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

Minutes of the 11th meeting
22 – 24 October 2024
14:00-18:00 / 09:30-18:00 / 09:30-12:30
Minutes agreed on 12th December 2024

Location: EFSA – Parma – Room M09

Attendees:

- Network Organisations (including EFTA and EU candidate countries):

Country	Name
Albania (ALB)	National Food Authority
Austria (AT)	Austrian Agency for Health and Food Safety
Belgium (BE)	Scientific Institute of Public Health
Bulgaria (BG)	National Center of Public Health and Analysis
Croatia (HR)	Croatian Institute of Public Health
Cyprus (CY)	State General Laboratory
Czechia (CZ)	National Institute of Public Health
Denmark (DK)	National Food Institute, Technical University of Denmark *
Estonia (EE)	Ministry of Regional Affairs and Agriculture*
Finland (FI)	VTT Technical Research Centre of Finland
France (FR)	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
Germany (DE)	Federal Institute for Risk Assessment (BfR)
Greece (EL)	Independent Authority for Public Revenue Directorate General of General Chemical State Laboratory, 2nd Chemical Service of Athens
Hungary (HU)	National Food Chain Safety Office
Iceland (IS)	The Icelandic Food and Veterinary Authority – MAST*
Ireland (IE)	FSAI
Italy (IT)	Istituto Superiore di Sanita
Lithuania (LT)	State Food and Veterinary Service
Luxembourg (LU)	Luxembourg Veterinary and Food Administration ALVA
Malta (MT)	MCCAA - Malta Competition and Consumer Affairs Authority
Netherlands (NL)	Netherlands Food and Consumer Products Safety Authority (NVWA)
Norway (NW)	Norwegian Institute of Public Health
Poland (PL)	National Institute of Public Health NIH - National Research Institute
Portugal (PT)	Escola Superior de Biotecnologia - Universidade Católica Portuguesa
Slovakia (SK)	Regional Public Health Authority in Poprad
Slovenia (SI)	National Institute of Public Health

Spain (ES)	Spanish Agency for Food Safety and Nutrition (AESAN)
Sweden (SE)	National Food Agency
Switzerland (CH)	Federal Food Safety and Veterinary Office FSVO

online

- **Ad hoc Experts attending for agenda item 17 (styrene):**
  Eylül Bankoglu (Germany), Marie-Christine Chagnon* (France), Ksenija Durgo (Croatia), Roland Froetschl* (EMA), Ana Rivas* (Spain), Kabadi Shruti* (FDA), Ciska van Doseum* (EMA) and Martin Walter* (EMA)
- **Ad hoc participants attending for agenda item 17 or the entire meeting:**
  Eylül Bankoglu (Germany), Athanasios Kourkopoulos* (Netherlands), Benjamin Teneul* (France), Annick Van den Brand* (Netherlands)
- **European Commission (EC)/Other EU Agencies representatives:**
  EC SANTE, ECHA, Unit B2, EC JRC, EC SANTE, ECHA, Unit B3
- **Intergovernmental organisations**:
  Council of Europe, EDQM
- **Members of Committees and Panels invited as speakers**:
  Riccardo Crebelli* (EFSA Panel on Food Contact Materials, FCM Panel), Marcel Mengelers* (EFSA FCM Working Group on Food Contact Materials, FCM WG), Gilles Rivière (EFSA FCM Panel), Laurence Castle (EFSA Panel on Food Additives and Flavourings, FAF Panel) and Emma Di Consiglio (EFSA FCM WG)
- **EFSA**:
  FIP (Food Ingredients and Packaging) Unit: Eric Barthélémy (FCM Network Coordinator, Chair), Daniele Comandella (FCM Team), Zainab Al Harraq (FCM Team), Valeriu Curtui (Head of Unit), Gloria López-Gálvez, Sandra Rainieri (FCM Team Leader) and Katharina Volk (FCM Team)

  MESE (Methodology and Scientific Support) Unit: Maria Chiara Astuto, Alicia Paini

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 to share, consult and discuss projects, approaches and results since from the earliest stages, and not only when they are finalised. He reminded the importance to know the Guidelines for EFSA Networks' participants and alternate participants as well as the Actors involved in the information flow[1]. Good practices on communications with EFSA regarding the organisation of the FCM Network meetings were clarified.

[1] https://www.efsa.europa.eu/sites/default/files/afguidelinesnetworkrepresentatives.pdf

Eight additional participants (with specific interest and/or expertise) from four Member States (HR, DE, FR and ES), the European Medicines Agency (EMA) and the US Food and Drug Agency (US FDA) participated to the discussion of agenda item 17 on the re-assessment of styrene.

Finally, he highlighted the representation of 25 EU Member States, 2 EFTA Member States, one EU candidate country, the Council of Europe (CoE), the European Chemicals Agency (ECHA) and the European Commission (EC SANTE and EC JRC). He thanked them all for attending the meeting fostering collaboration and sharing knowledge.

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

2. Adoption of the Agenda

The agenda was adopted without changes. The minutes of the 10th meeting of the Network on Food Contact Materials held on 20-22 October 2023, Parma, were agreed by written procedure on 27th November 2023 and published on the EFSA website[2].

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

Gilles Rivière (EFSA FCM Panel, 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 related projects 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. In total, 57 projects related to the area of FCM, carried out by 20 institutions from 16 Member states were identified. 3 new projects that have been identified since the 10th Network meeting."

[2] https://www.efsa.europa.eu/sites/default/files/2023-12/fcm-network-10th-meeting-minutes-updated.pdf

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 future projects, ii) check the list before starting a new project, iii) ensure that the list is updated. It was also highlighted that new projects should comprise all the FCM related projects from the MS, i.e. including those from national Institutions other than the one of the MS representative. Thus, there is a need to liaise with these Institutions and, if needed, to invite them to present their project(s) at the FCM Network meeting.

The Network participants were invited to provide insights on the advancement of the projects added to the list since the 10th Network meeting.

Network participants noted that not all the projects on FCM currently running in their Member State were included in the list. The same issue was identified at the last meeting. 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 extracted. Only members of national Focal Points and of the Advisory Forum have access to the database. Moreover, the update of the database is on a voluntary basis. The Network Chair provided feedback on the request made at the 8th and the 10th FCM Network meetings to give to the Network participants access to the R4EU MS database. The request has been reiterated; it is unfortunately not possible yet, but efforts are being made to give to Network Participants at least viewing rights to start with. An additional issue was that information on the content of projects (even high-level) was often not shared with the National Focal Points as it was considered confidential. The Network Chair stressed that the Network meeting should be used as a platform to share confidential information, and so the sharing of confidential information should be encouraged.

The Network participants were invited to address these matters with their national Focal Points and liaise with them to ensure an updated database (especially before and after Network meetings).

Additional information was reported from BE, EL and DE.

DE reported an ongoing project dealing with the search of a suitable simulant for milk to be used in migration testing of rubber FCM. The project will entail the preparation of rubber specimens containing known amounts of specific potentially migrating substances; these materials will be tested for migration at various conditions of time and temperature in different selected simulants.

BE reported the following projects:

- **SCREENFOOD** ('Metrology for food safety in the circular economy: targeted and screening methods for contaminants in food and recycled packaging', 2024-2027). In this project, coordinated by the National Metrology Institute of Italy (INRiM), reference methods and reference materials for quantifying substances in food and food packaging will be developed. The project will focus on PFAS and mineral oil in food and various substances in food contact materials, including the development of untargeted screening methodologies. In addition, interlaboratory comparisons will be organized for each topic. More information can be found on the website www.screenfood.eu.

- **METROFOOD-FED.BE.** METROFOOD.BE is the Belgian node of METROFOOD-RI, the research infrastructure that brings together high-level metrology services in food and nutrition to enhance food quality and safety. Within this project, different services will be developed. Currently, there is an open call to offer the possibility of subsidised access to food analysis services. One open call focuses on the physicochemical characterization of inorganic nanoparticles applied in food contact materials by electron microscopy and evaluating their possible release into food by ICP-MS/ICP-OES. A second open call concerns a platform for migration, hazard and risk assessment of chemicals from food contact materials (FCMs). More information can be found at the following link: https://metrofood.be/open-calls/.

EL reported the following information after the meeting:

- In the project on "Starch-based biodegradable food packaging films with molecularly encapsulated bioactive substances and reinforced with nanoclay", carried out by the International Hellenic University, a biodegradable film based on starch and reinforced with nanoclay was developed. The mechanical and physicochemical properties of the film, its biodegradability and its antimicrobial potential -after the incorporation of antimicrobial compounds- were evaluated and found promising for packaging applications. A safety assessment of the film has not been conducted as further research is needed before industrial application.
- In the project on "cyclic oligomers in foods: determination and toxicity evaluation", a sensitive UHPLC-TOF-MS method was developed for the determination of polyethylene terephthalate and polybutylene terephthalate cyclic oligomers in whole blood samples. Polyethylene terephthalate trimer was detected - for the first time in literature - in four out of the 34 samples tested, at levels ranging from 6 to 25 µg/L. The results showed that oligomers from plastics can end up in the human bloodstream, however further research is necessary to assess the potential human exposure. This project was carried out by the Department of Nutritional Sciences and Dietetics of the International Hellenic University, the Department of Chemistry and the School of Medicine of the Aristotle University of Thessaloniki in collaboration with the Department of Food Science of the Aarhus University in Denmark.

5. Risks of new trends in food contact materials

Els Van Hoeck (BE) presented the risks associated to new trends in food contact materials. The abstract provided by the speaker is reported below.

"Due to constant pressure from consumers and authorities to reduce the use of fossil-based plastic, new types of food contact materials (FCM) are being placed on the market. The TREFCOM (RT 21/4) project aims to investigate the new trends related to FCM. First, an in-depth market study was performed to identify all the new trends already available on the market, intended to replace disposable plastic materials or being advertised as environmentally friendly. Next, 99 representative samples have been selected for the analysis of potential organic and inorganic migrants. Migration experiments were conducted, followed by (un)targeted analysis of organic and inorganic substances. In total, 513 organic substances belonging to different classes,

such as plasticisers, pesticides, primary aromatic amines, mineral oil, PFAS, trace elements, etc., were targeted. All samples were compliant with applicable legislation when available. Afterwards, a worst-case risk assessment was performed using the RACE tool developed by EFSA. It can be concluded that potential health risks exist for PFAS and mineral oil. In addition, a target screening method for substances included in Annex I of Regulation (EU) no 10/2011[3] was applied for the samples made of bioplastic, recycled plastic and silicones. Next, an untargeted screening approach was developed to evaluate the migration of a broader range of substances, including non-intentionally added substances (NIAS). Finally, a method based on ultramicrotomy and electron microscopy has been developed, which has allowed the identification of different types of (nano)particles in a subset of samples. During the presentation, an overview of the results will be given."

The Network discussed the details of the project activity and results.

One of the key issues identified at the 10th Network meeting was the lack of standards to identify substances in untargeted LC-MS screening studies. However, in this project standards could be purchased for the 90 substances selected for further assessment, showing that the migrants found were likely not reaction/degradation products (which would be likely not available as standards), rather IAS and/or contaminants.

CH asked whether perfluorinated substances other than carboxylic PFAS were investigated. For example, the PFAS-precursors perfluorinated telomers could have been of interest. The speaker clarified that the study investigated the presence of other types of PFAS such as sulfonic PFAS (which were found to be below the detection limit), but not of telomers.

Regarding migration testing, the speaker specified that that testing conditions were selected adapting those recommended by the JRC guidelines on kitchenware[4]. Since the guidelines address kitchenware and not food packaging, the conditions were adapted based on the type of sampled articles and their use. As a result, the used conditions might have been conservative with respect to migration. The analytical method used for the untargeted analysis and determination of NIAS has not been validated yet. As a matter of fact, this validation is one of the next goals of the project.

It was asked if the project investigated or intends to investigate the reason of the presence of PFAS and mineral oils, as it is key to understand whether they are contaminants or IAS. The speaker reported that the project did not focus on this, but indirect evidence may come from the project's next steps. The same articles will be analysed once again, and this may give a hint on whether the presence is incidental or not.

[3] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. *Official Journal of the European Union*, *12*, pp.1-89.
[4]Testing conditions for kitchenware articles in contact with foodstuffs: plastics metals, silicone & rubber, paper & board. JCR technical report; 2023. https://publications.jrc.ec.europa.eu/repository/handle/JRC134290

DE noted that applicants submitting applications to BfR often use the VEGA tool as the main piece of evidence supporting the absence of toxicity, i.e. without providing in vitro or in vivo toxicity data. The speaker noted that VEGA should be used as a supporting and not as the main piece of evidence. It was pointed out that for regulated substances the use of only in silico data cannot be accepted. However, they can be used for NIAS. The speaker also reported that a comparison between VEGA predictions and the results of toxicity tests was made, but the outcome was not made public, as this may be interpreted as an endorsement of the use of the tool to replace toxicity testing.

6. Chemical safety of polyhydroxybutyrate (PHB)

Ana Rodríguez Bernaldo de Quirós (ES) presented the ongoing activities on the safety of polyhydroxybutyrate (PHB) bio-based and/or biodegradable plastics. The summary provided by the speaker is reported below.

"Bio-based and/or biodegradable materials are being promoted as a sustainable alternative to conventional petroleum-based non-biodegradable polymers to be used in food packaging applications. Recently, polyhydroxyalkanoates, a class of natural aliphatic polyesters have attracted much attention as sustainable and environmentally friendly polymers. Similarly to petrochemically based polymers, bio-based polymers are subject to the regulatory requirements of food contact materials. In the framework of the project MIGRABIOQUANT funded by the Spanish Research Agency, the characterization and chemical composition of polyhydroxybutyrate (PHB) for food contact was investigated. For that purpose, a battery of analytical techniques, including FTIR spectroscopy, GC-MS, LC-MS, LC-HRMS and MALDI-TOF were used. A great variety of volatile and semi-volatile compounds, such as 4-hydroxybutyric acid, cyclohexanone, crotonic acid, methyl-4-hydroxybutyrate, heptanoic acid, dodecanoic acid etc. were tentatively identified using mass spectral libraries. Most of the compounds detected were related to the production and degradation of PHB. With respect to the non-volatile compounds two series of oligomers, namely hydroxyl-terminated and crotyl-terminated from trimer (n=3) up to undecamer (n=11) were tentatively identified. In addition, the main remarks extracted from the EFSA scientific opinion on the safety assessment of the substance poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) for use in food contact materials have been included in the presentation. The study was financially supported by the Ministerio de Ciencia e Innovación, Agencia Estatal de Investigación and by Fondo Europeo de Desarrollo Regional (FEDER). Ref.No. PID2021-124729NB- I00 " MIGRABIOQUANT"(MCIN/AEI/ 10.13039/501100011033/FEDER, UE)."

The speaker reported that the polymers subject of the study are not currently widely used in FCM, but their use may increase as part of the ongoing trend to use more "natural" and bio-based FCM.

It was pointed out that the use of LC-MS to characterise the composition of FCM and its migrants has recently gained ground and so it is now a routine technique beside the more standard GC-MS. However, substances that are searched are the expected ones due to the lack of MS libraries.

It was noted that the project used matrix-assisted laser desorption/ionisation (MALDI) as ionisation technique for the analysis of non-volatile compounds. While the sample preparation is easy and avoids fragmentation of large molecules, the sensitivity of the method is quite low (especially for the detection of low molecular mass substances).

7. Research on safety assessment of recycled paper and cardboard FCM

Athanasios Kourkopoulos (NL) presented an effect-based evaluation of the safety of recycled paper food contact materials. The summary provided by the speaker is reported below.

"The current hazard assessment of food contact materials (FCM) employs two primary sample preparation strategies. Migration approaches seek to mimic realistic conditions of contact between food and FCMs, selectively recovering migrating chemicals relevant to specific food categories. In contrast, exhaustive extraction approaches aim to retrieve the whole spectrum of chemicals present in the FCM. The study aims to investigate the impact of migration and exhaustive extraction approaches, along with the associated sample preparation conditions, on the chemical profile of extracts from FCM and subsequent hazard assessment results. Methods: Recycled paper and cardboard FCM samples have been selected for interaction with dry, acidic, aqueous, and fatty foods. Employing the migration approach, food simulants have been utilized as outlined in Regulation (EU) 10/2011 for these specific food categories. The samples underwent a 10-day incubation at 40°C while immersed in these simulants. Additionally, the same samples underwent exhaustive extraction using Soxhlet Extraction with a 1:1 Acetone-Methanol mixture. The recovered extracts were assessed for endocrine-disrupting (ER- and AR-CALUX), dioxin-like (DR-CALUX), and genotoxic responses (Ames and Micronucleus assay). Results: Our data show that the toxic response profile of the extracts depends on the choice of food simulant during sample preparation. Furthermore, samples subjected to exhaustive extraction displayed toxicity at lower concentrations in comparison to those prepared through migration, wherein food simulants were employed. Significance: These findings underscore the crucial role of aligning the selection of food simulants and other sample preparation conditions, such as temperature and contact duration, with the anticipated real-world use of FCM. The direct implication is that a well-informed choice in these parameters is pivotal for an accurate representation of migration from FCM to food. Additionally, the selection of in vitro biological assays and parameters of exposure is crucial for the accurate interpretation of the FCMs toxicity. Furthermore, the results of this research indicate the necessity for a framework that assesses endocrine disrupting chemicals. Thus, our study highlights the imperative of informed decision-making in ensuring the integrity of hazard assessments for FCMs."

The Network discussed the approach to risk assessment developed in the study. In this approach, the results of toxicity tests determine whether a chemical analysis of extracts/migrants is needed. This approach differs from the 'standard' approach used in the risk assessment of regulated products, such as that for plastic FCM (reg. (EU)

10/2011), where a chemical analysis is mandatory and the identification of (potential) migrants is key. It was highlighted that the developed approach does not aim to replace but to complement the 'standard' one.

The interpretation of the results from genotoxicity tests applied to mixtures such as migrat and extract was questioned due to the sensitivity of the tests that might not always be sufficient. Even if it is difficult to set a threshold notably due to the difference in potency of the substances, all substances present at low concentrations are likely not covered by the test.

The speaker clarified that the concentration of individual substances in extracts/simulants were not measured, hence it was not determined if it was below 50 µg/kg food (i.e. the upper migration level of tier 1 of the FCM Note for Guidance). The chemical analysis of extracts/simulants will be one of the next steps of the project. The analysis will be targeting chemicals selected from a suspect list generated for a number of relevant toxicity endpoints.

The study was reported to be under publication.

8. EFSA Assessment of NIAS from EFSA Opinion (2016) and from "wax, rice bran, oxidised" and "wax, rice bran, oxidised, calcium salt" (2024)

Laurence Castle (EFSA FAF Panel) presented the methodology recommended for the safety assessment of non-intentionally added substances (NIAS) in the 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 CEF Panel, 2016) and the assessment of NIAS carried out in the opinion on "wax, rice bran, oxidised" and "wax, rice bran, oxidised, calcium salt' for use in FCM (EFSA CEP Panel, 2024). The summary provided by the speaker is reported below.

"The safety assessment of NIAS (non-intentionally added substances) should take the same approach as used for authorised substances, since the same degree of safety should be warranted. This means following the generic process of (a) identification of the substances present in the material; (b) estimation of their migration level leading to an estimate of possible consumer exposure; (c) risk assessment which considers the potential exposure in context with any hazard (nature and potency) posed by the substances. The assessment of NIAS involves additional challenges, however. This presentation will focus predominantly on the recent (2024) evaluation of the NIAS, including the unidentified fraction, present in the title additives (rice bran waxes) that are themselves non defined mixtures."

The speaker pointed out that the Panel used information on the composition of the source of the rice bran wax (i.e. rice bran oil) to infer the potential identity of substances migrating into food. In fact, the safety of the material is linked to the specific source material. He pointed out that this is also the case for other recent EFSA assessments, especially when the FCM substance is obtained from a material of "natural" origin. It was discussed whether more detailed information on the composition of the source material and the manufacturing process should be

requested for the safety assessments. This matter is addressed by the recently published EFSA report on "Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials" [5].

The Network Chair underlined that the 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 CEF Panel, 2016) includes already applied/implemented practices (e.g., for the assessment of oligomers and NIAS other than oligomers) and further proposals (e.g. the exposure scenario).

It was asked how the FCM Panel could conclude on the safe use of the substance in various polymers (i.e. PET, rigid PVC, PLA) while migration tests were only carried out in PET. EFSA clarified that this was possible due to the similar diffusivity of those polymers and considering that the substance is used as a processing aid, i.e. the generation of different reaction products in different polymers is not expected.

The Network discussed the sensitivity of genotoxicity assays reported in this opinion and in general of those requested for FCM risk assessment. In the opinion, it is reported that the content of the potentially genotoxic compounds which might be part of the unidentified fraction (up to 5% w/w) "may be too low to elicit a response in genotoxicity assays". As a result, the Panel concluded on genotoxicity based also on other lines of evidence, i.e. not only on the results of genotoxicity assays. It was asked whether a minimum concentration of genotoxic compounds that could be expected to elicit a response has been identified. It was reported that the matter has been discussed but thresholds cannot be easily identified as there are many factors influencing the response in assays, such as the very different potency of genotoxic substances in these assays.

9. BfR NIAS concept for their safety assessment

Thomas Tietz (DE) presented the NIAS concept for the safety assessment of NIAS prepared by the German Federal Institute for Risk Assessment (BfR). The summary provided by the speaker is reported below.

"According to Article 3 of the Framework Regulation (EU) No 1935/2004, food contact materials (FCMs) must be manufactured in such a way that they do not transfer components to food in quantities that may endanger human health. In principle, intentionally (IAS) and non-intentionally added substances (NIAS; e.g. impurities, reaction and degradation products) must fulfil the requirements of the Framework Regulation in equal measure. However, it can sometimes be very difficult to prove the safety of NIAS. A first hurdle is the chemical-analytical identification and quantification of an often large number of unknown chemical structures. In addition, the provision of sufficient test material for toxicological tests can be problematic. Thus, a pragmatic assessment approach was developed, aiming to generate – with reasonable technical effort – sufficient data for NIAS migrating into food to enable a risk assessment. The prerequisites for the toxicological assessment of a substance

[5] European Food Safety Authority (EFSA). Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials. Vol. 20, no. 11. 2023.
https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2023.EN-8409

are its identification and quantification. The minimum of chemical analytical methods that should be used are described alongside a schematic approach for NIAS-testing in migrates or extracts of the commercial product prior to FCMs production and the final FCMs. In addition, a decision tree for risk assessment was developed, based on the principles set in EFSA's "Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials". Thus, migration-dependent data requirements are described, including non-testing approaches as in silico models and read-across alongside with possible resulting risk assessment outcomes."

The Network well received this activity considering it a step forward towards the harmonisation of NIAS assessment. The speaker encouraged Network participants to provide their feedback on the draft version of the concept (circulated after the meeting).

The speaker reported an ongoing project at the BfR based on published work of the Swiss institutions to understand whether in vitro testing could be made more sensitive to match the rapid development of analytical techniques. The progress of the project is occasionally shared and discussed with Swiss colleagues. At the drafting of the Minutes, the Network Chair noted that it would be very interesting to share this project with the Network at the next meeting.

It was noted that the concept is largely aligned with the approach currently used by EFSA based on the FCM Note for Guidance and the EFSA 2016 opinion. The major divergence is the proposal of a threshold of 10 µg/kg food for the safety assessment of not detected and/or identified NIAS even if the applied compositional analysis is considered appropriate. This would apply for example to the case of an appropriately conducted LC-MS analysis of migrants that resulted in a chromatogram with a "forest of peaks" where some peaks could not be identified/associated with a chemical structure. In this case, no additional information would be requested if migration of NIAS was < 10 µg/kg food, while for the current FCM risk assessment the absence of genotoxicity should be demonstrated if migration of NIAS was > 0.15 µg/kg food (67 times lower). The speaker reported that the additional pathway resulted from the observation that often not all the NIAS can be identified even if state-of-the art techniques are used and all recommendations from guidelines followed. The 10 µg/kg food threshold itself was a pragmatic threshold based on various regulations (i.e. the DE printing inks ordinance and Reg. (EU) 10/2011) and based on practical considerations (i.e. a LOQ for acceptable screening methods). When the printing ink layer is not in direct contact with foodstuff, printing inks which also contain non-listed substances may be used. These substances must not be classified as CMR under chemical legislation (CLP Regulation), in addition, a migration must not be detectable at a detection limit of 10 µg/kg food.

The speaker reported that the concept is recommending that compositional analysis is carried out using "at least" GC-MS, LC-MS/MS. The concept does not currently recommend or require specifications, e.g. on sensitivity, as it was preferred to assess each method case-by-case. BE noted that this approach could be refined; for example, it could be recommended to demonstrate that the method used is able to quantify a specific substance down to a specific concentration.

The concept also evaluates if the default consumption of 1 kg food per day is "overconservative". If yes, an "assessment factor" may be applied to reduce the consumption used in risk characterisation.

The Network Chair underlined the value of this work and the need for the Network participants to answer the request for comments from DE. He underlined the general alignment with the EFSA Note for Guidance although the 10 µg/kg food threshold for detection of NIAS differs. Regarding the discussion and refinement of the request for the analytical methods, he stressed that the EFSA FCM WG pays attention in its request to applicants to ask for objectives, avoiding whenever necessary to specify the exact analytical methods to be applied. This aims not to take over the responsibility of the applicant(s). The analysis should be able to cover a range of volatility and polarity, as well as MW. Nowadays considering the use of LC/MS has become nearly a routine, it could be set as a minimum requirement in addition to GC/MS. Any other additional means (e.g., FID, MS/MS, HRMS, UV/VIS) necessary to address the presence and assessment of NIAS should be used. Derogations are acceptable as far as scientifically justified and supported.

10. Welcome and practical information

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

11. Norwegian study on PFAS in FCM

Inger-Lise Steffensen (NW) presented a Norwegian study on per- and polyfluoroalkyl substances (PFAS) in FCM. The abstract provided by the speaker is reported below.

"The Norwegian Food Safety Authority (NFSA) have an ongoing study at present on per- and polyfluoroalkyl substances (PFAS) analysed in food contact materials (FCM). The analyses are being done by the Technical University of Denmark (DTU). In total, 30 samples of FCM made of paper or board, six product samples from each of 5 categories of FCM have been collected in Norway and analysed for various PFAS. The FCM categories sampled are drinking straws, forms for baking muffins, pizza boxes, paper FCM - such as used for popcorn to make directly in microwave ovens at home and FCM of paper and board to be used for heating food directly in microwave or conventional ovens, such as plates or bowls, and possibly also cups and mugs, if they can be used in microwave ovens. The samples will be subjected to migration testing to food simulant. The content of PFAS substances will be analysed by a DTU FC430.3 accredited method for specific PFAS and by a high-resolution LC-orbitrap-MS method for suspect screening for other PFAS. Samples with high PFAS content and identified by NFSA for possible follow-up actions will be migration tested in triplicate. For PFAS substances without health-based guidance values (HBGV), risk assessments will be performed by the Norwegian Institute of Public Health (NIPH). At time of writing of this abstract, NFSA do not know if the analyses, risk assessments and the (draft) study report will be ready for presentation at the FCM Network meeting, but either way, some information about this study will be presented. If some results are available, they will be presented this year, or if not, maybe at the FIP meeting next

year, or a link to the published report can be distributed to the network participants when available."

Additionally, Stella Kontou (EL) presented the results of a Greek study on PFAS in paper straws. The summary provided by the speaker is reported below.

"A study conducted in 2022 in our laboratory and recent reports in literature have shown that certain PFAS may be present in paper straws. To obtain more occurrence data, the analysis of paper straws for the determination of 25 PFAs was included in this year's national control plan for food contact materials. The samples, 15 in total, were collected from the Greek market in the first semester of 2024 by the Hellenic Food Authority. The analysis of the sample extracts obtained according to EN 15519 was performed by LC-qTOF. It is noted that up to now, there are no national or European maximum limits for PFAS in paper straws. In this light, monitoring data are essential to assess the current situation and the need for preventive measures to reduce potential exposure to PFAS."

The Network Chair welcomed the sharing of the details of the Norwegian project prior to its finalisation. The speaker reported that the final report of the project is expected in 2025. Final results will be reported at the next Network meeting.

The details and the methodology used in the Norwegian project were discussed. The correlation between high levels of PFAS and the FCM type was highlighted as key information as often high PFAS levels are associated with certain FCM types (e.g. recycled paper and board). It was suggested to assess PFAS for which a HBGV is not available, as they may also be of concern. Regarding migration testing, it was noted that the selection of simulants intended to be used (methanol and 50% ethanol) may represent a very conservative exposure scenario. Therefore, the use of testing conditions mirroring actual uses would be useful. Microwave (MW) heating and ultrasonic (US) treatment were suggested as testing conditions that may be closer to the real conditions of contact. It was noted, however, that MW and US treatment could also promote the removal of the volatile fluorotelomers. It was suggested therefore to also perform a total fluorine content analysis on the materials and the migrates.

After the meeting, the speaker provided clarification on the methodology provided by DTU (which is carrying out the analyses). The studies with popcorn bags were conducted with bags that have not been previously used (i.e. heated in ovens). The migration conditions were designed to simulate PFAS migration under short-term, high-temperature applications. Performing migration tests on microwaved popcorn would not be preferable, as it does not align with the intended experimental conditions. The chosen simulants and conditions have been selected based on «fit for analytical detection» and for comparison with results from a previous project on PFAS. The lack of a harmonised approach for migration testing of paper and board, and in this case the very different behaviour of PFAS, makes it challenging to establish firm conditions for extraction and migration testing. Fifty % ethanol was selected as it is a simulant foreseen by Regulation (EU) 10/2011 and considering solubility issues with PFAS observed when using 10% or 20% ethanol. Total organic fluoride (TOF) measurement is not in the scope of the project, but could be measured as supporting information for the presence of PFAS. It is noted that TOF is not a direct measure of PFAS content. It derives from extractable and absorbable organofluorine compounds,

among them PFAS, but there might also be other organic compounds containing fluorine which do not fall under the PFAS definition. Ultrasonication is sometimes used to aid dissolution of physically bound PFAS. In this project, ultrasonication was done in closed Eppendorf tubes without observation of loss of volatile PFAS.

Regarding the Greek study, it was noted that the harsh migration conditions used (2 h at 60°C in 95% ethanol) often result in extraction rather than only migration, i.e. they reflect a very conservative exposure scenario. In such cases (i.e. an overconservative scenario resulting in a potential risk to consumers), risk assessment may address migration under less conservative conditions, e.g. those based on actual uses. However, it was pointed out that the conditions used may be appropriate in the case of paper straws, as they might be used in hot conditions and as they can lose their shape or get destroyed during use.

It was also noted that the safety of the PFAS not covered by the EFSA TWI was assessed by comparing their estimated concentration in the food with the limit value defined in the drinking water directive (DWD) for the sum of 20 PFAS (0.1 µg/L). ECHA reported that the value might be updated following a WHO-coordinated detailed human health assessment of relevant PFAS and establish health-based values for relevant PFAS in drinking water[6]. As part of this activity, WHO is expected to assess the adequacy of the PFAS limit values under the recast DWD and, if needed, to make recommendations on different limit values to ensure a higher level of protection of EU citizens. The results of this assessment are expected in 2026. On that basis, the European Commission will decide whether new limit values should be proposed through a targeted review of the DWD.

The European Commission reported that the matter of PFAS has been recently addressed by REACH and the waste packaging regulation to address the environmental concerns. This matter will also be considered in the upcoming revision of the FCM framework legislation. Regarding potential risk management actions, it was pointed out that it would be important to know if PFAS found in FCM are IAS or contaminants. There are not only limits to deal with the issue; also monitoring could be possible as for bisphenols.

12. RIVM research project on functional alternatives for BPA in FCM

Annick van den Brand (NL) presented the results from an ongoing RIVM project investigating functional alternatives for BPA in FCM. The summary provided by the speaker is reported below.

"The use of bisphenol A (BPA), a substance of very high concern, is proposed to be banned in food contact materials (FCMs) in the European Union. To prevent regrettable substitution of BPA by alternatives with similar or unknown hazardous properties, it is of importance to gain the relevant toxicological information on potential BPA alternative substances and monitor them adequately. We created an inventory of over 300 substances mentioned as potential BPA alternatives in

[6] https://circabc.europa.eu/ui/group/65764c73-4a57-45dc-8199-473014cf65bf/library/98d089ba-a021-41ac-ac1a-cd2a7ee5f742/details

regulatory reports and scientific literature. This study presents a prioritization strategy to identify substances that may be used as an alternative to BPA in FCMs. We prioritized 20 potential BPA alternatives of which 10 are less familiar. We subsequently reviewed the available information on the 10 prioritized less familiar substances regarding hazard profiles and migration potential obtained from scientific literature and in silico screening tools to identify a possible risk of the substances. Major data gaps regarding the hazard profiles of the prioritized substances exist, although the scarce available data give some indications on the possible hazard for some of the substances. In addition, very little is known about the actual use and exposure to these substances. More toxicological research and monitoring of these substances in FCMs are, therefore, required to avoid regrettable substitution of BPA in FCM. https://doi.org/10.1080/10408444.2024.2341020"

The Network discussed the project and other ongoing effort to assess and manage the use of BPA alternatives. BPA is likely not being replaced by one substance but by several. EC SANTE would expect that NL, that has national legislation on coatings, receive applications on the alternatives intended to be used to manufacture coatings. EC SANTE reported to have no information from stakeholders on alternatives but that ECHA is currently engaged in collecting information on uses, levels and toxicity of bisphenols that are being used or intended to be used to replace BPA. EC enacted a piece of legislation considering the potential concern of other bisphenols replacing BPA. PARC (Partnership for the Assessment of Risks from Chemicals) is also addressing the potential toxicity of BPA alternatives[7].

A recently launched project coordinated by KU Leuven (RADAR[8]) is also addressing potential replacements of substances of high concern (SVCH), such as BPA, with aromatic compounds.

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

Gloria Lopez Galvez (EFSA) 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 FCM network meetings of 2022 and 2023, the EFSA's actions linked to the Chemicals Strategy for Sustainability (CSS) and the One substance One assessment (1S1A) were presented. The current session aims to provide an update of the activities followed in the context of CSS-1S1A during the year elapsed, and mainly focused in the work done concerning the 'Early identification of cross-cutting substances', and the follow-up of the 'Study to map Data Requirements (DR) and Risk Assessment Methodologies (RAM)'. The early identification of cross-cutting substances has been piloted during four months with the mandates received on

[7] https://www.eu-parc.eu/news/risk-assessment/seven-bisphenol-alternatives-will-be-focus-attention-several-research-projects
[8] Renewable and safe Aromatic compounDs As Replacements for substances of concern. https://research.kuleuven.be/portal/en/project/3E240620

chemical substances; the aim was to identify any on-going or finished assessments from ECHA, EMA, the EC Scientific Committees and the food/feed assessments of Member States. The pilot confirmed the complexity of the task with concrete results on the timing to devote to the searches and the number of databases to check. The study on mapping DR and RAM finalised at the end of 2023 with the final report published in the EFSA webpage; the report listed a number of areas in which alignment is recommended, some such as terminology, testing provisions and data requirements for each endpoints. Work has been undertaken during this year in order to collect feedback from the stakeholders on areas (e.g. from Guidance documents (GD)) to harmonise. In relation to GD harmonisation the concept of an EU Library of Food/Feed GD is being explored by EFSA and its Advisory Forum. An update on the legislation supporting the 1S1A —some of the legal proposals still under EU Parliament's and Council's scrutiny— were also be presented, focusing on the CLP Revision, the re-attribution on task and the Regulation on data and the like impacts to EFSA."

The Network welcomed any sharing effort. DE welcomed the access to the shared data and noted that the recent example of BPA highlighted the need of sharing views during the phase of risk assessment. The speaker noted that the case of BPA (also melamine and BHA) would be reported as case studies at the upcoming 1S1A expert working group in November. The Network Chair indicated the FCM Network as a platform for sharing ongoing assessments as for styrene.

It was noted that the 1S1A approach focuses in principle on the hazard assessment, as hazard is intrinsic to the specific 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.–It was reported that the Classification, Labelling and Packaging (CLP) regulation does not require that a substance with hazardous properties is classified as hazardous if its content in an article is below a specific cut-off value.

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

Panagiotis Zarogiannis (ECHA) presented the ongoing ECHA activities on the safety assessment of drinking water materials. The summary provided by the speaker is reported below.

"On 23 April 2024, the European Commission published in the Official Journal of the EU six legal acts relevant to the implementation of Article 11 of the Drinking Water Directive (EU) 2020/2184 (DWD). DWD's objective is to ensure a high level of protection of the environment and of human health from the adverse effects of contaminated drinking water and its Article 11 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.

The recently published acts include the first European Positive Lists for starting substances, compositions and constituents for organic, metallic, cementitious and inorganic materials in contact with water, as well as the methodologies and

procedures for updating the positive lists through applications submitted to ECHA by economic operators and relevant Member State authorities.

In this session ECHA will provide an overview of the timeline and the notification and application processes involved in the maintenance of the European Positive Lists, the progress made with the development of guidance and IT tools for future applicants, and the implementation of DWD as a new regulatory process in ECHA and its Committee for Risk Assessment."

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.

The speaker reported that communication activities are foreseen to inform potential applicants and other stakeholders (e.g. a webinar is planned on 27/11 on the application process). The earliest date for the receipt of Notifications of intention is 31st December 2025, and the first applications can be submitted from 31st December 2026 onwards. The Network chair underlined the importance to communicate whether any of the substances currently authorised by Regulation (EU) 10/2011 or in national positive lists are notified under drinking water Directive.

15. 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.

"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 2027. EFSA also intend using IUCLID for the submission of applications of substances to be used in plastic FCM ('FCM substances', Reg. (EU) 10/2011), ideally from the period 2026-2028. 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 FCM infrastructure will be similar to the DWM IUCLID format developed by ECHA. In 2024 EFSA started working on the IUCLID FCM infrastructure, specifically on defining the table of content and on building specific dedicated templates (e.g., migration). 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 emphasised that the use of IUCLID both by ECHA (DWM) and EFSA (FCM) 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 tool to store chemical data from national-specific legislations. IUCLID can be tested on ECHA website[9].

EFSA clarified that IUCLID will replace the "e-submission in the food chain platform" (ESCF) as software used to submit application dossiers on FCM substances to EFSA (under Reg. (EU) 10/2011). ESCF will however continue to be used for communication within the authorisation process of FCM substances, which is a workflow managed by the EC. EC SANTE informed that IUCLID is likely to be used in all chemical sectors of DG SANTE in the future considering the ongoing legislative action on the Common Data Platform.

It was asked how the access to confidential data stored in IUCLID will be managed. EFSA (Front Desk and Planning unit) reported that IUCLID is not a licence-based software hence there won't be need of purchasing a licence and access will be granted to MS state representatives and assessors via specific credentials and a secure connection.

16. EC JRC activities

Stefanka Petkova Bratinova (EC JRC) presented the ongoing EC JRC activities on migration of melamine and formaldehyde from bamboo/melamine ware. The summary provided by the speaker is reported below.

"The European Union Reference Laboratory for Food Contact Materials (EURL-FCM) organised a proficiency testing round (FCM-23/01) for the determination of the mass fraction of melamine and formaldehyde in food simulant B solutions, in support to Commission Regulation (EU) 2020/1245. This proficiency testing exercise was open to EU National Reference Laboratories (NRLs) and Official Control Laboratories (OCLs). The EURL dispatched two well-characterised test items for analysis, namely (i) a food simulant solution B spiked with the specified substances, and (ii) four bamboo/melamine mugs for the migration tests. Twenty-five NRLs from 24 countries, and 18 OCLs (from Belgium, Germany, Italy and Spain) reported results. Analysing the spiked solution proved relatively straightforward, with over 95 % of the participants reporting satisfactory results. However, the compliance assessment of the mugs was more challenging; only 6 laboratories assessed correctly the compliance of test item 2 for both melamine and formaldehyde in line with the observations of the EURL, while several others presented compliance statements in line with the EURL but inconsistent with their own experimental results. This report

[9] https://iuclid6.echa.europa.eu/

provides a detailed discussion about the outcomes of this proficiency testing exercise."

The speaker provided details on the activities of the JRC.

The challenges in running proficiency tests on FCM articles as part of compliance controls was discussed. It was noted that the complexity required for some tests makes them not applicable to situations where a quick screening is needed, such as for large commercial hubs (e.g., harbour). It was pointed out that testing is usually carried out applying prioritisation, testing first the prioritised articles.

It was pointed out that migration conditions as laid out by the legislation may not always represent the worst-case scenario, which is in principle needed to evaluate the safety of materials and subsequently their compliance. In such cases, different conditions should be selected that represent a "true" worst-case scenario or reflect the actual uses. The example of styrene was mentioned. Styrene can considerably evaporate at the high temperature tested, resulting in low migration values not representative of the real uses.

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

Since the assessment is not finalised, hence not public yet, the Minutes are reporting only the summaries of the Mandate, progress, protocol and next steps.

Mandate, Answering the mandate, Progress and protocol

Zainab Al Harraq (EFSA) presented the conclusions from the 2020 EFSA opinion on styrene[10], the mandate on styrene received by the EC SANTE, the EFSA's approach to answer the mandate, an overview of the protocol and the methodology used to carry out the evaluation, the status of the evaluation and the milestones achieved so far. The summary provided by the speaker is reported below.

"Styrene is currently authorised to manufacture plastics without specific restrictions. Following the EFSA opinion on the International Agency for Research on Cancer (IARC) Monograph 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 SANTE has proposed to set a specific migration limit (SML) of 40 µg/kg food (based on the guidance value of 20 µg/L determined by WHO for drinking water[11], which is based on an existing TDI, water consumption and a 10% allocation factor). The mandate requests EFSA to address the potential 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 (EU)

[10] EFSA Scientific Opinion on the assessment of the impact of the IARC Monograph Vol. 121 on the safety of the substance styrene (FCM No 193) for its use in plastic food contact materials. EFSA Journal 2020;18(10):6247, 23. https://doi.org/10.2903/j.efsa.2020.6247.
[11] Guidelines for drinking-water quality, 4th edition, Geneva, World Health Organization; 2022; p.465. Based on: WHO (2003), Styrene in Drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality; assessment date 1993.

No 1935/2004. To address the genotoxicity potential and safety against the 40 µg/kg food SML, EFSA has favoured a fit-for-purpose process in a reasonable timeframe. The approach agreed to answer the mandate considers the evaluation of: the new studies submitted by the US Styrenics Industry Association (SIRC) to the EC SANTE, the reliability and relevance of the oral genotoxicity studies referenced in the IARC Monograph, 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. The protocols and the methodologies followed are based on EFSA's approved criteria and guidance documents (EFSA, 2010; EFSA, 2017; EFSA, 2023)[12]. The assessment is carried out by experts of the EFSA FCM WG, supported by consultations of the EFSA's Scientific Committee cross cutting WG on Genotoxicity and the CEP Panel (now FCM Panel). Some uncertainties and limitations have been identified in the assessment of the SIRC studies, for this reason additional genotoxicity data were requested to the business operator. In the meanwhile, the drafting of the scientific opinion has started, and a periodic update of the literature review is being performed to take into account all newly published evidence relevant for addressing the mandate."

Genotoxicity

Riccardo Crebelli (EFSA FCM Panel) presented the conclusions from the EFSA FCM WG on the four studies from the US SIRC, on the *in vivo* oral genotoxicity studies from the IARC Monograph, and the literature published between 1st January 2018 and 1st October 2024.

Toxicokinetics and human biomonitoring

Emma di Consiglio (EFSA FCM WG) and Marcel Mengelers (EFSA FCM WG) presented the conclusions on the evaluation of styrene ADME properties, the PBK (physiologically based kinetic) modelling and the human exposure data to styrene (human biomonitoring and dietary exposure).

Next steps

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

[12] EFSA, 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. doi: 10.2903/j.efsa.2010.1637.
EFSA Technical Report, 2023. Harmonised approach for reporting reliability and relevance of genotoxicity studies. EFSA Supporting publication 2023:EN-8270. doi: 10.2903/sp.efsa.2023.EN-8270.
EFSA Scientific Opinion, 2017: Guidance on the use of the weight of evidence approach in scientific assessments (2017) doi: 10.2903/j.efsa.2017.4971

The speaker informed the Network of an ongoing assessment on styrene by the Dutch Health Council (DHC) of the Netherlands[13], under public consultation at the time of the FCM Network meeting, which proposes a reclassification of styrene as suspected mutagenic substance (Muta cat.2). It was highlighted that the questions addressed by the DHC is different in scope than the one of EFSA, hence it does not affect the current EFSA assessment.

The speaker outlined the upcoming steps of the assessment. The draft opinion will be scheduled for endorsement at the FCM Panel plenary meetings in November and December 2024. A public consultation will be launched in the period December to January 2025, and a webinar before the end of the public consultation will be held. The adoption by the Panel is expected by March 2025.

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

Jonathan Briggs (EC SANTE) presented the EC SANTE 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 will shortly publish a scoping paper on which basis focus groups will elaborate policy options and continue consultation work. This will support the necessary impact assessment to support 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, including the first set of authorisation Decisions 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 next steps involve the preparation of a scoping paper (by end 2024) followed by an impact assessment and a legislative proposal, which is expected in 2027.

The Network discussed details of the FCM Framework legislation revision. It was asked whether the new regulation will also foresee the use of bioassays as part of the 'analytical methods' pillar. EC SANTE clarified that this will be addressed by consultation with specific experts addressing both 'traditional' and 'innovative' methods. Regarding the intended shift to the focus on the final material, it was noted that the new approach pushing to have 'inert' FCM, i.e. without migration, might be not feasible as something will always potentially migrate. EC SANTE stressed that inertness would be a driving principle rather than an ultimate requirement and will

[13] Draft advisory report for public review: Styrene. https://www.healthcouncil.nl/documents/advisory-reports/drafts/draft-reports/01/draft-advisory-report-for-public-review-styrene

be elaborated further in the upcoming scoping paper. EFSA shared the drive to promote inertness as it would push manufacturers to try to avoid migration, considering migration only if any other effort is not successful.

DE noted that it is not clear if the current standards of consumer safety would be kept if the assessment is re-calibrated through prioritisation and without the use of positive lists and SML. EC SANTE clarified that this shift is expected also to consider a proper evaluation of a large number of substances and materials, including the substances authorised by Reg. (EU) 10/2011 that may also need to be re-evaluated. Moreover, the shift is expected to increase innovation while maintaining high standards of food safety. EFSA stressed that the re-evaluation is needed but specific rules need to be adopted in order to avoid unnecessary 'full' re-assessments hence an unmanageable workload.

Regarding the use of lists of authorised substances, different views were expressed between EC SANTE and several MSs as well as EFSA on the feasibility to keep and extend such lists for more article types. In previous Network meetings, MSs, carrying out assessments prior to authorisation of substances used to manufacture non-EU regulated article types, reported generally up to 5 new substances/applications per year. This was considered manageable at EU level notably with the involvement of MS having already experience in their assessment. The re-evaluation of authorised substances could be based on intention of uses to reduce the actual list, and be planned on long term, similarly to the Drinking Water Directive/ECHA. EC SANTE stressed the current limitations; that the number of FCM substances is likely to be far greater than for drinking water materials, that the current list for plastics was not kept under proper review and that risk assessment work undertaken by Member States first needs to be published in full before it could be considered for supporting EU legislation. EC SANTE underlined the outcome of the evaluation of the current FCM legislation that demonstrated the limited capacity for continuing to use the current approach as it is and that a different approach could also better stimulate generation of information on NIAS.

The content of the 'quality' amendment to Regulation (EU) 10/2011 was discussed. Regarding the foreseen change of the 'plastic layer' concept, EC SANTE clarified that the amendment will specify that the determination of overall migration will be required only for multimaterials where the plastic layer is in contact with food. Regarding biocidal substances, it was noted that their assessment is in the remit of ECHA through the Biocidal Products Regulation (BPR), not EFSA. EC SANTE and EFSA replied that prior to 2011, biocidal substances were assessed to be used in plastic FCM but they were never authorised. The assessment of such additives for use in FCM plastic remains also under FCM legislation; however, the 'quality' amendment will solve this issue.

Regarding the measure on BPA and other bisphenols, the Network Chair (EFSA) noted that applications on bisphenols and bisphenol derivatives classified as CMR or ED for manufacturing FCMs should be submitted to EFSA in case they need to be used. It was asked why the EC SANTE does not intend to directly ban already the use of other bisphenols that will get a harmonised classification of CMR 1A or 1B, i.e. avoiding a lengthy application process that may result anyway in a ban. EC SANTE replied that severe risk management decisions like those made for BPA need a solid scientific evaluation and considerations on potential migration, on uses and on the socioeconomic impact of their potential ban. DE also noted that the safety

assessment is often based on health adverse effects that are different than those of the harmonised classification. For instance, BPA is classified as reprotoxic but is being phased out based on immunotoxicity effects. EC SANTE has indicated that the importance of other toxicological endpoints should also be considered as part of the revision, in line with the commitment in the EU's Chemicals Strategy for Sustainability.

19. Welcome and practical information

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

20. 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 EDQM in the context of the Council of Europe, and its activities will be presented. The introduction of the CD-P-MCA (FCM Steering Committee) will follow, and an update on the CD-P-MCA activities since the 10th network meeting will focus on the publication of the 2nd edition of the technical guide on metals and alloys, and on the several drafts in different stages of development. The upcoming guide on supporting documentation for demonstration of compliance, based on the principles of shared responsibility and safety, and an overview of its main tool - the checklist for production/compilation of documentation from in-house control - will be shared. An outline of the Coatings, Cork (in the process of consultation), Enamels, and Paper & Board Technical Guides will also be presented. Finally, a summary of the main conclusions of the recent EDQM/AESAN symposium, held in Madrid, and the date of the upcoming Plenary meeting will be shown."

The technical guide on documentation supporting compliance and safety of FCM was discussed, in particular the handling of confidential information. It was noted that the guide focuses on "supporting documentation demonstrating compliance - from which a Declaration of Compliance (DoC) may be derived – that may contain confidential information which has to be kept in-house and must be made available to official enforcement authorities, at their request". This may be in conflict with the need for sharing information (incl. confidential one) that is relevant for the safety through the supply chain, for example on substances that may migrate from FCM articles. The speaker clarified that such information indeed must be transmitted even if confidential; some of it would be part of the DoC. She also specified that the technical guide does not define what is confidential. However, it indirectly addresses the matter as it defines elements to include in the Declaration of Compliance, which should not be confidential.

The speaker provided clarifications on the content and timeline of CoE's current activities. Regarding the technical guide on cork, the document will be under public consultation up to the beginning of November 2024, with its publication expected in

2025. Regarding the technical guide on paper and board, the document is expected to address not only harmonisation needs with other pieces of legislation (e.g. PFAS limits from 10/2011) but also other elements such as migration testing conditions. Network participants were asked to share their experience on migration tests with paper and board together with their assessment at the next Network meeting.

21. Assessment of exposure from EFSA Opinion (2016): any new data that challenges the proposed approach?

Laurence Castle (EFSA FAF Panel, EFSA FCM WG) presented the assessment on exposure, especially on the surface area-to-volume ratio, proposed in the 2016 EFSA CEF Panel Opinion. The summary provided by the speaker is reported below.

"This presentation will focus on aspects of the surface area-to-volume considerations that go into the calculations behind estimates of exposure. It will cover those aspects described in the 2016 EFSA CEF Panel Opinion "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". It seems likely that any updating of the assumptions and rules on SA:V is more important for materials and articles used in industry than for 'retail' food packaging plastics. The short presentation does not bring new data to the table but aims to promote the discussion amongst network members."

It was noted that the 'default' surface to volume ratio (SA:V) of 6 dm^2/kg that is used to determine specific and overall migration according to Reg. (EU) 10/2011 is often not realistic, especially for industrial FCM and kitchenware, which often have very large or very small SA:V. This is leading to issues in compliance testing and control. The example of a spatula was mentioned (3 spatulas are needed to reach 6 dm^2) with the proposal to consider the total amount released from 1 item/spatula per day. The matter is also becoming more relevant for FCM packing food for the consumer owing to the increasing fraction of food that is sold in small packaging. (i.e. with high SA:V ratio, such as single-packaged slices of cheese with e.g. 2dm^2 in contact with 30g).

The speaker and the Network Chair highlighted the need to consider and balance both the consumption and the SA:V. The 2016 EFSA CEF Panel Opinion highlighted that (i) "Taking high percentiles of consumption of food/beverage potentially in contact with the FCM of interest and combining them with high percentiles of surface area/mass ratios for such applications, would lead to conservative scenarios that have a low probability of occurring in the population. High surface area to food mass ratio is observed for foods that are not generally consumed in large quantities on a daily basis." (ii) "Based on high potential consumption of water, milk, beverages and soup, the standard value of 6 dm^2/kg is an appropriate conversion factor to represent the surface to mass ratio of packaged foodstuffs when these other considerations are also taken into account" and (iii) "In the case of an FCM intended for specific applications only and if reliable data were available then a different surface area/mass ratio along with packaging use factors and other relevant parameters could be justified.". The default value must, however, be considered when a broad range of uses is foreseen.

EC SANTE reported that the SA:V matter and also a revised dietary exposure assessment approach are being considered in the ongoing revision of the FCM framework legislation. The matter of linking consumption data to SA:V of FCM present on the market was raised as an important information for FCM risk management.

22. Update of the EFSA Scientific Committee Guidance on Nano and of the EFSA Scientific Committe Opinion on the Margin of Exposure

Maria Chiara Astuto and Alicia Paini (EFSA) presented an update on the EFSA guidance documents on nanomaterials and the upcoming EFSA Opinion on the Margin of Exposure. The abstracts provided by the speakers are reported below.

"EFSA's 2021 Nano Guidance documents (Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles and the Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health (EFSA Scientific Committee 2021a;b))[14] are aimed to assess possible risk from the presence of nanoparticles in food and feed. They should be considered as complementary, and their application should be integrated into the risk assessment of relevant sectoral frameworks. Since their publication, the EFSA cross-cutting Working Group on Nanotechnologies has been working to promote the smooth and harmonised implementation across EFSA's regulatory frameworks. In light of the experience gained from practical cases and ad hoc surveys targeted to various stakeholders, possible elements for improvement were collected to consider future actions to further support applicants and risk assessors. Based on the input received, additional provisions and clarifications were produced to update the existing guidance documents. Furthermore, all feedback gathered will be considered in the new EFSA's self-task mandate to develop an updated guidance document for risk assessment of nanomaterials and materials containing nanoparticles in the food chain. The knowledge developed from the EFSA Project on the use of New Approach Methodologies (NAMs) for the hazard assessment of nanofibres (Vincentini et al., 2023[15]; Italiani et al., 2023[16]), and the ongoing EFSA NAMs4NANO project will be used to integrate further recommendations on the use of NAMs for addressing nanoscale considerations."

"In 2005, European Food Safety Authority (EFSA) published an opinion (EFSA 2005) proposing a harmonised approach for the risk assessment of chemical substances

[14] EFSA Scientific Committee et al., 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. *EFSA Journal*, *19*(8), p.e06768; EFSA Scientific Committee et al., 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. *EFSA Journal*, *19*(8), p.e06769.
[15] Vincentini et al., 2023. EFSA Project on the use of New Approach Methodologies (NAMs) for the hazard assessment of nanofibres. Lot 1, nanocellulose oral exposure: gastrointestinal digestion, nanofibres uptake and local effects. *EFSA Supporting Publications*, *20*(9), p.8258E.
[16] Italiani et al., 2023. EFSA Pilot Project on NAMs for the hazard assessment of nanofibers. Lot 2:'Exploring the use of gut-on-a-chip models for risk assessments of nanofibers'. *EFSA Supporting Publications*, *20*(11), p.8230E.

which are both genotoxic and carcinogenic which are present in food and feed. The EFSA Scientific Committee recommended using the Margin of Exposure approach – MoE (EFSA, 2005)[17]. The MoE is a ratio determined by comparing a reference point (RP) on an in vivo dose-response curve (such as a benchmark dose lower confidence limit (BMDL) derived from a rodent carcinogenicity study) with the estimated human exposure of the substance. In 2012, the EFSA's Scientific Committee was asked to deliver a statement on the applicability of the MoE approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food or feed (EFSA, 2012)[18]. In that statement, the EFSA's Scientific Committee agreed that the MoE approach can be applied to impurities which are both genotoxic and carcinogenic, irrespective of their origin. In 2022 the EFSA's Scientific Committee discussed the possibility to revise the opinion published in 2005 where the concept of the MoE was presented. The need for a revision of the MoE opinion comes as there are several challenges and limitations in the current application of the MoE approach that were highlighted by the experts of the EFSA's Scientific Committee, including the increasing detection of genotoxic chemicals in food and feed, the increasing sensitivity of analytical methods, and the anticipated decrease in conduct of carcinogenicity studies in the future due to animal welfare considerations. Because of these considerations, the revised guidance should also address the approach to be taken for genotoxic chemicals for which carcinogenicity data are not available. In December 2023, EFSA self-task mandate was established to identify areas requiring revision. The identified areas and their corresponding timelines were included in a scoping paper, which was made available for public consultation. Currently, the outcomes of this consultation are under discussion to finalise the terms of reference."

Regarding the revision of the EFSA opinion on the MoE, the Network Chair stressed the need to clarify the meaning and applicability domain of MoE and margin of safety (MoS) concepts as they have been increasingly used as part of safety assessments carried out by EFSA.

The objectives of the revision were discussed. FR asked whether the Scientific Committee (SC) would address also endpoints other than genotoxicity/carcinogenicity (which were addressed in the 2012 opinion). The speaker reported that the most pressing need is the clarification on the use of MoE as per the 2012 Opinion, then the SC will also address the application to other endpoints. IT asked if the revision will also address the use of NAMs to derive a MoS for specific endpoints such as bioactivity. The speaker clarified that this matter will be discussed by the SC considering the current OECD activities on in vitro methods to support defining a MoS.

CH asked why MoE is relevant for FCM since it had been devised for genotoxic carcinogens – and considering that data on carcinogenicity is usually not available or

[17] European Food Safety Authority (EFSA), 2005. Opinion of the Scientific Committee on a request from EFSA related to a harmonised approach for risk assessment of substances which are both genotoxic and carcinogenic. *EFSA Journal*, *3*(10), p.282.
[18] EFSA Scientific Committee, 2012. Statement on the applicability of the Margin of Exposure approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food/feed. *EFSA Journal*, *10*(3), p.2578.

provided. Moreover, in principle genotoxic substances are not authorised to be used to manufacture plastic FCM unless there is no exposure to consumers. The speaker stressed that nowadays the application of MoE goes beyond the assessment of only genotoxic carcinogens and is applied to other endpoints/adverse effects. Moreover, it can be applied to non-regulated substances, NIAS, reaction/degradation products.

Regarding the activities on the guidance documents on nanomaterials, EMA asked why the Committee decided to prepare a specific annex on electron microscopy. The speaker replied that the need arose in response to the usual poor quality of information on particle size received from applicants/business operators. The annex is therefore intended to support applicants/business operators in the generation of suitable data and assessors in appraising such data, and ultimately to make the risk assessment process more efficient.

23. EFSA Guidance on PET recycling and update on new technologies

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

"Following the presentation at the Network meeting in 2023, an update on EFSA's work in relation to the evaluation of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food was presented. On 30 July 2024, a scientific guidance19 on the criteria for the evaluation and on the preparation of applications for such processes was published, alongside with an administrative guidance[20] document. The starting point for the preparation of the scientific guidance document were previously applicable documents[21], which have been updated in consideration of new legislative requirements laid down in Regulation (EU) 2022/1616 and recent scientific developments. The presentation outlined the main changes in the evaluation criteria that were introduced following comments received during the public consultation of the scientific guidance document:

1) Migration modelling: the approach of applying an overestimation factor of 5 to all surrogate substances irrespectively of their molecular mass was changed to a tiered approach: overestimation factor of 5 is still valid for substances with a molecular mass ≤ 150 Da, while a factor of 10 was introduced for substances with a molecular mass > 150 Da.

[19] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2024.8879
[20] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2024.EN-8968
[21] Criteria for safety evaluation of PET recycling processes (2011): https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2184; Guidelines on recycling plastics (2008; administrative update in 2021 for alignment with the Transparency Regulation): https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.717

2) Exposure scenarios: the scenarios were updated considering consumption values for specific food categories, as laid down by the EFSA Scientific Committee (2017)[22] and the EFSA CEF Panel (2016)[23].

Finally, a high-level update on novel technologies was provided."

DE asked whether EFSA would react to a recent scientific publication reporting contamination of recycled plastic FCM articles with brominated flame retardants (BFR). It was clarified after the meeting that the publication refers to the US market where high BFR levels were found in styrene-based polymers, e.g. (high impact) polystyrene or acrylonitrile butadiene styrene, used for food contact, which is likely linked to contamination with electronic waste[24]. EC SANTE noted that the contamination by flame retardants might be due to the use of high levels of non-food plastic in the input of the recycling process, which should in principle not be the case given the general provisions on collection and pre-processing as foreseen in Regulation (EU) 2022/1616. The need of controlling and checking the input material is also highlighted in the new EFSA guidance.

EFSA pointed out that recycling technologies beside mechanical PET recycling are novel technologies that have not been assessed within the new Regulation (EU) 2022/1616. The procedure laid out in this new Regulation foresees a role for EFSA only after comprehensive data is submitted by the technology developer(s) to the Commission, including reports showing the first 20 incidental contaminants sorted by relative occurrence. When the data is considered sufficient by the Commission, EFSA may be requested to assess that novel technology. It was noted that the criterion of identifying at least the first 20 incidental contaminants detected in the input may not be the most relevant in terms of safety assessment of e.g. polyolefins as many of those substances would likely be hydrocarbons which one could anyway expect to be present due to the nature of the main polymer. There might be hazardous substances that may pose a concern present at much lower levels.

24. AoB - Update on harmonisation of the safety assessment of rubber

Thomas Tietz (DE) presented an update on the harmonisation of the safety assessment of rubber. The abstract provided by the speaker is reported below.

"The French Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the German Federal Institute for Risk Assessment (BfR) are in dialogue regarding the requirements for rubber food contact materials. In addition to comparing existing regulations, the aim of the exchange is to find out

[22] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4849
[23] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4357
[24] Liu M, Brandsma SH, Schreder E. From e-waste to living space: Flame retardants contaminating household items add to concern about plastic recycling. Chemosphere. 2024 Oct 1;365:143319. https://www.sciencedirect.com/science/article/pii/S0045653524022173?via%3Dihub

about future changes and discuss possibilities for harmonisation and mutual recognition. DE and FR invite other Member States (MS) to join this exchange. If interested, the relevant institutions of the MS may contact the BfR."

The Network Chair acknowledged the leading role of DE and FR on this matter.

DE asked to the Network to share any list from other rubber legislations in order to ensure mutual acceptance and encouraged other MSs to participate to the effort. FR noted that the French list on rubbers must be renewed in 2025, hence this will be a good chance to consider any list from other MS.

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

The Network Chair summarised some of the points recurrently raised during the discussions of the meeting and proposed potential follow-up activities.

No changes with regards to the previous meetings regarding **cooperation** on risk assessment activities and harmonisation of risk assessment methodologies and substances. It is acknowledged to be essential.

For each of the four areas of cooperation below, a call for MS leader was proposed and accepted. The leader/coordinator who accepted the role and responsibility are identified below. The topics will be scheduled at the next Plenary meeting. Member States are invited to express their wish to support the leaders and activities.

1. 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 should be completed/supported by a **database of their mass spectra**. The feedback from JRC on its work on a database of mass spectral data from FCM testing based on information from FCM NRL laboratories was postponed to the next meeting. **Belgium** accepted to lead this activity.
2. The need to discuss and update the assessment of **paper and boards**, notably in the light of the EFSA technical report on natural compounds (2023) was reiterated. **Austria** accepted to lead this activity.
3. The assessment of **NIAS** is being harmonised and related **multi-analytes screening analysis** are developing. In addition to GC-MS, screening methods with LC-MS are increasingly used routinely to complete the knowledge gap. Still, there are obstacles due to 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. **Germany** accepted to lead this activity.
4. **Germany** and **France** updated the Network on their activities on **rubber/elastomers** and underlined their willingness to move from collaboration to harmonisation. They invited the other Member States to join their effort including to share any list from legislation in order to ensure mutual acceptance. It is also important to agree on the methodology (tiered approach) and the migration testing in their details. **France** accepted to lead this activity in close

collaboration with **Germany**. The Netherlands expressed willingness to participate.

The safety assessment of **biobased articles** stays of common interest. Member States reported their ongoing activities and will continue to do so at the next meeting. In case of safety assessment, it was recommended to consider employing the EFSA Technical report on the principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials (2023), and to report on any challenges, issues, outcome.

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

26. 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 presentations given 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.