles (such as paper straws from biobased materials and dry banana leaves), various pesticides were found (such as chlorophenols or DDT). This means that also substances that are banned in Europe (such as DDT) should be analysed.

It was reported that consumers sometimes reuse articles for different applications with respect to those specifically foreseen and repeat the use of single use articles. This is a noteworthy concern.

16. EFSA discussion on the assessment of natural compounds and complex mixtures

Laurence Castle informed the Network on the ongoing EFSA discussion on the assessment of natural compounds and complex mixtures. The summary provided by the speaker is reported below.
"This work was started in anticipation of possible revisions of the FCM Framework legislation by the European Commission. As part of on-going discussions on possible options for FCM rules, it has been suggested that there could be a shift of focus onto the final material and a refocus on broader material types; including natural organic materials (paper, wood, fibres, plant-based etc) and substances derived from them. This activity can be seen in the wider EU context of supporting the use of innovative and sustainable packaging solutions, including the use of compostable, biodegradable and natural FCM. EFSA areas that have guided the discussions on the assessment of FCM substances from natural sources include: novel foods, botanicals, enzymes, FEEDAP additives, smoke flavours, and the overarching concept of QPS (Qualified Presumption of Safety). FCM examples that have been used to inform the activity include: ground sunflower seed hulls, bleached cellulose pulp from soft wood, coffee husk cups, citrus seeds/endocarp/skin cups, waste coffee grain cups, chitin and chitosan, starches, and polyhydroxyalkanoates. A draft assessment scheme was presented and discussed. This activity started in spring 2022 and reporting is expected in summer 2023. The concepts and the assessment scheme are still under development and so questions, comments and suggestions from the Network members are welcomed."

It was highlighted that the analytical characterisation of biobased materials used as final articles or additives (e.g. fillers) to manufacture plastic articles is a challenge. In fact, it is virtually impossible to know their full composition, and the assessment of the uncharacterised fraction of low molecular weight (<1000 Da) is difficult. It was suggested that when the substance/mixture/material originates from a non-modified food or a non-consumed part of a food plant, a chemical comparison with the food could be done. If the composition is considered

equivalent to the food or food plant it originates from, the exposure of the migrating constituents could be compared. If the composition is not equivalent, a QPS approach could be considered; otherwise, the exposure of the migrating fraction (<1000 Da) could be considered similarly to the standard assessment of FCM substances.

It was remarked that the discussion is ongoing and preparatory work is currently being carried out.

17. French research project on oligoesters migrating from food can coatings (OLIGO)

Ronan Cariou presented the ongoing French research project on oligoesters migrating from food can coatings (OLIGO). The summary provided by the speaker is reported below.

"Since the decline of the use of bisphenol A, the chemistry of the varnishes and coatings which are applied to the inner surfaces of metallic food contact materials is poorly documented. We hypothesised that can coatings are now diverse and bring forth various non-intentionally added substances (NIAS) to be described. Investigating complex components such as NIAS requires demanding non-targeted approaches. In a preliminary study, we investigated the coatings of 12 vegetable cans from the French market, where BPA is banned since 2014. More than 125 substances were pinpointed, among them additives such as epoxidised soybean oil and various NIAS. Mostly, 84 oligoester combinations from 8 diols and 4 diacids represented the dominant family. The stepwise organic synthesis of native and deuterated combinations of neopentyl glycol and isophthalic acid enabled a higher confidence level and monitoring in vegetable extracts. Migration of oligoesters averaged 330 µg/kg in the drained vegetables (43 to 1600 µg/kg). This preliminary study sheds light on the need to fulfil a proper risk assessment on this NIAS family (exposure and hazard characterisation). Further, a collaborative research project (acronym OLIGO) funded by the French National Research Agency is on-going to provide a provisional risk assessment related to oligoesters migrating from polyester-based food can coatings. One year after the kick off, a representative set of 7 reference standards have been synthesised. Two work packages are starting on (i) the exposure assessment through the sampling of ~100 canned items with planned identification of oligoesters and semi-quantification in foodstuffs, and (ii) with in vitro assessment of the synthesised substances focusing on genotoxicity, on endocrine disruption potency and on human liver metabolism using tritium-labelled compounds."

As can coatings are usually made of multiple layers, it was clarified that, in the OLIGO project, substances migrating from all the coating material (=every layer) were subject of analysis.

The complexity of NIAS analysis was discussed. One major issue that was highlighted was the lack of standard substances. In the project, reference standards were synthetised step-by-step with a high purity to ensure a proper quantification. Substances without standards were semi-quantified by using models. Benefiting from this work, efforts are being made to make the synthesised standards commercially available. It was highlighted how this is of strong mutual interest for all Member States, and JRC offered to collect, store, and distribute the synthesised NIAS reference standards amongst Member States, as needed.

Willingness to share the database(s) (of components of coatings, oligoesters, phenolic compounds) developed or updated within the OLIGO project was acknowledged. It was clear that there is a good opportunity to cooperate with other EU and national Institutions generating databases of substances used and/or migrating from FCM, such as those presented in previous Network meeting (e.g. the so-called "Belgium database"), under items 5 (CoE initiative) and 14 (for example, the TREFCOM project in BE). Additionally, as mentioned in 6th FCM Network meeting[10], sharing database of mass spectra would really support the evaluation of NIAS. The need to build a such shared European database of substances was re-iterated. This database could be created, preferentially using a dedicated software taking care of storing metadata and allowing data analysis. JRC informed the Network that a software of this kind (ACD Labs) has been used to collect substances listed in Regulation (EU) 10/2011 and others (e.g., NIAS), and that currently options for making the database publicly available are being explored. Additionally, a procedure for collecting data from various sources could be established to ensure the necessary data quality. It was proposed that JRC is best placed for preparing such procedure in the form of a short document that could be circulated within the Network for comments.

Finally, the risk assessment of oligoesters performed in the project OLIGO was discussed. Currently, within the OLIGO project, metabolism, especially potential hydrolysis of oligoesters, and absorption in the gastrointestinal tract (GIT) is not addressed. This issue is dealt within another project from France, funded by the "Trajectoire Nationale" funding scheme[11]. A potential collaboration between ONIRIS and ES within this project is under consideration.

18. What's next after the EFSA Partner grant on coatings (2019)

At the 7th FCM Network meeting (2019), considerations for an harmonised approach for the safety assessment of migrants from coatings were proposed by the Task Force on varnishes and coatings for FCM under the EFSA Partnering grant AFSCO/2017/01-GA07. Krista Bouma presented the follow up activities to this EFSA Partner grant on coatings (2019) that are currently ongoing at the CoE. The summary provided by the speaker is reported below.
"The CoE sets up an *ad hoc* working group on Coatings. This *ad hoc* CoE working group will be led by Belgium and the Netherlands. For coatings there is no harmonised EU legislation, except for Commission Regulation (EU) 2018/213 (BPA in coatings and varnishes) and Commission Regulation 1895/2005/EC (epoxy derivatives). Some member states have national legislation. Not all national legislation is available in English, CAS numbers are not always provided. National FCM legislation is difficult to enforce due to the principle of mutual recognition. Therefore there is a need for harmonisation. This working group will draft a Technical Guidance document for coatings. There are some points of discussion, whether it should be per type of coating, or per type of substate. The report of EFSA Task Force on varnishes and coatings will be used as input. The kick-off meeting will be held in 2023."

The CoE clarified that the working group on coatings will be established under the CoE steering committee on FCM, therefore its participants are representatives from countries that are members of the CoE. It was highlighted that as

[10] https://www.efsa.europa.eu/en/events/event/180710

[11] https://www.paysdelaloire.fr/les-aides/trajectoire-nationale-de-la-recherche-ligerienne

harmonisation of coating legislation is challenging, the working group would greatly benefit from the participation of experts in the field of coatings. For this reason, the CoE invited MSs to propose such representative experts.

19. CoE Technical guide on paper and board

Christa Hametner presented the technical guide on paper and board by the CoE. The summary provided by the speaker is reported below.
"Resolution CM/Res (2020) 9 on the safety and quality of materials and articles for contact with food (Part I) and the supplementary Technical guide on paper and board used in food contact materials and articles (Part II) supersede the previous Policy statement concerning paper and board materials and articles intended to come into contact with foodstuffs (2009). The Guide is aimed at industry (whole supply chain), private and enforcement laboratories as well as national authorities and represents the legal and technical state of the art in Europe (agreed by all Ministers of the CoE). It can be downloaded free of charge at https://www.edqm.eu/en/food-contact-materials-and-articles. An updated version was required for several reasons. First, the technical and scientific progress and discussions about the food safety of recycling qualities had to be considered. Furthermore, the scope should be broadened to also include tissue paper kitchen towels and napkins and therefore superseding the "Policy statement concerning tissue paper kitchen towels and napkins" (2004). Important changes by the current version are the resolution itself with its guiding principles in the Appendix, including no material specific restrictions but e.g. general requirements on intended and non-intended substances (e.g. risk assessment) or definitions of limits for overall and generic specific migration of substances. The current version no longer includes a list of substances used in the manufacture of those materials and articles, but instead references to national regulations and recommendations in Annex I. General requirements are defined, including e.g. criteria for inertness, sensory requirements and specific migration limits for some constituents or contaminants listed in Table 1 of Annex II. Rules for compliance testing are set and special procedures for the assessment of barrier and adsorbent effectiveness as well as the detection of recycled material are included. These requirements are supplemented by instructions for material specific supporting documentation and the necessary information in the declaration of compliance."

Clarifications were given regarding the "specific requirements for recycled paper and board", mentioned in the presentation (slide 8). Specific requirements are intended to be additional to the general requirements applicable to all FCM article types outlined in Resolution CM/Res (2020)9. Specific requirements include the use of input materials of suitable quality and other additional measures such as the use of a cleaning process, functional barriers (on the paper or board or as an internal bag) or functional adsorbents. Other specific requirements for recycled paper and board (such as details on barrier testing and adsorbers, shelf life of articles, exclusion criteria, sorting criteria) were discussed during CoE meetings but no consensus was reached.

The presence of printing inks in recycling inputs was underlined as a potential safety concern arising from recycled paper and board.

20. Danish project on per- and poly-fluorinated alkyl substances in paper and board for food contact - migration study in real food and food simulants

Gitte Alsing Pedersen presented the ongoing Danish project on per- and polyfluorinated alkyl substances in paper and board for food contact materials. The summary provided by the speaker is reported below.
"Migration of per- and polyfluorinated alkyl substances (PFAS) from paper food contact materials (FCM) potentially can pose a consumer risk. However, risk assessment of PFAS in food typically do not consider PFAS contribution from FCM. Moreover, migration studies are often limited to one subclass of PFAS or simplified by using food simulants. Information of migration of PFAS to real food is very limited. To assess the risk of PFAS in FCM, migration of three PFAS subclasses (perfluorinated carboxylic acids/sulfonic acids (PFCAs/PFSAs), polyfluoroalkyl phosphate esters (PAPs), and fluorotelomer alcohols (FTOHs)) from six paper based FCM were investigated in food simulants (50% and 20% ethanol) and different foodstuffs (oatmeal porridge, muffins, and tomato soup) under high-temperature conditions. Migration of PFCAs and FTOHs to all food samples was observed. Migration of PFCAs and FTOHs to 50% ethanol was significantly higher than migration to real food whilst FTOHs did not migrate into 20% ethanol. Dietary PFAS exposure for children were estimated (1.06 – 5.67 ng/kg bw/day) and compared to EFSA's Tolerable Weekly Intake TWI (4.4 ng/kg bw/week)."

It was noted that the simultaneous detection and quantification of anionic and non-anionic substances is particularly difficult when samples are per- and polyfluorinated alkyl substances. GR reported notably the difficulties to analyse FTOHs (see item 21). The details of the analytical method(s) used by DK are reported by Lerch et al. (2022, 2023)[12]. It was clarified that the articles tested for migration had not been used previously and that it is unclear whether they were coated, including with waxes. The details of migration tests were discussed. It was remarked that samples were prepared differently for tests using food and tests using food simulants: for migration into food, articles were used as such, while for migration into food simulants articles where cut into pieces. Therefore, the surface area exposed to simulants was larger than the surface area exposed to food, and tests with food simulants could be considered more conservative (worse-case scenario) than migration tests. This could explain the similar results observed for the migration into 20% and 50% ethanol and, more generally, the larger migration results observed into food simulants compared to food. The choice of the simulants, 20% and 50% ethanol, was also discussed in view of the recommendations to use 95% ethanol or isooctane. While isooctane would not be appropriate for testing PFAS, 95% ethanol would be. It was noted that the total immersion of cut pieces in 20% ethanol could already nearly be considered a total extraction.
DK clarified after the meeting that Tenax was not used as simulant as it has been demonstrated not to be an effective simulant for all food. Instead, DK used 50% ethanol that is recommended for testing migration into foods containing emulsifying lipids (Reg. (EU) 10/2011). Paper & board articles were cut into pieces

[12] Lerch, M, Nguyen, KH, Granby K, 2022. Is the use of paper food contact materials treated with per- and polyfluorinated alkyl substances safe for high-temperature applications? – Migration study in real food and food simulants. Food Chemistry 393, 133375, doi.org/10.1016/j.foodchem.2022.133375.
Lerch, M, Fengler R, Mbog G-R, Nguyen KH, Granby K, 2023. Review: Food simulants and real food – What do we know about the migration of PFAS from paper-based food contact materials? Food Packaging and Shelf Life, 35, 100992.

because it is not possible to make single-sided migration using 50% ethanol simulant. In the study on migration from microwavable plates, the plates were only coated with PFAS on the inner side, so it may be easier for the less viscous ethanol solution compared to the more viscous porridge and tomato soup to extract PFAS. Regarding the simulant for tomato soup, 20% ethanol could extract the perfluoroalkyl acids, but not the more apolar non-ionized fluorotelomer alcohols.

21. Greek projects on targeted and suspect screening analysis of paper and board

Stella Kontou presented ongoing Greek projects on targeted and suspect screening analysis of paper and board. The summary provided by the speaker is reported below.
"Paper and board food contact materials present unique analytical challenges as a large number of organic substances used for their production, such as additives and substances contained in coatings, dyes, adhesives, printing inks, as well as substances falling into the category of non-intentionally added substances (NIAS), may migrate to food. The first of the projects presented focused on the targeted analysis of volatile and semi-volatile perfluoroalkyl substances (PFAS) in paper and board FCM. A headspace – solid phase microextraction – gas chromatography – tandem mass spectrometry (HS-SPME-GC-MS/MS) method was developed, optimised and validated for the analysis of 6 representative PFAS from the groups of fluorotelomer alcohols (FTOHs), perfluorinated sulphonamides (FASAs) and sulphonamidoethanols (FASEs). Thirty two samples of paper and board FCM collected in 2020 from the Greek market were analysed. Approximately 30% of the samples contained 6:2 FTOH. Conversely, 8:2 FTOH, as well as the other targeted analytes, were not detected in the samples tested. In the second project, targeted and suspect screening techniques are combined for the analysis of aqueous and ethanol extracts of paper and board samples, using ultra-high-pressure liquid chromatography coupled to a quadrupole - time of flight detector (UPLC-qTOF). The target analytes selected include perfluoroalkyl substances, bisphenols, primary aromatic amines, benzophenone and other chemicals used as photoinitiators. Suspect screening was performed based on an in-house database, with the view to identify potential migrants from paper and board FCM with special emphasis on chemicals of emerging concern. Since this project is still in progress, only preliminary data on the PFAS and bisphenols identified in the samples were presented."

It was underlined that high levels of BPA were found in extracts of some paper and board samples (2 pizza boxes and 1 food box). Its presence is suspected to be due to the use of recycled material employed in their manufacture, even though this was not specified. DK and PT informed the Network that also during the projects mentioned under item 20 and 14, respectively, BPA was found in recycled paper and board materials, despite a ban for use BPA in paper and board. DG SANTE specified that if manufacturers add BPA intentionally, they should make this information available. If the potential migration of bisphenols from paper and board is a concern, that will be considered by the Commission.

The high prevalence of 6:2 FTOH in the analysed samples was noted, and the Network asked whether the FTOH class of substances was assessed by EFSA in its

opinion on the presence of perfluoroalkyl substances in food[13] (EFSA CONTAM Panel, 2020). From the CONTAM Panel opinion, FTOH substances in particular 8:2 FTOH was considered. With regards to plastics, either the substance 6:2 FTOH was added intentionally hence its use is illegal, or it is a NIAS. DG SANTE informed the Network of the restrictions for PFAS uses under REACH.

22. German and Swiss activities on printing Inks

Stefan Merkel presented the German Federal Institute for Risk Assessment (BfR) Ordinance on printing inks and the status of assessment activities. Beat Brüschweiler presented the new developments in the regulation of FCM printing inks in Switzerland and recent assessment activities by the Swiss Federal Food Safety and Veterinary Office (FSVO). The summaries provided by the speakers are reported below.

German activities: "Substances from printing Inks that are used for food contact materials can migrate into food. Due to the absence of a European Regulation the German Ordinance for Printing Inks for Food Contact Materials (FCM) was published in December 2021. It includes a positive list of substances used in printing inks for printing on FCM in 5 categories (monomers/starting substance, colourant, solvent, additive, photo initiator). If necessary to ensure consumer health protection, the list might contain limitations and restrictions. Only substances for which the BfR has issued a favourable opinion are included in this list. The risk assessment faces different challenges, for example varying compositions of substance mixtures used in solvents or different substance production processes (natural sources vs. synthetic production) leading to different impurity profiles. Furthermore, the evaluation of safety of NIAS such as degradation products of substances that intentionally decompose during printing (e.g. photo initiators) is a challenge for risk assessment."

Swiss activities: "The current Swiss Ordinance on Materials and Articles intended to come into Contact with Foodstuffs (FCM Ordinance, SR 817.023.21), Annex 10, consists of a list of toxicologically evaluated substances (part A) with their correspondent SMLs, and a list of non-evaluated substances (part B), which are substances that have no CMR classification and which should not be detected in the food (analytical limit is 10 µg/kg). In the new version of the Swiss FCM Ordinance that is expected to come into force at the end of 2023 or at the beginning of 2024, the whole part B (almost 4000 substances) will be deleted. Manufacturers will still be able to use such "non-evaluated" substances under the conditions that i) these substances have to be evaluated and risk-assessed by self-control of the manufacturers; ii) they should have no CMR classification; iii) they should not be detected in the food. The declaration of compliance for printing inks and printed materials is mandatory. The self-control of the manufacturers will be controlled by review of compliance documentation by the enforcement bodies. Since 2017, BfR and FSVO meet twice a year for a joint evaluation of applications of substances in printing inks. Approximately 4-5 applications are discussed per year. The competent Swiss and German authorities have expressed a clear intention to further harmonise the regulation of substances in printing inks. Petitioners are encouraged to submit their application dossiers simultaneously to BfR and FSVO."

[13] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6223

CH clarified that list B will be deleted to avoid misinterpretation by business operators who tend to consider those listed substances as authorised, even if some of them are potentially genotoxic. If used, the substances from list B should be evaluated by manufacturers, should be reported in the declaration of compliance, should not be detected in the food (analytical limit is 10 µg/kg) and not be classified as CMR. DE specified that the German ordinance only have one list of similar size as the Swiss list A (ca. 1000 entries) made of substances evaluated along the same lines as Switzerland. The Swiss *in silico* screening for genotoxicity or carcinogenicity potential of the substances from list B aims to alert the business operator(s) on their obligation to demonstrate that those substances – if they were to be used – are safe. It was underlined that the evaluation of any substances used in the manufacture of printing inks should include the assessment of NIAS and oligomers.

The joint evaluation by BfR and FSVO of substances in printing inks was again highlighted as a good example of cooperation supporting the harmonisation of the safety assessment of FCM substances.

23. CoE Multi-analyte methods for the determination of substances migrating from printed FCM

Stella Kontou presented the CoE multianalyte methods for the determination of substances migrating from printed FCM. The summary provided by the speaker is reported below.

"Following the Rapid Alert System for Food and Feed (RASFF) notifications of 2005 and 2006 for the migration of isopropylthioxanthone (ITX) and benzophenone into baby milk and cereals respectively, several official control laboratories developed methods for the determination of photoinitiators and run surveys on the occurrence of photoinitiators in printed FCM and their migration into food. This is a presentation of a collaborative study for the validation of protocols for such determinations, performed between 2018-2021 in the framework of the activities of the CoE on Food Contact Materials[14] by the ad hoc working group on printing inks, chaired by the Greek General Chemical State Laboratory (GCSL). Sixteen laboratories (nine National Reference, three Official Control, two University, one industrial R&D and the EURL) contributed to the protocols' optimisation and the design of the interlaboratory validation study. Ten analytes (6 photoinitiators, 3 degradation products and 1 plasticiser) and two matrices (food simulant 95% ethanol and oat flakes) spiked at two different levels were chosen. The statistical evaluation of the results allowed the publication of reproducible, fit for purpose protocols compatible with either LC-MS/MS or GC-MS/MS instrumentation[15]. In both cases they are based on matrix-match calibration curves with isotopically labelled internal standard for quantification. They include the transitions for each compound monitored, indicative collision energies and retention times that should be optimised for the instrument used and examples of operating conditions for the liquid or gas chromatography. They allow the quantitative determination of selected analytes with a reporting limit of 10 µg/L or 10 µg/kg. Food simulants can be analysed directly without any pre-treatment. For dry food samples, a QuEChERS based extraction of the analytes from the matrix is necessary."

[14] https://www.edqm.eu/en/food-contact-materials-and-articles

[15] https://freepub.edqm.eu/publications/PUBSD-161/detail

GR specified that the 10 analytes subject of the study were chosen based on various factors, including their occurrence in printing materials. The developed methodology is applicable to other matrices and substances, after minimal validation. CoE underlined the excellent work made by the various laboratories and the CoE in this collaborative study. It was specified that at the moment no follow-up activities are foreseen, but Member States can still submit proposals for additional grants on this topic.

24. BfR activities on silicone

Stefan Merkel presented the ongoing BfR activities on silicone FCM. The summary provided by the speakers is reported below.
"From food contact materials made of silicone, cyclic siloxane oligomers can migrate into food. BfR has summarized current toxicological data for silicone oligomers. Oligomers with a molecular weight up to 1000 Da (ring size D13) were considered as relevant. Silicone oligomers show structural similarity and thus, similar metabolites and comparable toxicological effects (not genotoxic, increase of liver and kidney weight) can be expected. Therefore, a group assessment is considered useful. The increase in kidney weight was the most sensitive toxicological endpoint. An exposure assessment and thus a complete risk assessment was not possible due to the lack of migration data from food. For testing the release of volatiles from silicone elastomers, a new method with better reproducibility was developed and validated by the German NRL for food contact materials".

Toxicity data available and gaps for five silicone oligomers migrating <5 mg/kg food were discussed (slide 4). It was pointed out that the toxicological data package depends on the oligomers and the available chronic/carcinogenic studies were performed by inhalation route. DE clarified that the real migration is expected to be much lower, even <50 µg/kg food for tempered materials. The derivation of the proposed health-based guidance value (slide 6) from animal chronic inhalation study was discussed. It was pointed out that an uncertainty factor (UF) of 100 may be low, and that an additional UF may be applied when considering inhalation studies. Post-meeting, DE clarified the calculation as follows: the BMDL05 (kidney weight, chronic inhalation study D4) was converted from ppm to mg/m^3 (D4) (Conversion factor of 24.45 based on 25°C at 1 atm), then inhalation to oral route was extrapolated, a correction factor for oral absorption was applied (absorption D4 for rat: oral 52%, inhalation 5%, SCCP (2005)), and finally the UF of 100 for rat/human extrapolation was applied.

25. ANSES and BfR activities on rubber

Bruno Teste and Stefan Merkel jointly presented the ongoing ANSES and BfR activities on rubber. The summary provided by the speakers is reported below.
"Rubbers are non-harmonized food contact materials at the European level. In the absence of specific regulation or specific directive for a category of material or object and in accordance with article 6 of regulation (EU) n°1935/2004, the existing national provisions apply. In France, a national decree is applied and was updated in 2020. In Germany there are no special measures for non-harmonized materials such as paper and board, silicon or rubber. Instead, BfR published recommendations that are widely used by industry and retail companies. In this context, France and Germany will introduce the similarities and differences from

these national documents concerning the list of substances, the migration testing conditions as well as some specific restrictions for rubber. The main challenges concerning rubber risk assessment identified by Germany and France are mainly focused on non-intentional added substances considerations in the technical dossier and the transposition of migration testing conditions from plastics to rubbers. These items will be discussed in order to pave the way to further discussions that may lead to methodologies harmonization."

The Network chair acknowledged the efforts made by FR and DE to prepare a joint presentation and to identify the commonalities and divergences in the assessment of rubber FCM. It was noted that there are more commonalities than divergences and harmonisation appear to be at hand. Such a harmonisation would benefit all EU actors. For example, harmonisation on tiers defining the toxicological information requirements would be especially beneficial. Both FR and DE base their assessment on the SCF Guidelines/EFSA Note for Guidance. However, FR has an additional tier for substances (both for non-intentionally and intentionally added substances, NIAS and IAS) migrating below 0,5 µg/kg food (based on the US FDA Threshold of Regulation) under which QSAR data is sufficient (no toxicological studies are requested). Whether it is appropriate or not, this results in different data requirements compared to DE and EFSA (SCF Guidelines/EFSA Note for Guidance). Also, the calculation of the migration could be aligned with the SCF Guidelines that is used by DE too. This would avoid divergences when the calculated migration is close to a tier. The migration testing conditions require more discussion between FR and DE for being fully harmonised.

One of the challenges is that food simulants foreseen for plastic materials (as from regulation (EU) 10/2011) are not suitable for rubbers. For example, oil is highly absorbed, and alternative simulants (ethanol 95%/isooctane) tend to underestimate migration and degrade rubber. The simulant alternative to milk (ethanol 50%) tends to overestimate the migration due to extensive swelling while ethanol 15% seems more suitable. Therefore, a need to develop jointly specific simulants for rubbers has been highlighted.

26. Discussion on the revision of the FCM framework legislation

Jonathan Briggs presented the ongoing revision of the FCM framework legislation. The summary provided by the speaker is reported below.
"The Commission is in the process of revising the overall EU FCM legislation. The revision will be based on the findings of the evaluation of the current EU FCM legislation, which was published earlier this year and will also reflect commitments given in key Commission strategies, including the Farm to Fork Strategy and Chemicals Strategy for Sustainability. The Commission has set out key areas to improve upon in its roadmap, including safety of the final FCM article, prioritisation of substances, availability of information in the supply chain, compliance and enforcement as well as consideration of elements to support sustainability. An important consideration in the design of new rules includes capacity in risk assessment, including at Member State level. A number of activities will support the revision and impact assessment work, including the ongoing public consultation."

The staff working document currently available on the EC website[16] mentions the accreditation of analytical methodology, which aims to encourage manufacturers to carry out a comprehensive characterisation of articles and migrating substances, especially NIAS. The Network pointed out that the accreditation process is complex and burdensome, likely resulting in longer times and costs for business operators that want to apply for authorisation of food contact substances. It was highlighted that it is virtually impossible to have accredited and validated methods for each and any substances present in FCM. In fact, even though it is mentioned in the staff working document, EC is currently not proposing such accreditation to be included in the new legislation. The roadmap sets out the vision for the future approach[17]. It was suggested to consider the cosmetics' regulation[18] to set appropriate enforcement models. The Network pointed out that setting appropriate analytical methods has been long discussed, but no outcome has been reached due to the complexity of the matter. In the last decade, the FCM European Reference Laboratory (EURL) has decided to focus on standardisation and validation of methods, what shifts the responsibility/accountability on single laboratories performing analysis on FCM.

Network participants were invited to provide insights on specific approaches that could be used in the revision of the FCM legislation. Breakout groups were organised on the three main topics: 1) prioritisation, 2) risk assessment and 3) risk management. The outcome of the breakout discussions were the following:

Prioritisation: A possible approach to support the prioritisation and assessment of FCM substances would be to use information collected by ECHA under REACH/CLP. The Member States acknowledged that this approach is valid but stressed that data collected from CLP and REACH dossier might not be enough for the risk assessment of FCM. For example, under CLP only substances >0.1% w/w need to be reported, which threshold is much higher than the one used in FCM risk assessment. Toxicological data submitted under REACH is often available only as a summary, without reporting details or raw data (which are commonly requested in FCM risk assessment). The proposed prioritisation scheme (slide 9) was discussed. It was pointed out that – in addition to hazard - exposure could be considered in tier 1 and 2. This would lead to consider hazardous substances not migrating (so no exposure) not to be of concern for consumers. On the contrary, for instance polyvinylchloride (PVC) (made with vinyl chloride) would be banned. It was opposed that this may not be the case as PVC may be considered an essential use that would be assessed possibly considering the migration/exposure. It was noted that the tier 2 includes nanomaterials, for which safe levels are not set, and Cramer class III substances which include reprotoxic and neurotoxic substances, endpoints possibly covered under priority 1 and intermediate to 1 and 2. Finally, it was pointed out that the scheme should also consider metabolic effects of substances.

Risk assessment: The Member States considered important to build practical and efficient cooperation, synergy with ECHA on drinking water articles. The importance to use relevant available data, e.g. from REACH and US FDA dossiers

[16] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022SC0163&from=EN

[17] https://food.ec.europa.eu/document/download/c2437e5d-2622-4f17-bbea-7befbe2c271a_en?filename=cs_fcm_iia_20201218.pdf

[18] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20221217

(especially toxicity studies performed according to OECD test guidelines) was also pointed out and it was noted that to facilitate the access to relevant information, this should be compiled into database or lists. For example, a list of NIAS including the most common NIAS found in FCM together with the materials in which they are expected would be helpful in giving guidance to manufacturers on expected NIAS. As discussed under item 5, CoE's lists of substances evaluated at EU or national level would be very helpful too. With regards to cooperation on risk assessment, the approach used for plant production products, where MSs Authorities prepare the assessment and EFSA review it, could be explored. Alternatively, experts from Member States (e.g. from national committees) could perform the risk assessment together with experts from EFSA's working groups. EFSA informed the Network that options including a wider role of Member States experts are under discussion.

Risk management. The Member States considered not feasible extending the use of positive lists of substances to all FCM article types, due the very large number of FCM substances used in some articles or potentially migrating from them (e.g. paper and board and thermoset coatings). It was proposed to set up a list of priority substances in FCM to be controlled by national authorities. This list could include substances currently listed with restrictions in European or national legislations, such as substances used in plastics FCM with a SML (reg (EU) 10/2011) and most common NIAS. It was pointed out that the list would be useful only if short. The list would be of limited use for FCM articles with complex composition and with a very large number of potential migrating substances, such as thermoset coatings or inks. Risk management could focus more on final articles, with a uniform approach for IAS and NIAS.

27. Welcome and practical information

The chair welcomed the participants and updated them on the agenda and the unfolding of the day.

28. EFSA Scientific Committee Guidance on nanoparticles

Maria Chiara Astuto and Irene Cattaneo presented the EFSA guidance documents on nanomaterials: "Technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles" and "Risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health". The summary provided by the speakers is reported below.

Guidance on technical requirements: "Following a mandate from the European Commission, EFSA has developed a Guidance on Technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (or Guidance on Particle-TR[19]), defining the criteria for assessing the presence of a fraction of small particles, and setting out information requirements for applications in the regulated food and feed product areas (e.g. novel food, food/feed additives, food contact materials and pesticides). These requirements apply to particles requiring specific assessment at the nanoscale in conventional materials that do not meet the definition of engineered

[19] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6769

nanomaterial as set out in the Novel Food Regulation (EU) 2015/2283. The guidance outlines appraisal criteria grouped in three sections, to confirm whether or not the conventional risk assessment should be complemented with nano-specific considerations. The first group addresses solubility and dissolution rate as key physicochemical properties to assess whether consumers will be exposed to particles. The second group establishes the information requirements for assessing whether the conventional material contains a fraction or consists of small particles, and its characterisation. The third group describes the information to be presented for existing safety studies to demonstrate that the fraction of small particles, including particles at the nanoscale, has been properly evaluated. In addition, in order to guide the appraisal of existing safety studies, recommendations for closing the data gaps while minimising the need for conducting new animal studies are provided. This Guidance on Particle-TR complements the Guidance on risk assessment of nanomaterials to be applied in the food and feed chain, human and animal health updated by the EFSA Scientific Committee as co-published with this Guidance. Applicants are advised to consult both guidance documents before conducting new studies."

Guidance on risk assessment of nanomaterials: "The EFSA has updated the Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, human and animal health[20]). It covers the application areas within EFSA's remit, including novel foods, food contact materials, food/feed additives and pesticides. The updated guidance, now Scientific Committee Guidance on nano risk assessment (or SC Guidance on Nano-RA), has taken account of relevant scientific studies that provide insights to physico-chemical properties, exposure assessment and hazard characterisation of nanomaterials and areas of applicability. Together with the accompanying Guidance on Technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (Guidance on Particle-TR), the SC Guidance on Nano-RA specifically elaborates on physico-chemical characterisation, key parameters that should be measured, methods and techniques that can be used for characterisation of nanomaterials and their determination in complex matrices. The SC Guidance on Nano-RA also details aspects relating to exposure assessment and hazard identification and characterisation. In particular, nano-specific considerations relating to in vitro/in vivo toxicological studies are discussed and a tiered framework for toxicological testing is outlined. Furthermore, in vitro degradation, toxicokinetics, genotoxicity, local and systemic toxicity as well as general issues relating to testing of nanomaterials are described. Depending on the initial tier results, additional studies may be needed to investigate reproductive and developmental toxicity, chronic toxicity and carcinogenicity, immunotoxicity and allergenicity, neurotoxicity, effects on gut microbiome and endocrine activity. The possible use of read-across to fill data gaps as well as the potential use of integrated testing strategies and the knowledge of modes or mechanisms of action are also discussed. The Guidance proposes approaches to risk characterisation and uncertainty analysis."

The appraisal criteria used to decide if nano-specific considerations are needed to complement the conventional risk assessment (Guidance on Particle-TR) were discussed. In the "screening of particle size" criteria (slide 12), the guidance states that "the detection capability of the method(s) used for this assessment should

[20] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6768

provide convincing evidence that the material contains less than 10% of particles (number-based) with at least one dimension smaller than 500 nm". EFSA clarified that the 10% and 500 nm values are pragmatic triggers. Excerpts from the guidance are reported below: "The rationale behind this appraisal route is that particle uptake from the GIT has been generally found to be possible for sizes up to 250 nm. […] An uncertainty factor of 2 is applied to account for the limitations of available screening techniques for size measurements resulting in a limit of 500 nm."; "Assuming a normal size distribution of the full material (which represents a worst-case scenario for conventional materials), 10% or less of the particles being smaller than 500 nm implies that the fraction of nanosized particles (1–100 nm) will be minimal and that the likelihood of a risk from their uptake is negligible".

With regards to the risk assessment of nanomaterials, the publication of two papers[21] that might question the suitability of conventional risk assessment was mentioned. One from the US FDA reports the case of silver nanoparticles in FCM that dissolve in contact with food and re-form later under certain conditions.

It was also questioned whether the EFSA guidance considers nanoparticles originated from abrasion of FCM articles and their standardisation. EFSA clarified that the EFSA guidance provides examples for this matter as illustrated in recently published EFSA opinions[22] considered abrasion of articles.

29. EFSA colloquium and Member States' activities on micro-plastics

Sandra Rainieri (EFSA), Stefan Merkel (Germany) and Marie-Louise Nilsson (Sweden) presented the planned, ongoing and past activities on micro-plastics. The summary provided by the speakers is reported below.

EFSA: "A coordinated approach to assess the human health risks of micro- and nanoplastics in food" (EFSA's Scientific Colloquium 25). A scientific colloquium on the state of knowledge and ongoing research on micro and nanoplastics was organised by EFSA in May 2021. The event aimed at facilitating the risk assessment of micro and nanoplastics for human health as well as the translation of new data into policy decisions by bringing stakeholders together, filling the gaps in scientific knowledge and foster collaboration and synergies. Overall, a large list of uncertainties was highlighted indicating that further efforts are still needed to generate the data necessary for a comprehensive human health risk assessment. Specifically, the major gaps identified were *i)* the lack of standardised analytical tools, essential for producing reliable scientific data; *ii)* the lack of scientific evidence, specifically good quality exposure data, mode of action and dose-response relationship data, important for shaping the risk assessment and enforce regulations and *iii)* the overall the need to better coordinate research and knowledge to optimise resources. Considering the state of the risk perception on

[21] i) Tianxi Yang, Teena Paulose , Benjamin W. Redan, James C. Mabon and Timothy V. Duncan. Food and Beverage Ingredients Induce the Formation of Silver Nanoparticles in Products Stored within Nanotechnology-Enabled Packaging. ACS Appl. Mater. Interfaces 2021, 13, 1, 1398–1412 – ii) Maryam Jokar, Gitte Alsing Pedersen & Katrin Loeschner, 2017. Six open questions about the migration of engineered nano-objects from polymer-based food-contact materials: a review, Food Additives & Contaminants: Part A, 34:3, 434-450, DOI: 10.1080/19440049.2016.1271462.

[22] Safety assessment of the substance silver nanoparticles for use in food contact materials (https://www.efsa.europa.eu/en/efsajournal/pub/6790); Safety assessment of the substance fatty acid-coated nano precipitated calcium carbonate for use in plastic food contact materials (https://www.efsa.europa.eu/en/efsajournal/pub/7136)

such topic, the need for a more transparent communication to stakeholders and citizens on the scientific knowledge and the work done to identify the risk for human health was also highlighted. Risk assessment of micro and nanoplastics is indeed a complex issue that requires expertise of different stakeholders, coordinated research initiatives and international cooperation in a full life-cycle risk assessment. As a follow up of the colloquium, EFSA has been directly involved in one project on the international comparison of risk perception of microplastic in cooperation with BfR, has been part of the advisory board of a number of European Projects and keep monitoring the development of this field through the various scientific projects ongoing in the EU and outside."

DE: "Micro-plastics can be analysed by many different methods like spectroscopic, thermo-analytical or optical methods but a standardized method does not exist. In 2020 the release of micro-plastic from the degradation of polypropylene feeding bottles during infant formula preparation was reported by Li et al. (2020)[23] These results were discussed at the BfR Committee for Consumer Products and further research for verification of these results was deemed necessary. Gerhard et al. (2022)[24] later showed that fatty acids and their esters migrate from some infant baby bottles and can precipitate when cooling down. This study showed that spectra of food additives can imitate spectra of supposed micro-plastic particles, leading to false positive results and to the overestimation of the number of micro-plastic particles."

SE: " In 2018 the Swedish Food Agency (Livsmedelsverket) was asked to conduct a review on health risks posed by the presence of micro- and nano-plasticsin drinking water, mapping the presence of such contaminants in drinking water in Sweden and to suggest risk management action to reduce the exposure, if needed. Focus was on microplastics since standardized analytical methods were not available for nanoplastics. Based on today's knowledge in combination with the drinking water survey in Sweden, human health risk as a result of exposure to nano or micro plastics in drinking water could not be identified or clearly indicated. A basis for risk management actions was therefore not found. Improvements in the assessment requires broader knowledge of occurrence and exposure as well as toxicological studies relevant for risk assessment."

The EFSA NAMS4NANO Project[25] was mentioned during the discussion. This project was designed in the context of the implementation of the EFSA Roadmap on New Approach Methodologies (NAMs) and aims to develop case studies addressing nano-specific considerations to promote the integration of NAMs results in chemical risk assessments. The second phase of this project will be launched in 2023 and will focus on designing case studies on nanoplastics, developing a risk assessment guidance for nano contaminants and promoting a harmonised international risk assessment for nanoplastics.

Regarding the presentation on Germany activities, the results from Gerhard et al. (2022) were further commented. DE specified that, currently, BfR has not

[23] Li, D., Shi, Y., Yang, L., Xiao, L., Kehoe, D.K., Gun'ko, Y.K., Boland, J.J. and Wang, J.J., 2020. Microplastic release from the degradation of polypropylene feeding bottles during infant formula preparation. Nature Food, 1(11), pp.746-754.

[24] Gerhard, M.N., Schymanski, D., Ebner, I., Esselen, M., Stahl, T. and Humpf, H.U., 2022. Can the presence of additives result in false positive errors for microplastics in infant feeding bottles?. Food Additives & Contaminants: Part A, 39(1), pp.185-197.

[25] https://www.efsa.europa.eu/it/art36grants/article36/gpefsamese202201-nams4nano-integration-new-approach-methodologies-results

identified any concern related to the release of micro or nanoplastics from components of FCM articles in food. However, relevant information (such as on exposure and hazard) are missing for carrying out an exhaustive safety assessment. DE informed the Network that BfR established a working group on microplastics which is coordinating research activities in Germany.

Regarding the presentation on Sweden activities, the statement "Microplastics as carrier of chemical substances indicate low risks for considered examples" (slide 9) was further discussed. SE clarified that the exposure to selected hazardous pollutants (such as BPA, PCBs and PAHs) was estimated based on their expected or maximum measured concentrations and on the amount of microplastics found in drinking water. SE invited the Network to read to the published report[26].

30. VKM report on Food and chemical substances relevant for monitoring

At the 7th FCM Network meeting, the results of the VKM report on the ranking of substances for monitoring in foods, drinks and dietary supplements - based on risk and knowledge gaps[27] were presented. As a follow-up to this activity, Inger-Lise Steffensen presented VKM's report on substances relevant for monitoring. The summary provided by the speaker is reported below.
"At request from the Norwegian Food Safety Authority, the Norwegian Scientific Committee for Food and Environment (VKM) identified food groups and food items consumed by the Norwegian population that were relevant for monitoring regarding content of one or more undesirable chemical substances. Undesirable chemical substances were defined as chemical substances in food that may constitute a potential health risk. VKM created a knowledge base (an Excel file) as a tool for planning and prioritising monitoring of foods and undesirable chemical substances. The substance groups included were flavourings, food additives, metals and metalloids, natural toxins, persistent organic pollutants, process-induced contaminants, substances in food contact materials, substances in food supplements and trace elements, in total >40 substances. Food items that are known contributors to exposure to an undesirable chemical substance were identified from quantitative and qualitative data, mainly from EFSA Opinions and VKM risk assessment reports. Four national dietary surveys were used for identification of food items and food groups habitually eaten by the Norwegian population. The habitual diet was used to identify potential unknown sources of the substances. The information on known and unknown sources was compiled in a knowledge base comprised of 456 undesirable chemical substance/food item pairs that were considered relevant for monitoring. For each such pair, information about food category, contribution to total exposure, including degree of contribution, origin of occurrence data, availability of Norwegian occurrence data, remarks regarding sampling, sources of the undesirable chemical substances in food and risk as a combined score of hazard and exposure, were included in the knowledge base. Careful planning of the sampling strategy is needed. Generic

[26] https://www.livsmedelsverket.se/globalassets/om-oss/regeringsuppdrag/rapport-mikro-och-nanoplast-i-dricksvatten.pdf

[27] 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
https://vkm.no/download/18.59c1cc3017057cd177f1653b/1582108692752/Ranking%20of%20substances%20for%20monitoring%20in%20foods,%20drinks%20and%20dietary%20supplements%20-%20based%20on%20risk%20and%20knowledge%20gaps%20revidert2.pdf

guidelines on sampling strategy, including sample number and frequency, were provided in the report. The study is described in a VKM report[28], which is available on the VKM website[29]."

Norway clarified that up to now, Norway have used food categories in the system called KBS. However, steps are now taken for a future harmonisation of these food categories with those used by EFSA.

31. EFSA new Focal Point Framework and tailor-made activities

Drago Marojevic presented the new EFSA Focal Point (FP) Framework and related tailor-made activities. The summary provided by the speaker is reported below.
"The Transparency Regulation notably aims at enabling closer cooperation of Member States and EFSA in order to improve the sustainability of food safety risk assessment and developing comprehensive risk communication in Europe. Appropriate cooperation mechanisms will need to be developed or adapted and the review of the FP Network is part of this effort to strengthen collaboration for the benefit of EFSA and Member States alike. Following an external evaluation of the FP Network carried out in 2021 and the work carried out by the AF Steering Group on the new FP Operational Framework (AFSG) composed by EFSA and AF/FP representatives, EFSA and Member States delivered the new FP Operational Framework which will be in place as of 2023. The new framework is based on a model which is multiannual, flexible and tailor-made. Multiannual with the implementation of a 5 years Framework Partnership Agreement; flexible as it envisages five areas of work: 1) Knowledge and information management and support to scientific production 2) Engagement, collaboration and partnerships, 3) Capacity building, 4) Data, 5) Risk Communication; tailor-made as it will comprise the implementation of principal activities (26 activities common to all Member States for the five years) and tailor-made activities, which are "project" either with a collaborative nature or considered a priority by EFSA and specific Member States. The budget allocated for the principal activities is 2.1M while for the tailor-made ones, EFSA envisages a financial investment of 4.5M in 2023 up to 10M in 2027. The new FP framework and activities will be accompanied by overarching key performance indicators (KPIs) per area of work which will help to assess the overall impact throughout the years and to monitor how the framework will contribute to the expected operational results of the EFSA Strategy. Moreover, a close monitoring of the implementation will be the key element of the new FP framework. EFSA envisages dedicated meetings and monitoring activities with the MS throughout the year so to allow an early identification of possible bottlenecks but also to ensure the sharing of best practice within the Network."

The Network asked for more information on the changes brought by the Transparency Regulation to the focal point framework. So far, focal points were limited to few fields agreed *a priori* with Member States. Now, EFSA can support tailor-made activities proposed by MSs, that are considered a priority by EFSA and specific Member State(s). When a new activity is proposed by a Member State, this is considered, evaluated and potentially approved by the focal point group in

[28] VKM, Camilla Svendsen *et al.* (2022). Food and chemical substances relevant for monitoring. Report from the Scientific Steering Committee of the Norwegian Scientific Committee for Food and Environment. VKM Report 2022:18, ISBN: 978-82-8259-393-9, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

[29] https://vkm.no/english/riskassessments/allpublications/riskrankingofundesirablesubstancesinfoodwhichfoodsarethemostrelevanttomonitor.4.3339a32617b42a935c96ca6f.html

EFSA. Such activities can foresee a cooperation between Member States. EFSA invited the Network representatives to contact their national focal points to be informed on the national ongoing activities and possibly participate to them.

32. Training on the VERMEER FCM tool for estimating the migration and evaluating different hazards relevant to FCM compounds

Els van Hoeck provided training on the VERMEER FCM tool for estimating the migration and evaluating different hazards relevant to FCM compounds. The summary provided by the speaker is reported below.
"Within the European Life–VERMEER project (ENV/IT/000167), software platforms for risk assessment were elaborated by combining tools for exposure assessment with *in silico* models for hazard predictions to identify substances of high risk and propose safer alternatives. Specifically for food contact materials (FCM), the VERMEER FCM tool was developed according to the regulatory requirements. The VERMEER FCM software is integrated with MERLIN-Expo and is freely available (https://www.vegahub.eu/portfolio-item/vermeer-fcm/). Overall, VERMEER FCM consists of 3 modules that allow (i) to model the migration of chemicals into food, (ii) to predict toxicological endpoints relevant to substances with the potential to migrate from FCM and (iii) to automatically check whether the compound of interest is included in Annex I of Regulation (EU) No 10/2011. The three modules can be run either separately or in combination. The migration model has been newly developed and allows deterministic and probabilistic simulations. Hazards are predicted by QSAR models publicly available in the VEGA hub. The selected models align with the requirements described in EFSA's note for guidance for preparing an application for the safety assessment of a substance, including models for genotoxicity, subchronic toxicity, reproductive and developmental toxicity and carcinogenicity. Next, regulatory information, including specific migration limits and use restrictions, was assembled from Regulation (EU) No 10/2011. In order to apply the VERMEER FCM tool, users are asked to provide information regarding the chemical(s) of interest (including the SMILES formula and physicochemical properties), the FCM and the food concerned, and other relevant parameters such as the contact temperature and the contact time between food and FCM. The VERMEER FCM tool currently focuses on plastic FCM but will be extended to other FCM types. Finally, the applicability of the tool is demonstrated using a case study, and the future potential has been illustrated."

With regards to future development, the tool could include a semi-automated workflow including (Q)SAR models to support the risk assessment of non-evaluated food contact material substances (SILIFOOD project, slide 42). The part of the tool predicting the migrant's hazards will include additional endpoints such as endocrine disrupting activity. This could be useful to prioritise the assessment of substances such as NIAS. The Network participants were encouraged to visit the website of the "CONCERT REACH"[30] project for additional non-testing methods and models to predict hazards of chemicals.

The functioning of the tool was further discussed. It was highlighted that the tool cannot be used to estimate migration of substances for which there is no physicochemical information at all ("total unknowns"). The tool needs at least the molecular mass and the SMILE code as input value. Then, it can use modelled parameters to estimate migration values. For example, if the partition coefficient

[30]Concerting experimental data and in silico models for REACH https://www.life-concertreach.eu/project/

between food and FCM is not given, the tool uses an overestimated default value. The tool is in principle applicable to FCM other than plastic, but this has not been tested so far. Thus, at the moment, it can only be used for organic substances migrating from plastics. Developers of the tool are focusing in adapting it to predicting migration from paper and board, to which the Network expressed high interest. JRC informed the Network that a task force on migration modelling is established at the FCM EURL and the existing "practical guidelines on migration modelling for the estimation of specific migration"[31] are still valid. The Guidelines should be extended to take into account recent advancements in the field, notably on paper and board. JRC highlighted that retrieving data to extend and test the models is difficult and invited the Network representatives to share their experimental data on migration. The chair further encouraged JRC and BE to agree on the data needed to test their migration models and invited the Network representatives to share those data. This could be facilitated by an agreed (between JRC and BE) simple template document, specifying the data needed and instruction on how to report them. The document could be circulated to the Network representatives.

33. AoB

The importance of guidelines and tool for prioritisation was brought forward as the topic of prioritisation was discussed all along the meeting for several purposes: the review of positive list of authorised substances (Drinking Water, item 8), the setting of responsibilities and actor(s) for performing an EU assessment (revision of the FCM regulation, item 26), the assessment of NIAS (VERMEER FCM, item 32), the monitoring and control (VKM, item 30).

V. Golja briefly presented the work of the enamel working group at the Council of Europe. Enamel differs from ceramics because lower temperatures and different starting materials are used for its production. The group is preparing a Technical Guide that will describe the test methods to measure the release of elements from enamel and limit values for elements that the European Commission has not yet considered in ceramics - that is, for Li, Sb, Cu, Mn, Zn and Fe.

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

Gilles Rivière summarised some of the points recurrently raised during the discussions of the meeting and proposed potential follow-up activities.

The exchange of information is key to avoid duplication and create synergies. This requires notably **shared European databases** as highlighted during this and previous Network meetings. A better access by Member States representatives along with cooperation at national level with EFSA focal points is needed to benefit of the EFSA "R4EU database on **Member States risk assessment plans**". it is essential i) to report in advance the future projects and ii) to check the list before starting a new project. European database(s) of **evaluated substances** at EU and national levels as well as of identified (possibly evaluated) **NIAS together**

[31] https://publications.jrc.ec.europa.eu/repository/handle/JRC98028

with their mass spectra would avoid duplication and support the evaluation of NIAS. This needs to be coordinated at the EU level.

Complementary to databases, ***in silico*** **tools** on hazard, possibly combining both the migration modelling and the hazard identification such as the VERMER FCM would support the **prioritisation** of substances (both IAS and NIAS) that is particularly important given the large number of substances used and/or migrating from FCM. Several tools and methods can be potentially used for prioritisation (e.g. ECHA/DW, ECHA/substances for further regulatory action, EFSA phthalates, EFSA/opinion on substances without SML, BE/strategy for non-harmonised FCM, NW/monitoring in foods). An overview and comparison of the different methods applied for the same or different prioritisation purposes become necessary to support the harmonisation of methodology(ies).

Various harmonisation efforts between Member States were acknowledged, such as between DE and CH on printing inks, and between DE and FR on **rubbers**. Clear opportunities for cooperation on rubber were identified at the Network meeting in 2019. The opportunity was taken, and commonalities and differences/divergences were identified with more commonalities than divergences. Willingness to move from collaboration to harmonisation that is at hand was noted. Such a harmonisation would benefit to all EU actors. The need to extend collaboration and harmonisation efforts to other fields was stressed.

Safety of **biobased articles** and the related assessment of **natural compounds and complex mixtures** is an important topic which is also the subject of many scientific publications. Member States reported their ongoing activities that illustrate their interest in the topic. EFSA is discussing on potential approaches to the risk assessment of compounds of natural origin, which the concepts and the assessment scheme are still under development. All the activities on this area need to be followed closely keeping the Network informed.

The focus of projects and activities on FCM is often on the "usual suspects" that are known hazardous substances and substance(s) of 'high interest', for example phthalates and contaminants. An increased interest on "non-usual suspects" IAS and NIAS is necessary to which recent and ongoing **multi-analytes screening analysis** activities are useful.

Finally, the network was informed on the current status of the **revision of the FCM framework legislation.** Network representants gave their first thoughts and will have the more opportunities to provide their input.

35. Concluding remarks

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.

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.