NETWORK MEETING ON THE COOPERATION AND HARMONISATION OF RISK ASSESSMENT OF FOOD CONTACT MATERIALS (FCM) THE 'EFSA FCM NETWORK'

Minutes of the 10th meeting
17th – 19th October 2023
14:00-18:00 / 09:30-18:00 / 09:30-12:30
Minutes agreed on 27th November 2023

Location: EFSA – Parma – Board room

Attendees:

- Network Participants (including EFTA Countries):

Country	Name
Austria	Thomas Schwartz Christa Hametner*
Belgium	Els Van Hoeck
Bulgaria	Valentina Hristova-Bagdassarian
Croatia	Nino Dimitrov*
Cyprus	Nektaria Varnava
Czechia	Jitka Sosnovcová
Denmark	Bina Bhattarai
Estonia	Külli Suurvarik*
Finland	Merja Virtanen*
France	Fernando Aguilar*
Germany	Friederike Kühne
Greece	Stella Kontou
Hungary	Gabriella Gaál
Iceland	Katrin Guðjónsdóttir*
Ireland	Karl McDonald
Italy	Emanuela Testai*
Lithuania	Skirmante Ambraziene
Luxembourg	Sandy Nosbusch
Netherlands	Krista Bouma
Malta	Gianella Pisani*
Norway	Inger-Lise Steffensen
Portugal	Maria de Fátima Poças
Slovakia	Karolína Rimbalová
Slovenia	Viviana Golja
Spain	Ana Rodríguez Bernaldo de Quirós Juana Bustos
Sweden	Marie-Louise Nilsson
Switzerland	Beat Brüschweiler

- **Experts attending for agenda item 4 (styrene):**
  Ulrike Gündel* (Germany), Shruti Kabadi* (US FDA), Francesca Marcon* (Italy), Dominique Masset* (attending on behalf of EMA) and Martin Walter* (attending on behalf of EMA)
- **Experts attending for agenda item 15 (rubbers):**
  Benjamin Teneul* (French DGCCRF)

*online participant

- **European Commission/Other EU Agencies representatives:**
  Jonathan Briggs (EC SANTE), Stefano Frattini (ECHA, Unit B4), Niko Hellsten* (ECHA, Unit B4) and Eddo Hoekstra (EC JRC)
- **Intergovernmental organisations**:
  Teresa Carrilho* (Council of Europe, EDQM)
- **Members of Committees and Panels invited as speakers**:
  Riccardo Crebelli*, Marcel Mengelers*, Gilles Rivière (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids, CEP Panel), Laurence Castle (EFSA Panel on Food additives and flavourings, FAF Panel) and Emma Di Consiglio* (CEP Working Group on Food Contact Materials)
- **EFSA**:

  FIP (Food Ingredients and Packaging) Unit: Eric Barthélémy (FCM Network Coordinator, Chair), Daniele Comandella (FCM Team), Valeriu Curtui (Unit Head), Zainab Al Harraq (FCM Team), Gloria López-Gálvez, Sandra Rainieri (FCM Team Leader) and Katharina Volk (FCM Team)

  COM (Communication) Unit: Arthur Healy and Isabel Mandel

  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. He remarked that especially in FCM, with the fragmentation and limited harmonised legislations at EU level of the so-called "non-plastics" FCM, the work towards greater harmonisation is essential. Additionally, he underlined the importance of involving the Network through early-stage information, approach and results sharing and discussion of relevant plastic and related EFSA generic Mandates on risk assessment methodologies such as for example the ongoing assessment of styrene (agenda item 4) and the preparation of the ESFA Technical report on Mixtures of natural origin used to manufacture food contact materials (agenda item 12).

Additional participants from Member States (with specific interest and/or expertise on the topics of the meeting) as well as representants of the European Medicines Agency (EMA) and from the US Food and Drug Agency (US FDA) participated to the discussion of agenda item 4 on the re-assessment of styrene.

Finally, he highlighted the representation of 24 EU Member States, 3 EFTA Member States, the Council of Europe (CoE), the European Chemicals Agency (ECHA) and the European Commission (EC SANTE and JRC). He thanked them all for attending the meeting fostering collaboration and sharing knowledge.

Apologies were received from representatives from Latvia, Romania and Poland for the entire meeting.

2. Adoption of the Agenda

The agenda was adopted without changes. The minutes of the 9th meeting of the Network on Food Contact Materials held on 20 April 2023, Parma, were agreed by written procedure on 9th May 2023 and published on the EFSA website[1].

3. Declarations of Interest and statement of confidentiality

The derogation for Network participants and hearing experts to submit a Declaration of Interest (DoI) was confirmed to be extended until end 2024. All participants signed a statement of confidentiality.

4. EFSA-Q-2023-00365: Safety assessment of styrene

4a. Mandate, Answering the mandate

Gilles Rivière presented the mandate on styrene received by the EC and the EFSA's approach to answer the mandate.

Styrene is currently authorised to manufacture plastics without specific restrictions. Following the EFSA opinion on the International Agency for Research on Cancer (IARC) Monography and the data received from the industry indicating that migration of styrene monomer from styrenics plastics into food is likely to exceed 10 µg/kg food, EC has proposed to set a specific migration limit (SML) of 40 µg/kg food (based on the guidance value of 20 µg/kg determined by WHO for drinking water, which is based on an existing TDI and a 10% allocation factor). The mandate requests EFSA to address the genotoxicity associated with oral exposure to styrene and to answer as to whether the use of styrene, if authorised in accordance with Article 5 of Regulation (EU) No 10/2011 subject to the above mentioned SML of 40 µg/kg food, is in accordance with Article 3 of Regulation (EC) No 1935/2004. To address the genotoxicity potential and safety against the 40 ppb SML, EFSA favours a fit-for-purpose process in a reasonable timeframe. The approach agreed to answer the mandate considers the evaluation of (i) the new studies submitted by the US Styrenics Industry Association (SIRC) to the EC, (ii) the reliability and relevance of the oral genotoxicity studies referenced in the IARC Monograph, (iii) the toxicokinetic studies referenced in the IARC Monograph, along with (iv) new *in vivo* studies (oral exposure) published since the IARC Monograph that will be retrieved through a literature search covering genotoxicity, toxicokinetics and human biomonitoring. Additional data to answer potential uncertainties and lack of information will be requested if needed and a public consultation will be held.

4b. Progress and protocol

[1] https://www.efsa.europa.eu/sites/default/files/2023-05/minutes-9th-meeting-of-the-fcm-network.pdf

Zainab Al Harraq presented an overview of the protocol and the methodology that are being used to carry out the evaluation. She also presented the status of the evaluation.

4c. Genotoxicity

Riccardo Crebelli presented the preliminary conclusions from the EFSA FCM WG on the two recent studies from the US SIRC and on the *in vivo* oral genotoxicity studies from the IARC Monograph and the literature.

4d. Toxicokinetics and human biomonitoring

Emma di Consiglio and Marcel Mengelers presented the preliminary conclusions on ADME properties and the human biomonitoring of styrene.

4e. Next steps

Zainab Al Harraq presented a wrap-up of the session on styrene and the next steps foreseen for the completion of the evaluation.

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

Gloria Lopez Galvez presented the ongoing EFSA activities in the context of the Chemicals Strategy for Sustainability (CSS) and the One substance One assessment (1S1A). The summary provided by the speaker is reported below.

"In the Food Contact Materials (FCM) network meeting of November 2022, an introduction to the Chemicals Strategy for Sustainability (CSS) and the One substance One assessment (1S1A) was presented. The current session aims to be an update of the activities being followed and implemented by EFSA in the context of CSS-1S1A. The presentation focuses on the following activities: 'Early identification of cross-cutting substances', 'Piloting the 1S1A approach', 'Study to map Data Requirements (DR) and Risk Assessment Methodologies (RAM)', 'Contribution to the EU-Common Data Platform on Chemicals (EU-CDPC)'. The early identification of cross-cutting substances will be tested with chemicals (on on-going or finished assessments) from ECHA, EMA, the EC Scientific Committees and the food/feed assessments of Member States; the searching strategies and the application of 1S1A concepts (e.g. data sharing) will be examined. The collaboration with ECHA on the development of the Drinking Water Directive (DWD) is a real and on-going example of the testing the four pillars of the 1S1A: initiation, allocation, data and methodologies. Whilst piloting within the DWD, some misalignments in data requirements between REACH and FCM were identified, being that the main driver for the study to map the DR and RAM across the various regulatory areas on chemicals in the EU, which principal aim is to identify commonalities and differences across the operating frameworks. The establishment of the EU-CDPC with chemicals data is a major objective of the 1S1A; several building blocks will compose this platform as e.g. a repository of health limit values, a central database with regulatory submissions (IUCLID), occurrence data (IPCHEM). An update on the legislation supporting the 1S1A —still under preparation— will also be presented, focusing on the CLP Revision, the re-attribution on task and data and the like impacts to EFSA."

The Network welcomed the intended collection of data on chemicals generated in the context of various regulatory frameworks and the preparation of shared common databases. The participants stressed the effort needed to make data harmonised and interoperable, as well as the quality required for their (re)use. Some of the data may be not of the quality needed to support risk assessment as currently performed. The case of mineral oil hydrocarbons (MOH) was mentioned as the JRC developed a harmonised analytical test methods to detect MOH in food infant formula only recently. This implies that data on the MOH in foodstuff that has been generated so far might not have been obtained using methods granting the same required quality. It is important that users of data collected in database are aware of the variabiliy in the quality of the collected data. It was also proposed that the collection of data could go together with an assessment of data quality. This should however be brought into context. For instance, EFSA and/or ECHA consider the validity of the received raw data for their assessment. So the need for quality check depends on the type of data collected and made available (raw data versus summary; data already assessed or not). It was clarified that the responsible of the quality of data included in databases will be the EU institutions that were responsible for its collection (e.g., via submission of applications) or generation. The database will be managed by ECHA.

It was noted that the 1S1A approach focuses in principle in the hazard assessment, as hazard is intrinsic to the speficific chemical regardless its use. Conversely, the risk assessment of chemicals depends on the specific regulatory frameworks/specific uses, which have different requirements and protection objectives/purposes. The harmonisation on data requirements and risk assessment methodologies will be discussed upon the receival of the results of a study that EFSA has commissioned and that will finalise at the end of November 2023. It was reported that the Labelling and Packaging (CLP) regulation does not require a substance with hazardous properties to be classified as hazardous if its content in an article is below a specific cut-off value.

6. ECHA activities on the safety assessment of drinking water materials

Stefano Frattini presented the ongoing ECHA activities on the safety assessment of drinking water materials. 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 it 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 over a 15-year period according to expiry dates, which have been assigned on the basis of a proposal by ECHA. In this session ECHA will provide an update on the work done in the first 9 months of 2023 towards the establishment of information requirements and the setting up of the DWD application process, including the adoption of the implementing legislation."

The Network appreciated the participation of ECHA to the meeting. The collaboration between ECHA and EFSA in the effort for harmonising as far as possible the assessment of substances used both in Drinking Water and Food Contact Materials was acknowledged.

ECHA clarified their prioritisation exercise to (re-)assessing substances placed in the first European positive list of substances in drinking water materials (DWM). The assessment of the substances was prioritised based on their « hazard classification, REACH registration status and knowledge on past risk assessments ». Then, their assessment was scheduled over the period based on the identified priority. It was questioned how ECHA could risk assess such a large number of substances (ca. 587 foreseen between 2025 and 2028). ECHA clarified that the number of substances is a conservative estimate. As the list was created using substances from EU and national positive lists from different regulatory contexts, not all of them are expected to be used in DWM. It is also expected that quite a number of substances are already or will have been phased out by the time ECHA starts their assessment.

It was highlighted that the quality of the toxicity data provided or generated to support the assessment of DWM would be key to ensure their effective usefulness. It was also asked if the toxicity tests submitted as part of the applications are requested to be compliant with OECD test guidelines and good laboratory practices (GLPs). ECHA clarified that the legal acts implementing the DWD include requirements on quality parameters of the submitted studies and that both migration and toxicological tests should be performed according to GLPs.

The Network chair (EFSA) highlighted that the re-use of the assessment of substances in different regulatory contexts is welcome and it is also a goal of the 1S1A strategy. The case of the EFSA opinion on silver nanoparticles in FCM[2] offers an example of such re-use. In that case, the CEP Panel used the ADI set by ECHA as part of a REACH evaluation for its own assessment.

7. IUCLID for the submission and assessment of applications

Daniele Comandella (EFSA) presented the use of IUCLID in the submission of applications on regulated products. The summary provided by the speaker is reported below.

[2] EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Safety assessment of the substance silver nanoparticles for use in food contact materials. EFSA Journal. 2021 Aug;19(8):e06790.

"IUCLID (International Uniform ChemicaL Information Database) is a software to record, store, maintain and exchange data on chemical substances. It is currently used for submitting, storing and evaluating data on chemicals falling under several EU legislations (REACH, CLP, SCIP, PPP, BPR), and it will be soon applied to other areas such as drinking water materials (DWM) and food contact materials (FCM). ECHA is currently preparing the IUCLID infrastructure to allow the submission of DWM applications (Dir. (EU) 2020/2184, art. 11), with the aim of having it ready by 2025 and of receiving the first application in 2026. EFSA will also use IUCLID for the submission of applications of substances to be used in plastic FCM ('FCM substances', Reg. (EU) 10/2011), ideally from the period 2025-2027. Due to the commonalities between DWM and FCM substances, both in the information requirements (e.g., migration data) and in the approach to the safety assessment, the IUCLID infrastructure for FCM substances will build on the DWM IUCLID format developed by ECHA. EFSA is closely following ECHA's work by participating to ECHA's Guidance and IT tool user groups, where EFSA is providing feedback on the information requirements of DWM IUCLID sections and on the Guidance supporting applicants in the submission of DWM applications. The use of IUCLID will bring about a substantial change in the way EFSA assesses FCM applications, as both submission and evaluation are expected to take place via IUCLID. Access to EFSA applications by Member States representatives will have to be done via IUCLID."

The Network chair (EFSA) stressed that the use of IUCLID in the FCM area both by ECHA and EFSA will improve the interoperability, access, data/information sharing among EU agencies, EU Agencies and Member States, as well as amongst Member States. Since Member States will have to use IUCLID to get access to EFSA applications, it was suggested that Member States also consider the use of this software to store chemical data from national-specific legislations.

EFSA clarified that IUCLID will replace the "e-submission in the food chain platform" (ESCF) as software used to submit application dossier on FCM substances to EFSA (under Reg. (EU) 10/2011). ESCF will continue to be used for submitting application for the authorisation process of FCM substances, which is a workflow managed by the EC. The use of IUCLID is currently not foreseen for the other regulated products evaluated by EFSA that are currently using ESCF (e.g., food enzymes and food additives).

It was asked whether the data submitted and stored in IUCLID will be publicly available. ECHA specified that applicants can flag certain fields as confidential during the submission phase. The non-confidential information should be available to the public.

8. New guidelines for Network Participants

Maria Ciaula (EFSA) presented the new EFSA's Guidelines for Network participants. The summary provided by the speaker is reported below.

"In July 2023 the EFSA Engagement and External Relations Unit, in cooperation with the Risk Assessment Logistics Unit published the updated Guidelines for Network Participants. The revision was necessary in order to align the guidelines to the 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 updated in June 2021. The main change provided in the Guidelines is a new definition of network members who are now identified as "participants": the direct reference to their representation of the Member State is removed in favour of a wider notion of scientific cooperation. In terms of outputs and transparency, the updated Guidelines clearly mention that agenda and minutes for each network meeting are made publicly available on the EFSA website. Personal data protection and competing interest management information are provided in a more detailed and structured way. The updated guidelines captured also the EFSA internal reorganisation concerning the logistic support and the administrative procedures for meeting organisation which moved from the administrative staff within the Scientific Unit to the newly created Risk Assessment Logistics Unit."

9. Welcome and practical information

The Network chair (EFSA) welcomed the participants and updated them on the agenda and the unfolding of the day.

10. Spanish Research Agency about the Chemical safety of bio-based and/or biodegradable plastics for food contact

Ana Rodríguez Bernaldo de Quirós (SP) presented the ongoing activities on the safety of bio-based and/or biodegradable plastics at the Spanish Research Agency and at the University of Santiago de Compostela. The summary provided by the speaker is reported below.

"The replacement of conventional plastics by sustainable and environmentally friendly materials, in the manufacture of food packaging, is a priority of the EU and an essential part of the "Farm to Fork Strategy" which aims at "creating a fair healthy and environmentally friendly food system". Bio-based and/or biodegradable plastics represent a sustainable alternative; they contain in their chemical composition complex mixtures of substances. These substances can be present in the final product and therefore can migrate to the food. The European Framework Regulation 1935/2004 requires the safety of all substances migrating from food contact materials into food. On the other hand, it is expected that human exposure to chemicals migrating from bio-based plastics will increase with the increase in the use of these materials in food contact applications. The presence of migrating substances in food constitutes a risk for the consumers health which must be known and assessed. The project strategy includes several steps, namely, characterization of bio-based and/or biodegradable plastics for food contact, development of targeted and non-targeted methods to identify potential migrants, study of the migration of the compounds previously identified in bioplastics in food, and exposure assessment. A preliminary study is carried out to identify volatile and non-volatile compounds in several samples of plastic materials for food contact labelled as bio-based and/or biodegradable. The polymers were identified as polyester-based materials, polypropylene (PP) and polylactide (PLA). Purge and Trap (P&T) coupled to GC-MS was used for the determination of volatile

compounds. Monomers such as 1,2-propanediol, and phthalic acid, additives such as the antioxidant BHT, alkanes and solvent residues, among other compounds, were tentatively identified. The analysis of non-volatile compounds was accomplished by LC-HRMS. IAS such as erucamide and oligoesters and caprolactone oligomers, were some of the detected compounds. The Project is founded by the Ministerio de Ciencia e Innovación, Agencia Estatal de Investigación and by the Fondo Europeo de Desarrollo Regional (FEDER). Ref.No. PID2021-124729NB- I00 "MIGRABIOQUANT" (MCIN/AEI/10.13039/501100011033/FEDER, UE)."

The details of the project were discussed. The speaker (SP) provided clarification on the analytical methodology used to identify potential migrants from bio-based plastics, and stressed opportunities and challenges of the project. While the LC-HRMS screening for the identification of substances is considered useful, a concern was shared on the limited availability of analytical standards and the lack of extensive mass spectra libraries.

EFSA informed the Network that the CEP Panel assessed the bio-based plastic PHBH (in 2018 and 2019[3]), where the potential migration of oligomers and degradation products into food was addressed. This evaluation provides a practical and useful example of safety assessment of substances produced by fermentation of carbon source using a genetically modified microorganism.

It was noted that the effectiveness of biodegradability/compostability and the possible release into the environment of substances not fully degraded may need to be considered.

11. NVWA research project on biobased food contact materials

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

"Due to the SUP directive and the transition to a circular economy, plastic food contact materials are being replaced, often by renewable plant-based materials. In 2022 a total of 28 samples from the Dutch market was analysed for plant protection products, PFAS and certain elements. Some samples contained plant protection products that are not authorised in the EU. Extra attention should be paid to straws, as there is also direct oral exposure. Most samples contained traces of PFAS. 3 out of 4 investigated bamboo materials contained 6:2 FTOH up to 17 mg/kg. These PFAs are not authorised, but could be present as NIAS. High contents of aluminium, manganese, iron, zinc and barium were found. Elements with a low health-based guidance value, such as arsenic, lead and mercury, were found in relatively low contents. A general GC-MS screening revealed the presence of plant

[3] "Safety assessment of the substance poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) for use in food contact materials", evaluated in 2018 (superseded, https://www.efsa.europa.eu/en/efsajournal/pub/5326) and 2019 (https://www.efsa.europa.eu/en/efsajournal/pub/5551)

extractables, but also plasticisers, antioxidants or hydrocarbons, not all of these substances were authorised. In plant-based materials substances were found that may impose a health risk. For plant-based food contact materials, such as paper, wood, bamboo and bagasse no harmonised EU legislation exists. To a certain level there is national legislation in the Netherlands, however, not specific enough for the substances found. In 2023 paper straws were investigated and low amounts of PFAS were found, up to 20 µg/kg. They will be investigated further for certain elements and general GC-MS screening. For enforcement it is very difficult to distinguish between non-intentionally added and intentionally added substances. It is therefore recommended to set specific requirements, such as SMLs, for these substances in biobased food contact materials."

The evaluation of per- and polyfluorinated substances (PFAS) in the analysed materials was discussed.

Regarding the analysis of PFAS in consumer articles, the speaker (NL) noted that the analysis was targeted to detect known PFAS, so it might have missed unknown PFAS. DE suggested to verify an intentional addition of PFAS by measuring the total fluorine content. The low levels of individual PFAS may not be the result of intentional use of PFAS but could reflect non-intentional carry-over.

The participants discussed again (as in agenda item 10) the challenges of using LC-MS to identify potential migrants. The speaker (NL) clarified that LC-MS was only used to perform target analysis. Non-targeted LC-MS analysis was not performed due to the lack of related MS spectra libraries. It was noted that the lack of mass spectra libraries is a widespread issue, as only few libraries are available in the market and limited in terms of number of substances listed. DK noted that some strategies could be explored to fill gaps in mass spectra, such as sharing a database amongst MSs competent Authorities. For example, a database could be generated using International Chemical Identifier (InChI) strings that are specific to a substance. Once data are acquired with MS-MS, some MS data handling software can correlate the MS-MS from substances detected in the samples to the MS-MS in the database . In the event of a match of the MS-MS, one could look deeper into the flagged compounds. This could support the identification of substances and facilitates the untargeted workflow.

While it is not surprising to detect contaminants and plant protection products in plant-based articles, it was highlighted that most of the active substances identified in articles imported from outside the EU are not authorised in the EU.

Regarding the risk assessment/management of PFAS, it was reminded that no specific EU regulation other than art. 3 of Regulation (EU) 1935/2004 would apply to plant-based FCM articles (including those that have been coated). The speaker (NL) clarified that the identified substances could be assessed based on Chapter VII (textiles) of the Dutch FCM regulation, and pointed out that the risk assessment should not only address the starting substances, but also the final articles.

It was stressed that many claims on the natural origin of consumers articles are used as part of a marketing strategy ("greenwashing"), and that consumers ignore that plant-based materials can be less safe than non plant-based materials. The speaker (NL) reported that a survey showed that also articles producers often ignore this risk and assume that natural materials are safe *per se*.

12. EFSA-Q-2023-00256: Safety assessment of substances from renewable biological origin to manufacture FCM

Laurence Castle (EFSA FCM WG) presented the EFSA technical report on the principles that could be used in the safety assessment of mixtures of natural origin to manufacture FCMs. The abstract of the report is reported below.

"This presentation introduces the final draft of the EFSA Technical Report entitled "Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials". An earlier draft was presented for feedback at a previous FCM Network meeting and the report is now finalised and it is anticipated to be published in November 2023. The report is intended to serve as a background document for the EFSA Scientific Committee. There is increasing interest in the use of substances obtained from renewable biological resources (non-fossil) to manufacture materials and articles intended for food contact. They may be single substances or simple well-defined mixtures, but more commonly they are complex mixtures with a substantial fraction that is uncharacterised. The source materials are plant biomass and (to a lesser degree) animal biomass. Waiving some of the data requirements for the safety assessment of FCM substances seems acceptable if they are derived from edible food sources (e.g., food as such or the non-eaten parts, and or food ingredients). Minor components or contaminants that migrate and give rise to concern (based on their chemical, physical or toxicological properties), but are already present in the diet, should not be (re-)evaluated. Rather, their exposure from FCMs should be compared with that from the diet. If an increase in total dietary exposure is only minimal then the presence of 'substances of concern' when used to make FCMs could be acceptable. All other components and impurities in the mixture, should be assessed using the established FCM guidelines and cross-cutting EFSA guidance documents. The report concludes with recommendations on several topics that have a cross-cutting character and which may benefit from further considerations and developments by the EFSA Scientific Committee."

EFSA informed the Network on the next steps that will be taken on this technical report. The deadline to publish it is end of 2023, but an earlier publication date is expected. The technical report should be presented to the EFSA Scientific Committee, which ensures harmonisation in the assessment of the various EFSA areas and it should be considered in its workplan for 2024.

The Network welcomed and expressed support to the work of EFSA. Addressing this topic is considered a priority in the light of the recently increased industrial and societal focus on packaging materials of natural origin.

It was noted that the report seems to focus on materials that might be used as or into plastic FCM, and little space is given to other materials such as paper and board. EFSA acknowledged that the report makes use of its experience in the area of plastic FCM, for example by using case studies from application dossiers submitted to EFSA. However, the report is not limited to substances used in plastic and the principles should apply to all FCM types such as paper and board.

13. Q&A on all three presentations: commonalities and differences

The Network Chair (EFSA) highlighted the similarities and differences among agenda items 10 to 12. The commonalities found were:

- FCM materials/articles/substances of natural origin are not safe *per se*.
- Materials of natural origin are expected to contain substances of concern.
- The safety assessment mainly uses analytical results from targeted analysis of known contaminants/constituents of concern.
- Screening non-targeted analysis methods are also used, predominantly with GC-MS, as the effective use of LC-MS is hampered by the lack of mass spectra libraries. This gap does not allow a complete identification of contaminants, as many are not expected to be amenable by GC-MS.
- To address the complexity of such materials, the risk assessment may need to include the evaluation of the safety of the final article.

The Network Chair (EFSA) also questioned the "sustainability" when referring to material from third countries and stressed that the biodegradability of materials and its impact on food safety (life-cycle) is not considered. EC JRC reported that articles labelled as "bio-compostable" usually do not biodegrade at environmental conditions in a household compost bin but require higher temperatures, and more generally well controlled conditions. On this note, NL suggested that the safety evaluation of FCM articles made from waste should consider the entire life-cycle of the material. ECHA noted that some consideration on life-cycle are already in place for PBT/vPBT substances within REACH and may be of interest. NL reported that producers do not have a clear idea of the safety implications of using waste for producing FCM. Also, consumers are confused regarding the correct sorting after the use of FCM articles of natural origin.

It was pointed out that paper and board articles have been under the spotlight for a while, resulting in considerable knowledge being collected, e.g., on potentially migrating NIAS and IAS. Nonetheless, such knowledge has not yet led to establishing an agreed set of rules for their safety assessment. It was suggested that the main reason of this is the lack of suitable and harmonised analysis methods for the identification and quantification of substances potentially migrating from potentially complex mixtures. There is a substantial quantity of analytical results, but of very different quality, as different laboratories used different methods, resulting for example in very different detection limits (LoDs).

ECHA reported that the effective identification of NIAS related to the applied substance has been addressed in the legal acts implementing the DWD, by including recommendations on the use of suitable methods such as GC-MS. More considerations on analytical methods are expected in the guidance (currently under preparation) which will support applicants in the preparation of dossiers on drinking water materials.

14. SILIFOOD project – risk assessment of non-evaluated substances migrating from food contact materials

Els Van Hoeck (BE) presented the SILIFOOD project on the risk assessment of non-evaluated substances migrating from food contact materials. The summary provided by the speaker is reported below.

”Currently, the safety assessment of non-evaluated food contact material (FCM) substances is hampered by the lack of a legislative framework and clear guidance. To this extent, a (semi-) automated workflow based on (quantitative) structure-activity relationship models and the collection of existing toxicological knowledge has been developed, i.e. the SILIFOOD tool. The starting point was the Rapid Assessment of Contaminant Exposure (RACE) tool of EFSA. In line with this methodology, information sources related to genotoxicity, carcinogenicity, health-based guidance values (HBGV) or reference points were identified. Specific attention was paid to information related to the endocrine-disrupting potential of chemicals. Additionally, in silico models predicting several relevant toxicological endpoints were included in the workflow. All (Q)SAR models were selected from the VEGA Hub (https://www.vegahub.eu). Next, the workflow was implemented and automated. The final result is a stand-alone application that can be run using the CAS number, the SMILES or the FCM number as a chemical identifier and generates a report with the collected data in a few seconds. Finally, the applicability of the tool was demonstrated with a case study on diisobutyl phthalate.”

The Network chair (EFSA) acknowledged the great work made by BE, which could be used to support the safety assessment of non-evaluated substances. In particular, he highlighted that the tool provides the basis for a specific methodology or guidance to support the safety assessment of NIAS and non-evaluated IAS and their prioritisation. Users should nevertheless be cautious and have knowledge and experience in safety assessment to appreciate its benefit and its limitation. It was remarked that this tool is not expected to replace the need for business operators to carry out a proper safety assessment of IAS. BE noted that the tool would also help industrial stakeholders and risk managers to preliminary understand if a potential replacement substances is expected to be hazardous.

It was asked if the tool was compared or based on other available tools in particular the OECD QSAR toolbox. BE replied that comparisons were made. An advantage of SILIFOOD is that it is publicly available. The VEGA tool also shows combination of several predictions to get a final/overall prediction (which could be an advantage).

The tool is being fine-tuned and will be online on the VEGA website shortly after the network.

15. Systematic evidence map on PET oligomers

Beat Brüschweiler (CH) presented the systematic evidence map on oligomers that may migrate from poly(ethylen terephthalte) PET. The summary provided by the speaker is reported below.

"The presence of polyethylene terephthalate (PET) oligomers in food contact materials (FCMs) is well-documented. Consumers are exposed through their migration into foods and beverages. However, there is no specific guidance for their safety evaluation. This systematic evidence map (SEM) aims to identify and organize existing knowledge and associated gaps in hazard and exposure information on 34 PET oligomers to support regulatory decision-making. The methodology for this SEM was recently registered. A systematic search in bibliographic and gray literature sources was conducted and studies evaluated for inclusion according to the Populations, Exposures, Comparators, Outcomes, and Study type (PECOS) framework. Inclusion criteria were designed to record hazard and exposure information for all 34 PET oligomers and coded into the following evidence streams: human, animal, organism (non-animal), ex vivo, in vitro, in silico, migration, hydrolysis, and absorption, distribution, metabolism, excretion/toxicokinetics/pharmacokinetics (ADME/TK/PK) studies. Relevant information was extracted from eligible studies and synthesized according to the protocol. As result, literature searches yielded 7445 unique records, of which 96 were included. Data comprised migration (560 entries), ADME/TK/PK-related (253 entries), health/bioactivity (98 entries) and very few hydrolysis studies (7 entries). Cyclic PET oligomers were studied more frequently than linear PET oligomers. In vitro results indicated that hydrolysis of cyclic oligomers generated a mixture of linear oligomers, but not monomers, potentially allowing their absorption in the gastrointestinal tract. Cyclic dimers, linear trimers and the respective smaller oligomers exhibit physicochemical properties making oral absorption more likely. Information on health/bioactivity effects of oligomers was almost non-existent, except for limited data on mutagenicity. In conclusion, this SEM revealed substantial deficiencies in the available evidence on ADME/TK/PK, hydrolysis, and health/bioactivity effects of PET oligomers, currently preventing appropriate risk assessment. It is essential to develop more systematic and tiered approaches to address the identified research needs and assess the risks of PET oligomers."

The Network chair (EFSA) acknowledged the importance of the work for the safety assessment of oligomers migrating from FCM. More and more experience is gained through safety assessment of starting substances and their NIAS prior to their authorisation and through such generic projects.

The Network discussed the details on the methods used, which are described in the supplementary information of Schreier at al. (2023)[4]. The speaker (CH) clarified that the majority of the PET oligomers considered in the project have a molecular mass <1,000 Da, which is the cut-off value currently used by EFSA[5] to identify the fraction of substances that are likely to be absorbed by the gastrointestinal tract, thereby presenting a potentially toxicological hazard. The Network chair (EFSA) suggested Member States to consult the 2016 EFSA opinion on "Recent

[4] Schreier VN, Çörek E, Appenzeller-Herzog C, Brüschweiler BJ, Geueke B, Wilks MF, Schilter B, Muncke J, Simat TJ, Smieško M, Roth N. Evaluating the food safety and risk assessment evidence-base of polyethylene terephthalate oligomers: A systematic evidence map. Environment international. 2023 June 1;176:107978. https://doi.org/10.1016/j.envint.2023.107978

[5] EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials. EFSA Journal. 2008 Jul;6(7):21r.

developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials"[6], which includes specific considerations on the safety assessment of oligomers migrating from plastic FCM.

The Network discussed the application of the threshold of toxicological concern (TTC). AT reported that industrial applicants make extensive use of the TTC concept to support the safety of substances used in FCM, e.g. by demonstrating that the potential migration of a substance is below a given TTC threshold (for example 90 µg/person per day for Cramer Class III substances). It was noted the TTC concept can be applied to oligomers only if they are not part of the exclusion groups as reported by the EFSA opinion on "Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment"[7]. Moreover, it was stressed that the TTC values may need to be applied to the whole class of similar substances instead of individuals.

16. Proposal for harmonisation of the safety assessment of rubbers

Friederike Kühne presented several proposals for the EU-wide harmonisation of the safety assessment of rubber FCM. The summary provided by the speaker is reported below.

"Beside the framework regulation - there is no EU-wide regulation for rubber in contact with food. Therefore, national regulations apply. France has adopted a legal regulation, while in Germany the BfR published the recommendations XXI, XXI/1 and XXI/2 on commodities based on natural and synthetic rubber. In both countries, regulations are currently being revised. Against the background of the generally applicable Regulation (EC) No. 1935/2004, there are opportunities for harmonising risk assessment and the implementation of these regulations."

The Network chair (EFSA) acknowledged the leading role and efforts made by France and Germany in the harmonisation of the risk assessment on rubber and welcomed the proposals made. He also urged them to progress before their national legislation enters into force (2025 and 2026 for FR and DE, respectively). The objective could be to reach, at minima, mutual recognition what implies harmonisation of the safety assessment methodology. The Netherlands envisage its

[6] EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Journal. 2016 Jan;14(1):4357

[7] EFSA Scientific Committee, More SJ, Bampidis V, Benford D, Bragard C, Halldorsson TI, Hernández-Jerez AF, Hougaard Bennekou S, Koutsoumanis KP, Machera K, Naegeli H., Nielsen SS, Schlatter JR, Schrenk D, Silano V, Turck D, Younes M, Gundert-Remy U, Kass GEN, Kleiner J, Rossi AM, Serafimova R, Reilly L, Wallace HM, Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment. EFSA Journal. 2019 Jun;17(6):e05708.

contribution, as the Dutch legislation already foresees a positive list on substance used in rubber FCM.

The issue of food simulants to be used in migration testing, which was also raised at the 8th Network meeting (2022), was brought forward by FR and discussed again. The identification of suitable food simulants was stressed to be a key element in moving forward with harmonisation efforts. Food simulants reported in Reg. (EU) 10/2011 may not entirely be suitable for rubber. For example, the simulant used for milk (50% ethanol) may lead to overestimation of migration. For this reason, ad-hoc measures are taken; for instance, DE is currently using migration testing in 50% ethanol to show compliance and in milk to show non-compliance. DE informed the Network that a project dealing with identifying a suitable food simulant for milk in contact with rubber was about to be launched. The Network noted that the harmonisation would benefit from coordination by EU institutions. The EC JRC offered the expertise of the FCM EURL in identifying conditions for migration testing and asked Member States to inform the FCM EURL on reported issues with food simulants and on the conditions used to perform migration testing as part of safety assessment and compliance testing. Member States may also consult the JRC technical guide on testing conditions for kitchenware articles in contact with foodstuffs that addresses those rubber[8]. ECHA underlined that application dossiers on drinking water rubber articles will be submitted to ECHA. The dossiers should contain information on the migration of the applied substances and on their hazard, that could be re-used in the assessment of FCM rubbers (in contact with foodstuff) performed by Member State authorities. The Member States took note of this possibility noting that migration testing in food simulants or real food will still be necessary.

The harmonisation on tiers defining the toxicological information requirements between France and Germany, already commented on at the 8th Network meeting, was further discussed. 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 respectively) migrating below 0.5 µg/kg food (based on the US FDA Threshold of Regulation (ToR)) under which QSAR data is sufficient (no toxicological studies are requested). This results in different data requirements compared to the SCF Guidelines and EFSA Note for Guidance applied largely in EU. Noting that the EFSA Scientific Committee concluded in 2005 or 2012 on the non-applicability of the ToR, the Network chair (EFSA) recommended FR to reconsider its application and to favour EU harmonisation. FR acknowledged the history of this tier approach that may indeed need to be updated in the future. It was questioned to which extent confidential data submitted for a given regulated product could be used in another regulatory context, as this may need the approval of the data owner.

[8] Beldi G, Senaldi C, Robouch P, Hoekstra E. Testing conditions for kitchenware articles in contact with foodstuffs: plastics metals, silicone & rubber, paper & board.

17. Shared EU databases of evaluated substances (IAS and NIAS)

Els Van Hoeck (BE) presented the ongoing efforts to prepare a shared EU databases of evaluated substances (IAS and NIAS). The summary provided by the speaker is reported below.

"Thousands of substances can migrate from food contact materials. Different inventories merged all the information available at the Member States or European level. However, it has been proven very challenging to keep these inventories up-to-date. Furthermore, these inventories focus on starting substances, but most migrating substances are probably non-intentionally added substances (NIAS). Much research is performed, and many NIAS are identified, but the information is not collected and saved in an open-source database. Recently, tools have been developed to predict theoretical NIAS (e.g. oligomers). However, it remains unclear which substances are used or to which substances the consumer is exposed. Alternatively, high-end analytical techniques and approaches could be applied. An overview of the prediction models and their application to identify substances migrating from FCM was given. Finally, the presentation was followed by a thorough discussion on the possibilities and limitations of the databases and how they can be improved for the future, meaning the organisation, financial support and identification of the most important hurdles."

The Network chair (EFSA) thanked Belgium for the overview prepared as a follow up action from the 8th FCM Network meeting and acknowledged BE leading role and efforts in the development of shared database of EU evaluated substances. He stressed that this activity has reached an advanced stage, and it may benefit from EU coordination and notably (financial) support to ensure its sustainability over time, its update and its maintenance.

The speaker (BE) pointed out that users of data collected into the database should consider that the information is from different formats and various degrees of quality, as for example generated through different analytical methodologies and purposes. To facilitate the evaluation of data quality, it was proposed to consider using quality descriptors. Also, to harmonise the quality of data that is being generated as part of applications submitted in the field of FCM (Member States and EFSA), it was questioned whether applicants should be required to share with the FCM EURL the mass spectra of the evaluated substances together with a sample and the analytical method for compliance testing and be a condition for their authorisation.

The Network chair (EFSA) pointed out that there have been several approaches or tools devised to identify IAS and NIAS migrating from FCM, for example the approach proposed by Song XC (2022)[9], which uses information from chemical analysis and *in silico* tools to predict the identity of migrates. DK noted that this specific approach can be used only if the right analytical instrumentation (ion mobility mass spectrometer) is available, which might not be the case for many

[9] Song XC, Canellas E, Dreolin N, Goshawk J, Nerin C. Identification of non volatile migrates from food contact materials using ion mobility–high-resolution mass spectrometry and in silico prediction tools. Journal of agricultural and food chemistry. 2022 Jul 20;70(30):9499-508.

laboratories of national authorities. Also, the ion mobility mass for control purpose was questioned as it may be more useful for confirmation than for primary detection and identification.

18. EC JRC activities and template on sharing data on migration

Eddo Hoekstra (EC JRC) presented the ongoing EC JRC activities regarding sharing data on migration from FCMs. The summary provided by the speaker is reported below.

"The presentation updates the Network on topics relevant for the FCM risk assessment network. It addresses JRC's finalisation of work on mineral oil in food. It informs the meeting about finalised and running proficiency tests and gives an update on the kitchenware guideline on test conditions for paper and board. Work on vitreous materials are highlighted and a form for requesting migration data to develop migration models will be presented."

The speaker (EC JRC) provided details on the activities of the JRC. Regarding the development of migration test methods to support the revision of the Ceramic directive, JRC prepared and used artificial apple juice as food simulant. The speaker (EC JRC) highlighted that "real" apple juice could not be used as it has high background noise during chemical analysis. Citric acid, which is the food simulant recommended by the CoE technical guide on metal and alloys used in FCM[10], is not suitable as it fumes at high temperature used for simulating the baking process.

The template to share data on migration modelling, whose preparation by JRC in collaboration with BE was agreed during the 8th Network meeting, was presented. EC-JRC informed the Network that the template has been already circulated among national reference laboratories and should be available on the EC JRC website. The link will be shared with Network participants after the meeting.

The speaker (EC JRC) clarified that the migration of substances from plastic drinking water contact materials (DWCM) could be modelled using the existing models that are already developed for FCM as long as the substance and DWCM combination is in the same validated range[11].

Concerning the organisation of proficiency tests that include a migration step the speaker noted that it is often very difficult to find a proper material that 1) shows detectable migration of a substance and 2) that at the same time is homogeneous and/or stable during the period of the proficiency test. The proficiency test on migration of styrene is a recent example.

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[10] Council of Europe. Committee of Experts on Packaging Materials for Food and Pharmaceutical Products. Metals and alloys used in food contact materials and articles: a practical guide for manufacturers and regulators. European Directorate for the Quality of Medicines & HealthCare (EDQM); 2013.

[11] E.J. Hoekstra, R. Brandsch, C. Dequatre, P. Mercea, M.R. Milana, A. Störmer, X. Trier, O. Vitrac A. Schäfer and C. Simoneau; Practical guidelines on the application of migration modelling for the estimation of specific migration; EUR 27529 EN; doi:10.2788/04517

19. Member States projects/research from the R4EU MS database

Gilles Rivière (EFSA FCM WG) presented the updated 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, 6 new projects that could be related to the area of FCM have been identified."

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, ii) check the list before starting a new project, iii) ensure that the list is updated (including removing projects that have been completed).

Network participants noted that not all the projects on FCM currently running in their Member State were included in the list. A potential reason was identified in the difficult liaising between Member State representatives and the national Focal Points, who fill the EFSA database "R4EU database on Member States risk assessment plans", from which the list is prepared. Only members of national Focal Points and of the Advisory Forum have access to the database. Moreover, the update of the database is on voluntary basis. The Network Chair (EFSA) provided feedback on the request made at the 8th FCM Network meeting to give the Network participants access to the R4EU MS database. The request has been reiterated all over the year, but unfortunately this is currently not possible. The Network participants were invited to liaise with their national Focal Points (especially before and after Network meetings), as recommended in the EFSA's Guidelines on Network Participants to exchange information on the activities related to FCM.

The Network participants were invited to provide insights on the advancement of the 6 projects added to the list since the 8th Network meeting. Regarding the BE project TREFCOM (Risks of new trends concerning materials and objects in contact with food), BE reported that a survey to identify the FCMs intended to replace Single Use Plastics (SUP) on the market has been concluded. It shows an increase of alternative presented as "green" such as silicones, wood-based and coconuts materials. The articles will be soon analysed for certain contaminants such as phthalates, bisphenols, pesticides and flame retardants. The type of analysis will be dependent on the sample type (e.g., coated and non-coated articles).

20. European Commission SANTE activities including on the revision of the FCM framework legislation

Jonathan Briggs (EC SANTE) presented the EC activities in the area of food contact materials. The abstract provided by the speaker is reported below.

"The European Commission is continuing with its revision of FCM legislation, based around the key pillars of improving safety of the final FCM article, prioritisation of substances, availability of information in the supply chain, compliance and enforcement, analytical methods as well as consideration of elements to support sustainability. The Commission is continuing with various studies and a number of consultation activities to support the revision and impact assessment work, which is likely to be published in 2025, together with a legislative proposal. Implementation of current FCM legislation also continues, including the introduction of further rules and clarifications on plastic FCM by way of an amendment to Commission Regulation (EU) No 10/2011, Commission Regulation (EU) 2022/1616 on plastic recycling, which entered into force on 10 October 2022 as well as the introduction of a prohibition on BPA in FCMs."

The principles of the revision of the FCM framework regulation were presented and discussed. The speaker (EC SANTE) clarified the timeline of the transition period given to ensure an effective capacity building (both for business operators and risk assessors/managers) after the entrance into force of the legislation. Given the diversity and breadth of the FCM area, the EC envisages different transitional periods for different materials and applications. Materials already regulated at EU level (such as plastic FCM) could have a short transition period.

The Network chair (EFSA) pointed out that the revision may be an opportunity to tackle the matter of safety level for migrating NIAS. Currently, the detection of substances down to 0.15 µg/kg food is needed to exclude the presence of genotoxic compounds. However, this is often not technically feasible, as such low detection limits may be not achieved by certain instruments or when analysing complex mixtures (such as materials of natural origin).

21. Welcome and practical information

The Network chair (EFSA) welcomed the participants and updated them on the agenda and the unfolding of the day.

22. Food Risk Assess Europe (FRAE) Wiley Journal

Arthur Healy and Isabel Mandel (EFSA) presented the newly launched Food Risk Assess Europe (FRAE) journal. The summary provided by the speakers is reported below.

"One of EFSA's key roles is to build pan-European food safety expert networks and ensure effective knowledge sharing across the Member States. To support this goal, EFSA has launched a new online journal called Food Risk Assess Europe (FRAE). The new journal serves as an open access repository of selected scientific articles

from national food safety agencies across the European Union. Benefiting from the reach and functionality of Wiley Online Library, FRAE will promote collaboration and provide a stronger evidence base for the EU risk assessment community. While each national agency predominantly evaluates food safety risks within its own borders, many of these assessments can be relevant at the European level as well. FRAE enables Member States to share their assessments with the wider community more effectively. It will leverage the knowledge available in the national agencies for the benefit of all and will improve accessibility by the provision of English abstracts and summaries as needed. To engage with FRAE, enquiries/requests to publish can be directed to the email address: efsa.author@efsa.europa.eu"

It was clarified that EFSA will decide whether a work can be published on FRAE based on its relevance to the food safety assessment. EFSA will bear all the costs of the publication. The Network chair (EFSA) stressed that the FRAE journal will allow to effectively share the risk assessment activities carried out in Member States including the evaluation of applied substances that is not really covered by the R4EU MS database. The abstracts will be translated to English free of charge, thereby making it more transparent and accessible to all Member States.

23. Council of Europe activities

Teresa Carrilho (CoE) presented the ongoing CoE (EDQM) activities in the field of food contact materials. The summary provided by the speaker is reported below.

"The representative of the EDQM of the Council of Europe presented the Organization to any new participants in the meeting, followed by an update of the work - concluded or ongoing - of the working groups dedicated to some FCM, not specifically regulated by the EU. Such is the case of enamel, that is going to be referred to later. Such work consists of reviewing old policy statements and preparing new guidance thereon. The participants can also find relevant links where they can follow EDQM activities on FCM or download the Resolution CM/Res(2020)9 and the technical guides already published. Finally, a provisional calendar of the upcoming work was shared, as updated in the last CD-P-MCA, that was held in Strasburg, in June 2023."

ECHA noted that the CoE intends to work on resins for adsorption and ion exchanges as part of its activities implementing the Resolution CM/Res(2020)[9]. This work is relevant to ECHA as these materials are also used in contact with drinking water. It was suggested that ECHA and CoE liaise and report the outcome at the FCM Network meeting next year. That will be the occasion to present and better understand this non-specifically EU harmonised material/article types.

24. Council of Europe activity on enamels

Viviana Golja (SI, on behalf of CoE) presented the ongoing CoE activities on enamels. The summary provided by the speaker is reported below.

"The chair of the Ad Hoc group for enamel, which operates under the auspices of the Council of Europe, described enamel in contact with food and how it differs from ceramics. The Council of Europe prepared a survey in which member countries were asked to describe enamel testing and the number of samples they tested in the years 2015-2018. The conclusion of the survey was that control of enamels in contact with food is limited. Different countries approach enamel testing in different ways and use different simulants and testing conditions. The survey showed that the release of some elements can be quite high (e.g., Al, As, Cd, Co, Li, Ni). Therefore, it is necessary to harmonize methods, test conditions and limit values. The Ad Hoc group is compiling scientific and professional information on manufacture and release of elements from enamel into foods and simulants. They will prepare a Technical Guide which will contain an analytical method for testing enamel in contact with foods and specific release limits for the various elements released from it. In cooperation with the industry, they received test plates which will be used to develop an analytical method and approach to testing that will mimic the release into food."

The Network chair (EFSA) noted the progress of the activity and emphasised its importance in the harmonisation of the assessment of enamel FCM.

The speaker (SI/CoE) provided insights on the migration testing methods that will be developed as part of a dedicated technical guide on enamels. Migration testing from enamel need to reflect their uses, and so to be tested at higher temperature than ceramics and to cover repeated uses. The CoE clarified that it will work in collaboration with business operators, notably to get information on the composition of the tested enamels.

The Network discussed the food simulants intended to be used. The use of acidified tomato puree instead of « real » tomato puree is due to the need to have a fixed and lower pH. The use of coffee was discussed as it is acidic and widely used in contact with enamel FCM. It was commented that the use of real foods or drinks is difficult as they have background concentrations of the analytes that need to be analysed. EC JRC underlined the general need to know more about the pH of foodstuffs. SI/CoE will follow up as to whether the CoE technical Guide on metal and alloys provides more information on this matter.

EC SANTE recommended to address the question of the particle size in the technical guide.

25. Training: assessment of 'waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstock, low viscosity' for use in FCM (EFSA, 2022)

Laurence Castle (EFSA FCM WG) presented the methodology applied for the safety assessment of 'waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstock, low viscosity' for use in FCM. The abstract of the corresponding opinion is reported below.

"These waxes are FCM substance No.93 which currently has an SML of 0.05 mg/kg food and the restriction 'Not to be used in contact with fatty foods'. An applicant requested to extend the use to all food contact types, including fatty foods, for

long-term storage at room temperature or below. The assessment of FCM No.93 was selected for this presentation because it illustrates several interesting examples of risk assessment tools and approaches used by the EFSA CEP Panel. FCM No.93 is formally a non-defined mixture (in ECHA terminology a UVCB) and due to preferential diffusion the migrate has a composition different to the additive used. Consequently, the assessment had to take into account this variability in requesting that representative samples should be used for migration testing and for toxicological testing. The waxes are complex mixtures of different hydrocarbon components and the assessment needed to use a combination of a WMA (whole mixture approach), a CBA (component-based approach), and a TTC (threshold of toxicological concern) approach for a complete assessment. Another interesting feature is that the in vitro tests for genotoxicity made use of an extraction approach using DMSO. This was done to avoid that the components of most likely concern (especially 3- and more-ring mineral oil aromatic hydrocarbons (MOAH), if they were present) would be excessively diluted by the saturated hydrocarbons (MOSH) that are essentially insoluble in the in vitro test media. The assessment was published in early 2023[12].”

The Network discussed the implications of the EFSA opinion in the risk management of FCM No. 93 waxes:

In its Opinion, the EFSA CEP Panel proposed to condition the use of FCM No. 93 waxes to its manufacture with an obligatory hydrogenation step to limit the residual content of MOAH. It was questioned how to ensure compliance, what parameters quantitively relate and limit the presence of MOAH at the estimated level if controlled using available supporting documentations provided by business operators (such as declaration of compliance). Manufacturers could declare compliance without having checked the content of MOAH. It was suggested that this could be addressed by specifying a maximal residual content of MOAH in the restriction.

It was noted that EFSA concluded that FCM 93 waxes “does not raise safety concern for the consumer if used as an additive to a level ensuring that its migration in food is no more than 5 mg/kg in food”. However, migration tests showed that migration in fatty food could be much higher (e.g., 142 mg/kg of total-hydrocarbons ≤ C35). It was asked if setting specifications for FCM. No 93 waxes would help mitigating this risk. L Castle (EFSA FCM WG) clarified that the applicant actually proposed additional specifications, but did not demonstrate how those would help in ensuring the safety, so EFSA did not accept them. The Network Chair (EFSA) underlined that the EFSA CEP Panel highlighted in its conclusion that migration might exceed the proposed limit under some of the intended uses proposed by the applicant (fatty foods). This is quite usual in such cases. This aims to alert both business operators and risk managers that these conditions of contact deserve particular attention (e.g. control, reduction of the amount used, limited contact time and/or temperature).

[12] EFSA Panel on Food Contact Materials et al., Safety assessment of ‘waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstock, low viscosity’ for use in food contact materials. EFSA Journal. 2023 Feb;21(2):e07761.

The EC clarified that it is currently considering the EFSA's opinion also taking into account the recently published EFSA CONTAM opinion on mineral oils.

26. Draft EFSA Guidance on PET recycling

Katharina Volk presented the draft EFSA Guidance for the submission of application of mechanical PET recycling processes to produce FCM. The summary provided by the speaker is reported below.

"EFSA's work in relation to the development of a scientific guidance on the criteria for the evaluation and on the preparation of applications of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food (EFSA-Q-2023-00351) was provided. In the context of this work, the so far applicable scientific guidance documents will be combined and updated in consideration of new legislative requirements laid down in Regulation 2022/1616 and recent scientific developments, where applicable. In order to take into account scientific developments, a literature review on certain topics of interest has been conducted and some intermediate results were presented to the Network. Furthermore, a high-level overview of the draft requirements for the content of the technical dossier was provided. The timeline of the workplan, including a targeted consultation for Member State institutions and a public consultation, was provided."

The Network chair (EFSA) invited the Network participants to provide comments to the draft guidance during the targeted consultation for Member State institutions, which is expected to be opened in December 2023.

27. AoB

None.

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

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

Cooperation on risk assessment activities and harmonisation of risk assessment methodologies and substances are essential.

The usefulness of a **shared European database of substances, IAS and NIAS, evaluated at EU and national levels** was reiterated. This is key to increase the reusability and sharing of data and to avoid duplication. This activity is aligned with the "one substance one assessment" (1S1A) strategy and the principles of the revision of the FCM framework legislation (pillar D on information systems). The database prepared by BE was acknowledged, and now needs sustainability, funding (from EU and/or Member States) for its maintenance and update. The possibility to support the development of the database in a project within the PARC initiative, for

example as a proof-of-concept project will be explored. There was quite a consensus that the database of substances evaluated at EU and national levels should be completed/supported by a **database of their mass spectra**. Difficulties and ongoing related projects were discussed. JRC informed that it is currently working on a database of mass spectral data from FCM testing based on information from FCM NRL laboratories. JRC will report about this activity at the next Network meeting.

The safety assessment of **biobased articles** is of common interest. Member States reported their ongoing activities and EFSA presented its draft technical report on the assessment of substances from renewable biological origin to be used in FCM. It was considered necessary to follow up and discuss the assessment of **paper and boards and cork**, notably in the light of the mentioned EFSA technical report. **Migration testing conditions** should be fine-tuned in this area too, for example regarding the type of food simulants used. DE informed that BfR is currently updating its migration testing conditions guidelines trying to harmonise them with JRC guidelines where appropriate. JRC welcomed this effort and noted that it is particularly important harmonise at least the time and temperature used in migration testing.

Useful also to the assessment of biobased articles, the prediction (hazard, migration) and the effective and harmonised **multi-analytes screening analysis** of "non-usual suspects" IAS and NIAS are necessary. GC-MS is often used while screening methods with **LC-MS** need to be developed to complete the knowledge gap. The mentioned obstacles are the lack of mass spectra libraries for LC-MS, the scarcity of analytical standards on the market and the use of different analytical methodologies resulting in data of different quality (difficult to re-use or to use for safety assessment).

Clear opportunities for cooperation between FR and DE on **rubber/elastomers** were identified at the Network meeting in 2019 (7th FCM Network meeting)[13]. The opportunity was taken, and commonalities and differences/divergences were identified with more commonalities than divergences (8th FCM Network meeting in 2022)[14]. Willingness to move from collaboration to harmonisation was noted and an update was given. In view of approaching deadlines for the French and German regulations (2025 and 2026 respectively), it is important to agree on the methodology (tiered approach) and the migration testing in their details. NL expressed willingness to participate. Harmonisation of the migration testing could benefit from being coordinated by JRC, and DE, FR and JRC will liaise on the use of food simulants. It was noted that the assessment of migrating NIAS needs attention. The need to extend collaboration and harmonisation efforts to other fields was stressed.

Finally, the network was updated on the development of the **revision of the FCM framework legislation**.

[13] https://www.efsa.europa.eu/en/events/event/7th-meeting-fcm-network
[14] https://www.efsa.europa.eu/en/events/8th-meeting-fcm-network

29. Concluding remarks

The EFSA 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 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 Network chair (EFSA) 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.