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

Location: EFSA – Parma – Board Room M10

Attendees:

- Network Participants (including EFTA countries):

Country	Competent authority / Organization
Austria	AGES Austrian Agency for Health & Food safety
Belgium	FPS Health, Food Chain Safety and Environment
Bulgaria	Ministry of Health, National Center of Public Health and Analyses
Denmark	Technical University of Denmark DTU National Food Institute
Finland	Finnish Food Authority
France	Anses
Germany	BfR
Greece	General Chemical State Laboratory
Hungary	Hungarian National Food Chain Safety Office
Ireland	The Food Safety Authority of Ireland
Italy	National Institute of Health
Lithuania	State Food and Veterinary Service
The Netherlands	Netherlands Food and Consumer Product Safety Authority
Norway	Norwegian Institute of Public Health (NIPH) The Norwegian Scientific Committee for Food and Environment (VKM)
Portugal	University of Aveiro
Romania	National Institute of Public Health
Slovakia	Public Health Authority
Slovenia	National Institute of Public Health
Spain	University of Santiago de Compostela
Switzerland	Federal Food Safety and Veterinary Office (FSVO)

- **Ad hoc Experts:**
  Agnieszka Anna Niklas* (Norway, item 13), Mélanie Di Mario* (Belgium, item 15), Athanasios Kourkopoulos* (Netherlands, item 17), Olga Rojo Poveda*, Johan Robbens*, Mirjana Andjelkovic* and Andreja Rajkovic* (Belgium Federal Agency for the Safety of the Food Chain (FASFC), item 27)

*online
**online on the third day

Industry associations (item 6- 8; 18-19):
Confederation of European Paper Industries (CEPI) and International Confederation of Paper and Board Converters in Europe (CITPA)

- **European Commission (EC)/Other EU Agencies representatives:** EC SANTE, ECHA* (Unit B3), ECHA* (Unit B4), EC JRC**
- **Intergovernmental organisations**: Council of Europe CoE, EDQM
- **Members of Committees and Panels invited as speakers**: Gilles Rivière (EFSA FCM Panel), Laurence Castle (EFSA Panel on Food Additives and Flavourings, FAF Panel)
- **EFSA**:
  FIP (Food Ingredients and Packaging) Unit: Eric Barthélémy (FCM Network Coordinator, Chair), Daniele Comandella (FCM Team), Zainab Al Harraq (FCM Team), Thomas Hemy-Dumas (FCM Team) and Sandra Rainieri (FCM Team Leader)

  FEEDCO (Feed and Contaminants) Unit: Elena Rovesti (Contaminants Team)

  MESE (Methodology and Scientific Support) Unit: Lucian Farcal (Scientific Committee Team)

1. Welcome and apologies for absence (Day 1)

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 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.

Finally, he highlighted the representation of 26 EU Member States, 2 EFTA Member States (NW, CH), 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.

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

Apologies were received from the representative from Latvia for the entire meeting, Czechia for the third day, Luxembourg for the third day and Italy on the first day from 14.00 to 16:30.

2. Adoption of the Agenda

The agenda was adopted without changes. The minutes of the 11th meeting of the Network on Food Contact Materials held on 22-24 October 2024, Parma, were agreed by written procedure on 12th December 2024 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) is still applicable. All participants with an EFSA account accepted the "EFSA Confidentiality Statement and Data Protection Notice".

4. Background work and discussion at the Network on paper and board: safety assessment, challenges, commonalities and differences

Thomas Hemy-Dumas (EFSA) presented an overview of the work of the FCM Network in this field from 2014 to 2024. The summary provided by the speaker is reported below.

"Paper and board (P&B) are widely used FCMs but remain non-harmonised at EU level, leading to divergent national approaches and testing practices. Four countries operate specific national frameworks: Italy (DM 21/03/1973 and 03/06/1994,), the Netherlands (Warenwetregeling Ch. II), Belgium (Royal Decree 11/05/1992), and Germany (BfR XXXVI series). These four countries apply different categorisations of materials/uses. All four countries indicated alignment with the EFSA Note for Guidance as the basis for risk assessment, but it was not verified whether it was a full alignment (e.g. same tiers, triggers). BfR XXXVI explicitly prescribes test methods and draws on shared EN standards, EN 645/EN 647 (aqueous extracts), EN 14338 (Modified PolyPhenylene Oxide (MPPO) for dry/baking), EN 10955 (sensory/organoleptic testing; "test dough") and EN 15519 (organic extracts), with additional specific features such as high-temperature/thermostability checks. For the other Member States mentioned, the status of discussions in previous Network meetings did not clearly establish which tests are actually applied in practice

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

for the safety assessment. The EFSA FCM Network (2014–2024) has discussed other activities related to P&B such as NIAS, recycled fibres, PFAS, inks/oligomers and efforts toward analytical method harmonisation. For instance: Italy's monitoring on phthalates, solvents, hydrocarbons from inks, adhesives; NL–DE's harmonised Safety Data Sheet (SDS) pilot and a review by RIVM on the estimated contribution of paper and board to total dietary exposure to MOAH and MOSH; Belgium/Sciensano's genotoxicity prioritisation; Germany's oligomer and printing-ink projects; Denmark's PFAS strategy and effect-based screening; Greece and Norway's PFAS monitoring (incl. paper straws); France/ANSES's TTC decision trees and semi-quantification workflows; Austria project to update P&B assessment frameworks. The Council of Europe provides a common safety framework via its Technical Guide under Resolution CM/Res(2020)9, which defines quality requirements, test applications and monitoring indicators (e.g. DIPN, BPA, UV-F), while the JRC works on harmonising test conditions, NIAS interpretation, and inter-lab validation."

MS representatives provided insights on their national legislation.

DE noted that the 21st Ordinance amending the German Consumer Goods Ordinance (so called Printing Inks Ordinance) is also relevant to paper and board (P&B) FCMs, and informed that the XXXVI Recommendation on P&B is being updated. DE underlined the use, in its assessment of P&B, of a surface to volume ratio (S/V) of 13.3 dm² instead of the 6 dm² used for plastics.

BE clarified that its legislation is limited to contact with fatty and "humid" foods, and that a new legislation is expected to enter into force in 2026-2027. The reform will take into consideration the technical guide of the Council of Europe. The national risk assessment body may perform targeted testing or occasional evaluations of substances to support national positions.

NL clarified that in the Netherlands P&B FCM are regulated in chapter II of the Warenwetregeling Verpakkingen en gebruiksartikelen. There are requirements for the final product: for heavy metals, organic substances, total fluorine and fluorine compounds. At this moment only one polymeric PFAS is authorised for P&B FCM. PFAS may also be present as NIAS, especially in recycled materials. Recycled P&B is authorised as raw material. Therefore, risk assessment efforts should focus on the analysis of the final articles and the substances that can migrate, both IAS and NIAS.

5. Council of Europe technical guide on paper and board

The speaker presented the ongoing update of the CoE (EDQM) technical guide on paper and board. The summary provided by the speaker is reported below.

"The 2nd edition of the Technical Guide on Paper and Board is in preparation and should be finalised in 2026. The 1st edition from 2021 needs some editorial corrections. Further amendments are planned for the chapter "Compliance

Testing", including updated references to the upcoming 5th edition of the JRC Guideline. In Annex II "Specific migration limits (SML) for some constituents or contaminants" substances or substance groups (bisphenols, MOAH, phthalates, PFAS, chloropropanols and formaldehyde) require updates or amendments."

The Network Chair praised the update of the technical guide representing an advancement in the field. The Network discussed the reasons for establishing the recommended SML.

The Network discussed the case of mineral oil aromatic hydrocarbons (MOAH). DE reported that the BfR XXXVI Recommendation on P&B reports that "There should be no detectable transfer of MOAH from food contact materials to food"[3]. The EC is currently addressing the contamination of food by MOAH and considering a specific limit in food[4] based on the performance requirements for MOAH analyses reported in the related JRC technical report[5]. It was noted that based on the SML (0.5 mg/kg food simulant) proposed in the draft 2nd Edition of the CoE technical guide and the $BMDL_{10}$ reported in the EFSA CONTAM Panel opinion[6] (0.49 mg/kg bw pd). Depending on the percentage of 3 and more ring MOAH assumed to vary from 1 to 10%, the margin of exposure (MoE) ranges from 600 to 6000, that is below the value 10,000 as being considered as raising concern for human health (cf. EFSA CONTAM Panel opinion). The speaker (on behalf of CoE) clarified that the SML was based on the limit currently considered by the EC and acknowledged the low MoE. Moreover, the known genotoxic PAHs (sum of benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene) that are included in the MOAH should not be detected at a limit of detection of 0.001 mg/kg food (Annex II of the CoE guide). It was reported that the EDQM WG will rediscuss the matter soon.

EL expressed concern on the presence of contaminants in recycled P&B, which prevents the use of recycled P&B for direct food contact with wet or fatty food. Limits reported in the CoE technical guide are set for contaminants in the raw material with no distinction between recycled and virgin materials. This questioned the need to set different limits for virgin and recycled P&B.

Following to the discussion, the Network Chair acknowledged that the SMLs proposed in the draft 2nd Edition of the CoE technical guide are still not agreed among all representant MSs, hence not fully harmonised. The Network chair

[3] Recommendation available on https://empfehlungen.bfr.bund.de/recommendations?locale=en.
[4] https://food.ec.europa.eu/document/download/fc82efb9-e180-45ff-8202-3df60ec00fb2_en?filename=cs_contaminants_catalogue_moah_ntfs_js_0.pdf.
[5] Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials https://op.europa.eu/en/publication-detail/-/publication/85bdda9a-3656-11e9-8d04-01aa75ed71a1/language-en.
[6] EFSA Panel on Contaminants in the Food Chain (CONTAM), Update of the risk assessment of mineral oil hydrocarbons in food. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8215.

highlighted that MSs should find a consensus and agree to fully support the proposal from the CoE towards harmonisation.

6. Manufacturing virgin paper and board

CEPI/CITPA presented an overview of the current industrial processes for the manufacturing of virgin paper and board that may be used as FCM. The summary provided by the speaker is reported below.

"A detailed exploration of the manufacturing processes involved in the production of virgin paper and board (P&B), emphasising their critical role in ensuring food packaging and safety, is presented. Virgin P&B, which is derived from freshly processed wood pulp, is extensively utilised within the food industry. It is imperative to comprehend the manufacturing process of these materials to ascertain the risks associated with virgin P&B when utilised as food contact materials. By outlining the raw materials involved – fibres and chemicals – and the pulping techniques that result in cellulose fibres, the most critical parameters influencing the potential chemical substances that may migrate from virgin P&B into food are addressed. Emphasis is placed on the selection of non-fibre raw materials. These materials are added during the process as functional and process chemicals, as well as they are applied during the coating step. Their selection criteria are explained based on national regulatory requirements and current industry standards and guidelines that help ensure P&B materials meet food-grade quality requirements. The significance of communication within the value chain of P&B products is outlined, from the information on raw materials to the finished food contact article. A comprehensive, step-by-step overview of the P&B production process is provided, detailing the impact of manufacturing parameters on properties critical for food packaging applications."

The speaker (CEPI/CITPA) reported that the approach for safety assessment used by industry largely considers the BfR Recommendation; however, also approaches from non-EU institutions are considered such as FDA documents and Chinese standards. The additives used in the manufacturing of P&B FCM are those reported in the positive list of the BfR Recommendation. Mineral fillers and starch are the most abundant in weight (~10%) especially in the manufacturing of cardboard. They are usually employed as additives in the inner plies and as coating of the reverse side layer. In addition, functional chemicals are added in quantities usually below 2% of P&B.

The Network noted that in previous Network meetings, P&B articles were shown to be contaminated by pesticides, most likely coming from the raw starting materials (wood). Therefore, it would be important to track the origin of wood as well as listing the plant species used in the manufacture. The speaker (CEPI/CITPA) reported that industry is actively tracking the raw materials; however, it is often difficult to do this efficiently, especially if the

production volumes of certain articles are high (e.g. cardboard) and if the materials are imported from outside the EU. Additionally, the composition of the natural raw starting material is variable, so it is mixed to reach an average composition. However, its exact composition is not known, hence it is not guaranteed that it is not contaminated. It was noted that substantially more information on raw materials is expected once the EUDR (EU Deforestation Regulation) becomes applicable.

EL flagged that PFAS contamination was attributed in certain cases to the water used during the manufacturing process (e.g. for paper straws with PFOA); so it was asked if and how industry is addressing this matter. The speaker (CEPI/CITPA) replied that manufacturing facilities generally have in-house water treatment plants aimed at purifying and recycling the water used. This should ensure the removal of contaminants, which are regularly monitored. However, contaminants such as PFAS proved difficult to be removed at low levels and may remain in the water used. The reused water can be mixed with fresh water, so diluting the residual contamination.

PT questioned the use of burned wood as a starting raw material. The speaker clarified that they should not be used.

On the chemical substances used (functional and coating chemicals, and process chemicals), the Network Chair noted that the BfR list is used. The speaker (CEPI/CITPA) answered that the BfR list is considered as the most recent and complete. In addition, FDA and other national lists are used. The Network Chair proposed the CoE and DE to reflect on this; thus, having only one list in use that is fully agreed amongst MSs for EU.

7. Converting virgin paper and board

CEPI/CITPA presented the current industrial processes for the conversion of virgin paper and board into FCM. The summary provided by the speaker is reported below.

"This presentation offers a comprehensive overview of the converting processes employed in the transformation of paper and board (P&B) into safe, functional food contact materials and articles. It outlines the objectives of converting, the primary converting operations, key safety and migration risks, and the good manufacturing and documentation practices that converters adhere to ensure products that are safe for contact with food. The presentation focuses on various processes, including printing, varnishing, coating, and laminating. It also examines the impact of these processes on chemical migration into food and the industry's strategies for selecting low migration inks, suitable coatings, and food-safe adhesives. A short overview of the manufacturing processes involved in the production of corrugated board is presented, furthermore the techniques of die cutting, along with slitting, perforating, embossing, and forming operations to produce shaped articles. The presentation highlights the way mechanical operations and multi-material structures can modify barrier properties, while introducing fundamental design considerations. The presentation summarises the regulatory and guiding documents, as well as industry's guidance, that are utilised by converters to

evaluate materials and processes. Emphasis is placed on the significance of supplier Statements of Composition for inks, varnishes, coatings and adhesives when assessing the safety of P&B materials and articles intended for contact with food."

After the meeting, the Network Chair noted that the application of coatings, printing inks, varnishing, etc. during the converting of P&B is common to other multi-materials. Therefore, the EU manufacturer Guidance documents (e.g. CEPE on coatings, EuPIA on printing inks) should be considered in the light of all the FCM types to which they apply. They should be critically reviewed to better understand the methodology they propose and the extent in which they address the safety assessment of the materials (e.g. chemical analysis, level of interest).

8. Safety of virgin paper and board according to Industry

The speaker (CEPI/CITPA) presented the safety assessment of paper and board FCM carried out by industry. The summary provided by the speaker is reported below.

"Ensuring the safety of virgin paper and board (P&B) materials and articles intended for food contact applications is a critical and complex challenge within the regulatory and manufacturing landscape. This presentation offers an examination of current industry practices and the regulatory frameworks that underpin the safety of these materials. One foundational issue is the absence of unified EU legislation governing safety of virgin P&B materials and converted products for food contact. This creates a heterogeneous regulatory environment that relies heavily on national laws and on EDQM and industry guidance documents from organisations such as CEPI, CITPA, ECMA, FEFCO and EuPIA. This underscores the necessity for harmonised legislation. The risk management process for unconverted P&B is outlined as a multi-tiered approach, starting with the rigorous selection of raw materials, including fibrous feedstock and chemical additives, continuing with process control, and concluding with extensive testing of P&B based on supplier communication and compositional disclosure, with the aim of managing potential IAS and NIAS exposure. Risk assessments use migration testing to simulate consumer exposure; however, this presentation critically examines the suitability of conventional testing regimes, particularly highlighting the challenges posed by the porous and absorbent nature of fibrous substrates. Additional attention is devoted to the role of the P&B converters who apply inks, varnishes, adhesives and coatings, each of which introduces additional safety considerations. The safety assessment of these converted components relies on supplier declarations, worst-case migration calculations and scenario-based risk evaluations. In the absence of harmonised EU provisions for these converted materials, the producers adhere to best practices according to their European industry associations as well as national regulatory documents. The industry's

initiatives for safety evaluation are explained, as well as its commitment to harmonising standards and promoting safe food packaging."

The speaker (CEPI/CITPA) provided further details on the safety assessment carried out by industry.

Migration is reported to be conducted in both food simulants (MPPO) and real food, while the use of liquid food simulants is an extraction rather than a migration. The methods applied are based on BfR and the JRC guidelines, but the selection of testing conditions is challenging (e.g. immersion only, liquid simulants for non-liquid foods). The issue on migration testing representativeness was noted and must be addressed. However, the lack of agreed alternatives to over-conservative migration testing conditions cannot be a reason not to address the potential migration in all the food types intended to be in contact. In all cases, migration into food prevails. DE commented when reviewing the Minutes that "The water extract (for example) is a widely accepted conventional method for migration testing of paper & board. Especially if the final use is unknown or diverse. For many cases (e.g. elements like aluminium, lead, cadmium, pAAs and chloropropanols) it was shown, that the water extract provides comparable results to migration experiments into liquid foods, if the respective surface to volume ratio is taken into consideration. In some cases – especially when surface treatment was applied to get water-resistant paper – the water extract can be over-conservative due to the sample preparation (cutting of the paper). Also for some analytes (e.g. bisphenols), the water extract can over-estimate migration into real foods like pizza. In these cases, migration experiments or conversion factors have to be developed on a case by case basis.".

The speaker (CEPI/CITPA) clarified that the approach presented is representative of the one currently used by the EU paper industry considering that manufacturers of food contact P&B materials are few and large entities. Converters usually rely on statements and on the provision of limited analytical information from manufacturers of P&B FCM and other relevant entities (e.g., printing-ink and adhesive suppliers). Based on this the converters carry out risk assessments. A detailed composition is not always disclosed. Regarding the toxicology assessment, the speaker reported that there are ongoing projects dealing with the matter.

The Network expressed its appreciation for the presentation and the information shared, as it contributes to a better understanding of the safety assessment made by Industry. It was noted that only few MSs (most notably DE) are able to consult reports on safety assessment of P&B. As a next step, more specific data from the industry on real cases would be informative.

9. 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": application to paper and board

Laurence Castle (EFSA FAF Panel) presented the 2024 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. The summary provided by the speaker is reported below.

"The EFSA Technical Report (TR) on 'Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials' was published in 2023. The TR describes the state of the art on this topic, based on an analysis of experiences and approaches in EFSA, Member States and wider. In particular, the TR was informed by 2 cases studies taken from plastic additives evaluated by the CEP Panel: FCM No 96 'Untreated wood flour and fibres' (EFSA CEP Panel, 2019) and 'Bleached cellulose pulp from pine and spruce' (EFSA CEP Panel, 2022). Although those Opinions were for additives intended for plastics, the 2 examples have a clear relevance to the assessment of paper & board as a FCM. This presentation described how the TR is directly applicable to the safety assessment of paper & board, including some limitations in scope since P&B is clearly not a food. According to the TR, the migrate from P&B should be characterised as fully as possible and all components <1,000 Da potentially migrating into food, should be assessed individually (Component Based Approach for those components identified) and/or assessed as a mixture (Whole Mixture Approach for any uncharacterised fraction). Approaches for that assessment are also described."

The Network discussed the challenges in the analytical determination of NIAS coming from P&B. It acknowledged that achieving LODs or LOQs equal to 0.15 µg/kg food (i.e. exposure corresponding to the TTC for genotoxic carcinogens) can be technically challenging.

It was noted that very often screening tests result into chromatograms made of a "forest of peaks", each one of which needs to undergo a safety assessment. However, such assessment may use elements other than identification – for example information about the manufacturing process. The Network Chair expressed interest in reviewing real and complete safety assessments for P&B. The industry was encouraged to share examples of safety assessments of P&B FCM. The full reports (inc. confidential data) should be shared (under confidentiality), otherwise a full understanding of industry activities could not be reached. The Network agreed to identify a couple of concrete substance-specific examples to illustrate the approach.

DE reported that in BfR Recommendation XXXVI on Paper and Board cellulose fibres are listed in the positive list of raw materials. A complete chemical characterisation of this raw material has not been requested by BfR at the time of listing.

10. EC JRC guidance on migration from paper and board: what is available and what is missing?

EC JRC presented the JRC guidance on migration of paper and board. The summary provided by the speaker is reported below.

"The presentation reported on the 5th edition of the JRC Kitchenware guideline, renamed "Guidelines on testing conditions for articles in contact with foodstuffs". It highlighted the updated structure of the guideline, the main differences with the previous edition, and it focused on the recommendations for testing of treated/coated and untreated/uncoated paper & board."

The speaker (EC JRC) reported that the 5th edition of the JRC guidelines is expected to be published by the end of the year. At the beginning of 2026, the work will begin on new guidelines, where also migration testing for P&B and other articles are expected to be further considered.

The Network discussed the details of the JRC guidelines. It was proposed that JRC includes the calculation/estimation of the migration based on the extraction tests.

It was noted that the guidelines recommend the selection of testing conditions based on material type (e.g. plastics, metal, P&B). However, in practice they should relate to the food contact conditions, not to materials and article type. Therefore, the Network remarked that it would be more appropriate to give the option to select conditions based on the food contact conditions. JRC welcomed the suggestion and explained that the approach based on material type was considered the best approach as the initial goal of the guidelines was to collect and rationalise available testing methods for migration testing. In fact, it has been already noted that the testing conditions such as the time and temperature "(based on plastic) may apply, assuming that in most cases consumers would make the same use of a specific utensil, independently of the material of which it is made." With regards to food simulants, JRC presented that, in absence of national and CoE recommendations, simulants used for plastics should be used. It should still be noted that if the tested articles fail to withstand the migration conditions, alternative approaches such as extraction tests (based on CEN standards) could be used. In all cases, food prevails over food simulants similarly to plastics.

It was noted that DE also has a guideline on how to test P&B FCM articles[7]. DE reported that the guideline was prepared considering and aligning as much as possible with the JRC guidelines.

11. Welcome and practical information (Day 2)

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

[7] https://www.bfr.bund.de/cm/349/testing-of-substance-transfers-from-consumer-articles-made-of-paper-cardboard-and-paperboard.pdf.

12. PFAS in paper and board

AT presented the outcome of a study on per- and polyfluoroalkyl substances (PFAS) in FCM. The abstract provided by the speaker is reported below.

"Paper and board products for food contact were examined for their presence of polyfluoroalkyl substances (PFAS). The study involved testing various products, including pizza boxes, drinking straws, paper bags, muffin cups, paper plates, napkins, and cardboard boxes. The testing strategy included both cold and hot water extraction methods for the different types of product applications. The analytes tested included PFAS compounds from perfluorobutanoic acid (PFBA) to perfluorotridecanoic acid (PFTrDA) as well as the respective perfluorosulfonic acids. Analysis was carried out according to DIN 38407-42 using solid-phase extraction followed by HPLC/MS-MS for the determination of the selected polyfluorinated compounds in the water extracts. The results indicated that 3 of the 24 samples released no detectable amounts of PFAS, and the group TWI of 4.4 ng/kg BW/w for the sum of four PFAS (PFOA, PFNA, PFHxS, PFOS) was not exceeded. The highest measured quantities of PFAS were PFHxA found in muffin cups and paper bags. In conclusion, there is a need for further testing under realistic conditions to demonstrate either compliance or non-compliance."

The Network elaborated on the findings of the AT study. The speaker (AT) noted that the concentration of PFAS found from muffin cups and straws may be due to an intentional use of PFAS as water-proofing agent. This may be corroborated by the finding that in one sample of muffin cups, chloropropanols were found with no trace of PFAS (i.e. indicating that another chemical with the same intended function as water-proofing agent was used). The speaker (AT) also reported that bisphenol S (BPS) and bisphenol A (BPA) were measured in the cold-water extracts of recycled corrugated cardboards of pizza boxes.

The Network noted that there was a considerable difference in the concentration of PFAS found from cold and hot water extracts, which extractions follows the recommendation of the JRC guidelines. PT underlined the need to better consider solubility, as water may not be suitable to estimate migration into certain types of food such as acidic, fatty food or milk. This strengthens the need for using appropriate test simulants and test conditions to estimate exposure. It was underlined that if the testing conditions are not deemed appropriate, "food prevails" over simulants, hence the potential migration should be tested in food.

EL reported that PFAS are routinely detected in P&B FCM during Greece's monitoring programs. EL reported on the PFAS found in paper straws at the 2024 FCM Network meeting. This year, monitoring efforts have focused on packaging articles such as paper bags and wraps. Undecafluorohexanoic acid (PFHxA) was the most prevalent PFAS found, what could be attributed to a shift in the type of PFAS used in the market. Short(er)-chain PFAS are gradually replacing long-chain PFAS as the latter are the focus of recent regulatory efforts. It was reported that a REACH restriction on the content of PFHxA in

P&B FCM will enter into force on 10/2026[8]. The restriction is the following: "*Shall not, from 10 October 2026 be placed on the market, or used, in a concentration equal to or greater than 25 ppb for the sum of PFHxA and its salts, or 1 000 ppb for the sum of PFHxA related substances, measured in homogeneous material*".[9]

13. Norwegian study on PFAS in FCM

On behalf of NW, Agnieszka Anna Niklas presented the outcome of a Norwegian study on per- and polyfluoroalkyl substances (PFAS) in FCM. The summary provided by the speaker is reported below.

"Per- and polyfluoroalkyl substances (PFAS) are synthetic compounds widely used for their oil- and water-repellent properties, including in paper and board food contact materials (FCMs). Due to concerns about PFAS migration into food, the Norwegian Food Safety Authority, in collaboration with the Technical University of Denmark (DTU Food), National Food Institute, conducted a survey of PFAS in FCMs available on the Norwegian market. Between March and June 2024, 30 FCM samples were collected across five regions of Norway and analysed at DTU Food using accredited LC-MS/MS methods. PFAS were detected in 11 of the 30 samples, including muffin forms, paper straws, pizza boxes, a popcorn beaker, and a paper plate. The sum concentrations of measured PFSAs ranged from 0.006 to 9.12 µg/kg food. Fluorotelomer alcohols were found in four samples (0.503–9.161 µg/kg), while monoPAPs and diPAPs were quantifiable only in one pizza box (0.05 µg/kg). Migration tests performed in triplicate revealed the highest PFAS migration in the popcorn beaker and muffin forms (ΣPFAS: 9.028; 3.145; 2.333 µg/kg food). Compared to a similar study in 2017, PFAS levels were generally lower. Non-targeted screening identified 5,200 features, with 1,159 suspected to contain three or more fluorine atoms (mass accuracy <2 ppm), although none matched compounds in the in-house library. These findings highlight the continued presence of PFAS in FCMs and underscore the importance of ongoing surveillance and analytical advancements."

The Network noted that fluorotelomer alcohols are the predominant PFAS measured in the present NW study while an increased presence of short chain PFAS was reported in the study described above under item 12 (AT). EL underlined that fluorotelomer alcohols are precursors of perfluoroalkyl carboxylic acids (PFCA).

IT noted that future studies should also address the presence of ultra-short chain (C<4) PFAS, whose use has reportedly increased in recent times.

[8] Commission Regulation (EU) 2024/2462 of 19 September 2024 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202402462.

[9] DE informed after the meeting that BfR will delete substance listings in the BfR recommendations XXXVI/1/2/3, which fall under the cited restriction.

The speaker (on behalf of NW) clarified that the source of the PFAS in the FCM articles was not established (residues/contaminants or intended uses).

The Network Chair noted that many studies on PFAS in FCM articles have been conducted in the MSs. There is a clear opportunity to share upfront projects and data, creating synergies.

The reports with the results of the survey and the risk assessment made by NW using the results of the presented survey were shared after the meeting and the link are reported in the footnote for convenience[10].

14. PFAS in paper straws, parchment papers, coffee filters, air-fryer liners, etc.

IE presented an ongoing Irish activity aimed at developing a reliable laboratory methodology for the determination of PFAS in FCMs. The summary provided by the speaker is reported below.

"PFAS is an abbreviation used to represent a large group (over 10,000) of manufactured chemicals called per- and polyfluorinated substances. PFAS are often referred to as "forever chemicals" because they do not naturally breakdown in the environment. As such PFAS can also be described as persistent chemicals, which can remain in the environment for long periods of time. PFAS have been used since the 1950s most often to make products resistant to water, stains and heat and have applications in many different industries, including computers, electronics, aerospace, cars, medical, as well as in consumer products like clothing and food contact materials (FCMs). Human health effects associated with PFAS exposure have been identified and are supported by different scientific studies. Concerns about the public health impact of PFAS have arisen due to their widespread occurrence and persistence, numerous exposures opportunities, and their potential bioaccumulation in the body. Because there are many types of PFAS chemicals, which often occur in mixtures and in many products, they are difficult to study. The current work aims to develop reliable laboratory methodology for the analysis of FCMs for PFAS and establish data on their occurrence in FCM packaging. "

[10] PFAS in paper and board food contact materials. Selected samples from the Norwegian market 2024. https://mattilsynet-xp7prod.enonic.cloud/_/attachment/inline/b558b355-f1a0-47ab-a6be-53c2f84cb6b8:cc1237a6d299ff14bf09ffc0b49bcec8c2a743bb/Rapport%20PFAS%20i%20matkontaktmaterialer%202024.pdf
Risk assessments of five per- and polyfluoroalkyl substances (PFAS) migrating from food contact materials (FCM) of paper and board collected on the Norwegian market https://mattilsynet-xp7prod.enonic.cloud/_/attachment/inline/ba1e2304-4611-41f6-871b-459515f17cb6:c91cfef0378881f07c6ed8b42cb9425aaca23283/Vurdering%20fra%20FHI_Risk%20assessment%20of%20five%20PFAS%20detected%20in%20FCM%20FINAL%2017.02.25.pdf.

The speaker (IE) reported that details on FCM articles (e.g. on the origin, traceability paperwork) were provided only by 4 out of 25 manufacturers, which is hinting at supply-chain communication issues. Traceability issues were mainly observed for articles retrieved in small shops and that were imported from non-EU countries.

The speaker (IE) informed that further sampling is scheduled for 2025 and 2026. The scheduled 2025 sampling of FCMs for PFAS analysis was completed on 23.10.2025. A total of 25 P&B samples were taken, including air fryer liners, paper plates, toaster bags etc. Analysis will be carried out with new improved analytical methods for PFAS testing, which are intended to obtain formal accreditation in 2026.

The Network noted that perfluoro phosphate compounds (PAPs) present in the analysed samples were among the most abundant PFAS found, which is a somewhat different outcome compared with the previous presentations (items 12 and 13). It was noted that the studies on PFAS reported at this meeting are using different methods. This makes the comparison of the various results complex and their use for risk assessment difficult. BE reported that a specific workflow for Compliance Testing of Emerging International Class wide Restrictions on PFAS[11] has been recently developed and will be soon included in a CEN method. The first step would be the measurement of total fluorine after combustion of the sample; then a target analysis would be carried out only if F is above a certain threshold. JRC noted that the first step of the method (total F) measures both organic and inorganic F, while only the organic fraction is meaningful for PFAS. EL stressed that it would be appropriate that all analysis include a targeted screening of PFAS.

15. Investigation of potential migratables from paper and board intended for takeaway

Mélanie Di Mario (Ad'hoc Expert) presented a Belgian study on the migration of various substances from takeaway paper and board FCMs. The summary provided by the speaker is reported below.

"Since the ban on single-use plastic articles in Europe, the food contact material industry has been forced to move to more sustainable alternatives. Paper and board FCM are convenient alternatives but must be safe for consumers. This study aims to investigate potential migrations of various substances (e.g., plasticizers, photoinitiators, primary aromatic amines, mineral oil, PFAS and bisphenols) from straws and takeaway articles made of paper and board. Twenty straws and fifty-eight takeaway articles were carefully selected and investigated using target analyses and (un)targeted screening. Twenty-three substances out of 91 substances targeted were found in takeaway articles and straws. Additionally, 80 more substances were identified through targeted screening of 100 compounds listed in Annex I of Regulation (EU) No. 10/2011 using LC-HRMS, and through untargeted

[11] https://pubs.acs.org/doi/10.1021/acs.est.4c06570

screening via GC-MS/MS. Finally, the associated risks were assessed using the RACE Tool of EFSA and an in-house tool developed at Sciensano, the SILIFOOD tool. The risk assessment highlighted potential risks, highlighting the potential risks for several types of articles regarding primary aromatic amines, mineral oils and PFAS."

The Network praised the comprehensive work carried out by BE that included identification, quantification and safety assessment of migratable substances.

AT noted that the study demonstrates that MOAH are commonly found migrating from P&B FCMs. For some samples, migration of MOAH was higher than 0.5 mg/kg food, i.e. the limit currently considered by the EC[12]. The speaker clarified that MOSH and MOAH were analysed following the JRC Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials[13]. Since migration was determined in food simulants, the Network suggested to follow-up with the determination into real food, especially into fatty food. As some foods may already contain MOAH from other sources, this could also inform on the contribution of FCM to the overall dietary exposure.

Regarding PFAS, the Network Chair underlined that once again, their source is not clear; both regarding the material (P&B, plastic) and the intention/contamination.

16. Q&A on migratable substances from paper and board

The Network Chair wrapped up the discussion and outlined the commonalities of the various topics presented. The migration testing conditions, the methods of analysis of the PFAS and their origin were the main topics. Other common points were the potential migration of other chemicals of interest such as BPs and MOSH/MOAH, the traceability and composition of imported articles, and the challenges in a complex and evolving regulatory landscape.

It was noted that harmonisation is needed at many levels: on nomenclature of PFAS, on testing methods, on the approaches used for their safety assessment. The lack of harmonisation does not help in using data shared among MSs.

The availability of the BE and JRC databases on substances in or migrating from FCM and their analytical results (including MS spectral libraries) was questioned. BE clarified that the so called "FCM Belgium database" of substances used in Food Contact Materials is not anymore online. JRC reported that the database of analytical methods to test FCM which might include spectral data on specific substances is being updated. Contrary to what was

[12] https://food.ec.europa.eu/system/files/2022-07/reg-com_toxic_20220421_sum.pdf.

[13] https://op.europa.eu/en/publication-detail/-/publication/97cb92c2-d29e-11ed-a05c-01aa75ed71a1/language-en.

mentioned at the 11th FCM Network meeting, JRC is not working on a mass spectral data based on information from National Reference Laboratories (NRL). However, data sharing seems to be hindered by confidentiality issues (a large part of the data hosted was provided by business operators), and by lack of time and resources. Also, cross-platform LC-MS spectral variability makes its implementation more difficult. EL informed the Network that it holds its own in-house high-resolution mass spectral database, but a comprehensive FCM specific spectral database needs to be developed for an efficient implementation of non-target screening approaches. There again, the question of MSs data sharing comes into play. The Network Chair underlined the continuous expression of interest for (a) shared European database of substances, IAS and NIAS, evaluated at EU and national levels completed by a database of their mass spectra.

17. Research on safety assessment of recycled paper and cardboard

Athanasios Kourkopoulos (Ad'hoc Expert) presented an ongoing research activity on the safety assessment of recycled paper and cardboard. The summary provided by the speaker is reported below.

"Recycled food contact materials (FCMs) often contain numerous contaminants, including non-intentionally added substances (NIAS) that originate from handling and recycling processes. These compounds can migrate into food and pose potential health risks, yet their safety assessment remains challenging due to chemical complexity, variability, and limited toxicological data. In this study, an effect-directed strategy was applied to recycled paper FCMs by integrating in vitro assays, suspect and non-targeted chemical analysis, and in silico predictive tools. Extracts prepared with food simulants under the conditions outlined in Regulation (EU) No 10/2011 exhibited estrogenic, androgenic, and dioxin-like activities, demonstrating the biological relevance of chemical migration. High-resolution mass spectrometry revealed more than 28,000 features, but only 32 compounds could be confidently identified and 76 tentatively assigned, including phthalates, bisphenols, and industrial additives. Most features remained unresolved due to the absence of reference standards and incomplete spectral databases. Database searches and computational hazard predictions provided further insight into potential endocrine-disrupting and genotoxic activities, although inconsistencies between predictive models and regulatory classifications underscored the need for validation. Overall, the findings highlight the substantial chemical complexity of recycled FCMs and show that while the effect-directed strategy is promising, it is still constrained by limited hazard data for key endpoints, insufficient potency information, a lack of predictive models for complex toxicities, the impracticality of linking all detected features to biological effects, sensitivity and specificity limits of bioassays, and the confounding influence of mixture effects. Addressing these challenges will strengthen the robustness of the effect-directed strategy for identifying and prioritizing chemical hazards migrating from paper FCMs."

The speaker elaborated on the details of the migration/extraction tests. Plastic-coated printed articles intended to contact aqueous and acidic foods were tested with the aqueous (10% v/v ethanol) and acidic food simulants (3% w/v acetic acid), respectively. Wax-coated non-printed paper intended for contact with fatty foods was tested with 50% v/v ethanol and vegetable oil, and plain non-printed paper intended to contact dry foods was tested with the dry food simulant (MPPO). The presence of recycled paper was confirmed from suppliers (paper mills). For each sample, the number of non-identified compounds assigned to Schymanski levels 2 and 3 was >2000.

As in vitro toxicity testing always identified a potential hazard, chemical characterisation was carried out for all the samples.

DE noted that despite the in vitro genotoxicity tests were all negative, the chemical characterisation of migrates or extracts identified the presence of genotoxic compounds. As already commented in previous Network meetings, bioassays have limited sensitivity. If a "whole-mixture approach" (WMA) is applied, there may not be a response if the levels of genotoxic compounds in the tested mixture are low. For this reason, the Guidance on genotoxicity assessment of mixtures (EFSA SC, 2019)[14] recommends (i) to apply a component-based approach (CBA) to the identified constituents and (ii) to fractionate the mixture (to remove inert, toxicologically irrelevant components from the mixture (e.g. high-molecular-weight polymers) to minimise the dilution of the components of interest in the tested sample, or to remove highly toxic components that may prevent testing adequately high doses of the mixture). Moreover, it was noted that the response of bioassays may be influenced by other factors, such as interference from the solvent used to dissolve or disperse the test item.

DE asked if the identified chemicals could be reasonably linked to the composition of the FCM articles. The speaker reported that chemicals such as PFAS, plasticisers, MOSH and MOAH were identified in the samples, and are likely migrating from the paper-based FCMs. Additionally, a wide range of toxic elements were found in extracts or migrates[15].

18. Manufacturing (and converting) of recycled paper and board

CEPI/CITPA presented the current industrial processes to manufacture and convert recycled paper and board FCMs. The summary provided by the speaker is reported below.

"This presentation provides a comprehensive technical and regulatory overview of the safety considerations involved in manufacturing and converting recycled paper and board (P&B) for use as food contact materials (FCMs). It addresses the unique challenges posed using recycled fibre due to the presence

[14] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5519.
[15] https://doi.org/10.1093/fqsafe/fyaf002.

of undeclared substances from inks, lacquers, adhesives, and other components from prior use, and the industry's risk mitigation strategies for these contaminants. Although recycled P&B is essential for achieving the goals of the circular economy, its use in scenarios involving food contact requires careful consideration due to the variability in the composition of recovered paper streams. The presentation outlines the entire production cycle, from the sourcing and classification of recovered paper grades, to repulping, cleaning and sheet formation, highlighting critical points where chemical and microbiological risks can be mitigated. The types and classifications of recovered paper are examined, including post-consumer and industrial waste, as well as the stringent sorting protocols adhering to CEPI's Responsible Sourcing Guidelines and excluding unsuitable grades per EN 643 to ensure that the quality of the feedstock meets both manufacturing performance and regulatory specifications. It provides a detailed examination of pulping techniques tailored to recycled materials, including mechanical and chemical pulping methods. The presentation emphasises the importance of contamination control and describes screening and cleaning technologies designed to meet stringent limits on residual inks, adhesives and other hazardous substances. Focus is given to the deinking process, where flotation and washing technologies supplemented by surfactants and enzymatic agents are optimised to achieve pulp brightness and purity standards that can be critical for product quality and safety. Overall, the aim of this presentation is to deepen understanding of the sophisticated cleaning process of recycled fibres to facilitate the production of safe food contact materials."

The speaker (CEPI/CITPA) reported that recycling P&B facilities do not usually carry out sorting steps but buy sorted materials, such as unprinted, printed, heavy printed paper. The various quality grades are then used to manufacture articles based on their intended contact conditions.

To the question on how the decontamination efficiency is determined, the speaker (CEPI/CITPA) clarified that no challenge test (similar to what is used for determining the decontamination efficiency in PET recycling) is carried out.

19. Safety of recycled paper and board according to Industry

CEPI/CITPA presented the safety assessment of recycled paper and board FCM carried out by industry. The summary provided by the speaker is reported below.

"An in-depth look at how recycled paper and board (P&B) are assessed for safety and used in food contact applications is provided. It outlines the technical, regulatory and risk management frameworks that underpin the responsible use of recycled fibres in packaging, emphasising the importance of harmonised practices and analytical approach. The industry's practices are guided by various documents, including the CEPI/CITPA Food Contact Guidelines and the CEPI GMP standards, as well as national and European references such as the BfR recommendations and guidelines and the EDQM technical guides. Together, these documents support a structured

methodology for ensuring the safety of recycled P&B materials throughout their lifecycle, despite the absence of harmonised European regulatory requirements. The safety assurance process begins in the design phase, incorporating fibre selection, barrier considerations, and customer specific requirements. The design phase is critical for mitigating risks associated with chemical migration and ensuring the materials are suitable for specific types of intended food contact. Risk management is addressed through stringent raw material sourcing protocols. A key challenge is the presence of non-intentionally added substances (NIAS), including residues from inks, adhesives, and coatings, which can be anticipated through targeted analysis or detected via non-targeted screening. The presentation identifies typical NIAS in recycled fibres, including bisphenols, mineral oil hydrocarbons (MOSH/MOAH), di-isocyanato-p-phenylene (DIPN), photo initiators, perfluoroalkyl substances (PFAS) and phthalates. National regulations impose specific migration limits and require functional barriers or equivalent risk mitigation strategies. The intended food contact type — dry, fatty or aqueous — directly influences material choice and safety evaluation. Testing regimes for recycled P&B mirror those for virgin materials, with the additional inclusion of migration simulation, targeted analysis and screening for NIAS. The industry has extensive testing protocols in place to demonstrate that recycled P&B can be safely used in both direct and indirect food contact applications, provided that appropriate risk management, GMP and testing are in place."

The speaker (CEPI/CITPA) clarified that the tests carried out by industry largely follow the JRC and BfR guidelines; however, specific methods are developed on a case-by-case basis. The safety of articles is also determined by conducting tests with real foods (e.g., ketchup, mayonnaise, , fast food, biscuits). The Network appreciated the effort made by industry and encouraged it to share data on the risk assessment of recycled P&B with MSs and the Network.

The Network noted that testing for non-dry foods (moist, fatty foods) is based on extraction, hence the migration potential should be considered based on extraction. Also, it would be important to test migration into food to gauge the representativeness of the potential migration calculated *via* extracts. It was acknowledged that testing with food comes with additional challenges, e.g. food has a complex composition that may interfere with the analysis, including possible background levels of analytes. Nonetheless, this issue needs to be addressed.

The approach currently used by industry to demonstrate the safety of recycled P&B FCM relies on the regular monitoring of the presence of substances/composition of mixtures, with tests being carried out with simulants and real food. The Network noted that for PET recycling, the safety of the process (i.e. its ability to decontaminate) is evaluated. So far, P&B industry has not implemented a similar approach.

DE welcomed the idea of investigating the applicability of the approach used for PET recycling to P&B recycling, highlighting that there might be challenges as the incoming material is very heterogenous. DE noted that a regular monitoring of incoming and outgoing materials is important and sharing these data with assessing authorities would be a starting point. It was pointed out

that BfR Recommendation XXXVI on paper and board in food contact does contain an annex dealing with the use of recycled fibres setting limitations for the sort of recycled paper and their sources as well as typical contaminants.

It was noted that the upcoming amendment to the plastic regulation (Reg. (EU) 10/2011) sets out criteria for the quality of FCM materials and articles. A similar regulatory approach may be considered also for P&B materials.

20. Safety assessment of recycled paper and cardboard FCM (views from a Member State)

AT presented the process and the challenges of the safety assessment of recycled paper and cardboard FCM. The summary provided by the speaker is reported below.

"The safety assessment of recycled paper and cardboard food contact materials (FCM) is a critical topic in ensuring consumer health and safety. Safety assessment is composed of four key components. 1. Hazard Identification: sources of harm in the paper-making process and NIAS coming from the input materials. This includes contaminants from process chemicals as well as printing inks, adhesives and coatings. The identification of these hazards is crucial in understanding the potential risks associated with recycled paper and cardboard FCM. 2. Risk Evaluation: The likelihood and severity of harm from identified hazards has to be analysed. Factors such as the type and conditions of use and type of food have to be considered to assess the potential transfer to food. Exposure based on consumption data would be an integral part. 3. Standard Comparison: The identified risk levels shall be compared to established science-based safety standards. This includes European legislation, guidelines and industry standards. 4. Risk Management: Measures to reduce risks to an acceptable level. This includes process control, end control, and specifications for input materials. Supporting documentation and declarations of compliance play an important role. This comprehensive assessment aims to provide insights into the safety of recycled paper and cardboard FCM, ensuring that these materials meet the necessary safety standards."

21. General discussion on the safety assessment of virgin and recycled paper and board

The Network shared reflections and observations based on the presentations on the safety assessment of virgin and recycled paper and boards.

The Network Chair recapped the commonalities and the main observations made during the discussions on virgin and recycled P&B[16]:

- P&B is a multi-material with inbuilt complexicity notably due to strong treatments that renders it distant from a natural compound. Only the raw material or produced fibers would be evaluated according to the EFSA Technical Report on mixtures of natural origin.
- Substances used in the manufacturing processes of P&B could be assessed according to the EFSA Note for Guidance as for plastics. This applies equally to the chemistry used in the converting processes (coatings, printing inks, etc.).
- A need for detailed chemical characterisation was highlighted.
- IAS should in principle not be an issue (composition analysis, supply chain information, migration analysis), and could be supported by a harmonised list. NIAS are a challenge and relate to the IAS and to the manufacturing process.
- Migration testing conditions should be harmonised especially in reference to the DE and the 'JRC' guidelines. For coated materials, it seems fine to use the same food simulants as used for plastic. The lack of one-side testing methodology, the need for estimation/calculation from extractions testing conditions and the fact that food prevails over food simulant in case of limitations (possible issue of background contamination) were highlighted.
- Detection and quantification of migrating IAS and NIAS were highlighted. For IAS, since their genotoxicity potential should be addressed a priori, no issue was found with the limit of detection (LOD, 50 µg/kg food). NIAS desserves dedicated chemical screening analysis; a LOD of 10 µg/kg food was mentioned but is 67 times higher than a migration value corresponding to the threshold of toxicological concern (TTC) for DNA-reactive chemicals.
- Presence of contaminants inherent to recyled P&B FCM and efficiency to decontaminate collected P&B is not quantified.
- The (intended) uses are important to be considered for the assessment as they link to the final materials and article types.
- Harmonisation efforts from MSs are needed along with more data to move ahead.

The Network Chair praised the information received by the industry. He noted that many MSs wished that industry shared more details, including reports on migration tests and safety assessments. In absence of data, it was noted that there might be other management option to ensure the safety, such as restrictions in use (the example of Italy was mentioned, where contact with recycled P&B is allowed only for dry food).

P&B articles are often manufactured to have a plastic functional barrier on the food contact side. JRC reported that questions have been received on the testing of plastic functional barriers for P&B articles, to which it is replied to first rely on Regulation 10/2011. AT noted that the CoE technical guide on Paper and board used in food contact materials and articles also includes a

[16] This was completed after the FCM Network meeting.

section on the determination of the effectiveness of functional barriers, which may use experimental testing (e.g. with surrogate substances) or calculations.

NL proposed to prepare a list of expected NIAS to be monitored as part of chemical targeted screening analysis.

DE noted that the application of in vitro bioassays is expected but their sensitivity is still not sufficient as the level of content of substances for which the characterisation is needed is very low.

The need for more detailed data from industry was reiterated, encouraging data sharing.

DE reported that BfR has consulted details on recycling processes applied to P&B in conjunction with an application for the listing of the use of recycled fibres originating from waste collection. The outcome of the evaluation is published in the protocols of the BfR Committee for Consumer Products (German language; 32., 33. and 34. Meeting[17]). The annex to BfR Recommendation XXXVI was amended accordingly.

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

Daniele Comandella (EFSA) presented the content of the EFSA database on risk assessment initiatives regarding projects and activities on FCM. The abstract provided by the speaker is reported below.

"In the context of closer collaboration between Member States, a database of different research projects has been built starting in 2015. It is fed on a confidential basis by the Member States and comprises information on several hundred Member State's risk assessment - related projects for all areas falling within the interest of EFSA. The data has been recently transferred to a new platform called "Risk assessment Initiatives database". 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 keep them updated, with the purpose of promoting awareness and stimulating cooperation between Member States. A search carried out just before this Network meeting identified 53 FCM-relevant projects, of which 4 are reported as ongoing and 3 are "new" projects (i.e. added after the last (11th) FCM Network meeting)."

The importance of this list of projects of interest for FCM was reiterated 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 clarified that the new projects worth reporting are all the FCM-related projects from the MS (i.e. including those from national Institutions other than the one of the MS representatives); they do not include the assessments of application

[17] https://www.bfr.bund.de/ueber-uns/einrichtungen-am-bfr/bfr-kommissionen/kommission-fuer-bedarfsgegenstaende/

dossiers. 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.

Additional information was orally shared from EL, SI and DE. The provided summaries are reported below.

- EL reported that the projects "Starch-based biodegradable food packaging films with molecularly encapsuled bioactive substances and reinforced with nanoclay" and "Cyclic oligomers in foods: determination and toxicity evaluation", the progress of which was reported at the 11th Network meeting, have been completed. The results have been included in three scientific publications[18]. No follow-up activities have been so far foreseen.

- SI informed on the ongoing project on "Enamels in contact with food". "In the field of enamelware intended for contact with food, the Ad Hoc Working Group on Enamel continues its activities under the auspices of the CoE (SI is leading the initiative). The mandate of the Working Group has been extended until the end of the next year. The outcome will be a Technical Guide providing recommendations on the testing methodology and limit values for the release of metals."

- DE informed on the projects "Risk assessment for elements release from lead crystal glass and metallic hip flasks" (ended in December 2024) and "Risk assessment for elements release from coated/uncoated metal food contact materials**"** (ended in September 2024).
  - "Risk assessment for elements release from lead crystal glass and metallic hip flasks. The release of 21 elemental ions from lead crystal ware and metallic hip flasks into different food simulants as well as alcoholic beverages was investigated via ICP-MS. Elemental ion release from lead crystal glasses into artificial tap water, 0.5% citric acid solution and white wine, respectively, was only observed for Pb. Within 24 h, Pb release from crystal glass was shown to increase with time. To account for repeated use, at least three consecutive release experiments were performed, which showed – with one remarkable exception – constant or decreasing levels of element ion release. After four months resting period, Pb release from crystal glass was higher than before. In contrast, all 21 elemental ions were detected to be released from the hip flasks into 0.5% citric acid solution, apple liqueur and herb liqueur, respectively. Release of Cd, Cr, Ni, As, TI, Sn and most prominently Pb from hip flasks was in the range of and above the respective release limit (SRL) as set by the Council of Europe (CoE). When focussing on the third repetition, only one out of six hip flasks met the suggested SRL for all determined elements in all test solutions. This demonstrates both, that the SRLs of the CoE can be met and that producers of hip flasks

[18] https://www.mdpi.com/2304-8158/13/20/3333 - https://www.mdpi.com/2304-8158/12/14/2739 - https://link.springer.com/article/10.1007/s00216-021-03741-6.

may have to review their manufacturing processes. Results have been published 30 September 2024[19].”

- “Risk assessment for elements release from coated/uncoated metal food contact materials. In 2022, element release from 194 metal items, both uncoated and enamelled, were examined as part of a nationwide monitoring programme. The German Federal Institute for Risk Assessment (BfR) evaluated the results of this study and assessed whether the amounts released could pose health risks. Most of the items examined released only very small amounts of the elements in question. It is the opinion of the BfR that these products are therefore suitable for contact with food. Some items on the other hand contributed substantially to people’s daily intake of certain elements, especially when other sources such as food were also taken into account. Only a few objects showed element releases that could exceed the derived HBGV or toxicological reference values. These items are not suitable for contact with food. The BfR recommends that manufacturers of such items improve materials and production processes in order to further reduce the release of elements into food. However, the vast majority of uncoated and enamelled metallic materials showed low to very low element release and are suitable for food contact. The BfR Opinion is available online.[20]”

23. Annex of the EFSA Scientific Committee Guidance on the safety assessment of FCM substances present in food intended for infants below 16 weeks of age

Gilles Rivière (EFSA FCM Panel, EFSA FCM WG) presented the recently published Annex A[21] entitled ‘Implementation of the EFSA SC guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age to the risk assessment of food contact material substances migrating into food intended for infants below 16 weeks of age and for which a standard chemical risk assessment has not been performed’. The summary provided by the speaker is reported below.

“The note for guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age (2017) describes the toxicological requirements to ensure safety for this special population. In the context of food contact materials, the toxicological data required depends on the level of migration. Therefore, an annex to the guidance was published to take into account the specificities of FCM. Overall, the thresholds of the tiers as well as the toxicological requirements were adapted to the infants below 16 weeks of

[19] https://doi.org/10.1080/19440049.2024.2406002.
[20] https://www.bfr.bund.de/en/opinions/metal-kitchen-utensils-do-substances-transfer-into-food/.
[21] https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2017.4849&file=efs24849-sup-0001-Annex_A_FCM+Assessment_ForInfants_Belo_16w.pdf

age. Special emphasis was given to the toxicokinetic parameters of the substance as well as some specific toxicological endpoints (repro and developmental notably)."

The Network discussed the details of the Annex and the reasons behind its preparation.

The speaker explained that the objective of the Annex is to clarify the data requirements for applications on substances intended to be used to manufacture plastic articles in contact with infant foods (including with water that can be used to reconstitute infant formula powder). Applicants should follow the sectorial FCM Note for Guidance plus the SC cross-cutting guidance documents as needed (e.g. on genotoxicity strategy, mixtures, read across, etc.). This is usually done for any EFSA assessment, so there is no intention of updating the Note for Guidance with information already reported in the Annex of the SC Opinion.

It was noted that the SC Opinion and its Annex A consider 16 weeks as the age cut-off, while EFSA reported in a more recent opinion published in 2019[22] that "most infants do not need complementary feeding for nutritional reasons up to around 6 months of age". It was clarified that the Annex A aims at aligning with the approach of the SC Guidance published in 2017. The FCM WG and Panel reported to the SC aspects of the guidance that may need to be reconsidered and made recommendations in that direction in the Annex A. On this particular matter related to the 16 weeks cut-off point versus 6 months, while it may not affect the criteria considered by the SC (consumption, body weight, etc.), the comment will be conveyed to the SC after the Network meeting.

DE noted that a migration above 3 µg/kg food would result in the request of submission of a One Extended Generation Reprotoxicity study (EOGRTS), i.e. a study that is animal and money-intensive. Such requirement seems excessive for such a migration level. The speaker acknowledged the matter and communicated that discussion are being held in other EFSA areas to reconsider the need of the EOGRTS study and alternatives. This issue was extensively discussed at the FCM WG but it was decided to align with the SC guidance and to make recommendations on possible revision. It should also be noted that the requirement for an EOGRTS applies certainly from 3 µg/kg food but covers a higher range of migration.

EC SANTE observed that the Annex may question the safety of already authorised substances in Reg. (EU) 10/2011, as the potential use in contact with infant food or water was not considered at the time of evaluation/authorisation. This may lead to the re-assessment of the safety of authorised substances. The Network Chair acknowledged the situation that was also noted by the FCM WG and mentioned that an approach similar to the 'nanoform' substances could be applied, i.e. only substances explicitly assessed and named as nanoform in the Union list are authorised to be used in nanoform. So, applications for substances (already) used to manufacture

[22] https://www.efsa.europa.eu/en/efsajournal/pub/5780.

plastic articles intended for contact with infant formula, water used to reconstitute infant formula and/or human milk could be required with a deadline after which only the substances explicitly assessed for these uses could be authorised (a transitional period would be needed).

24. EFSA draft statement on the information necessary for the assessment of the use of hazardous bisphenols and derivatives

Zainab Al Harraq (EFSA) presented the ongoing EFSA activity to draft a statement on the information necessary for the assessment of the use of hazardous bisphenols and derivatives. The abstract provided by the speaker is reported below.

"Commission Regulation (EU) 2024/3190 of 19 December 2024 on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives entered into force on 20 January 2025. This Regulation prohibits the use of BPA in food contact materials (FCM) and establishes that hazardous bisphenols other than BPA and their derivatives may be used in the manufacture of FCM and articles for a specific application if that use has been authorized. According to Article 6.4 of Regulation (EU) 2024/3190, EFSA "…shall publish scientific output detailing the information necessary for the assessment of the use of hazardous bisphenols or hazardous bisphenol derivatives, in the manufacture of a food contact materials and articles for a specific application, supplementing or updating where necessary the detailed guidelines referred to in Article 9(2) of Regulation (EC) No 1935/2004. The Authority and the European Chemicals Agency shall collaborate with each other for this purpose". Therefore, it was deemed necessary to elaborate an update of the current FCM guidance document specifying the requirements needed for the assessment of hazardous bisphenols and their derivatives for their use in FCM. The task should be completed by 19 January 2027."

EC SANTE clarified that the mandate was sent to EFSA based on specific considerations raised by the EFSA opinion on BPA published in 2023[23]. (i) The conclusion of the opinion was based on adverse effects elicited at very low levels of exposure; (ii) such low levels are usually observed for CMR and ED effects – but for BPA the adverse effect was for immunotoxicity; (iii) same effects may be caused by other bisphenols that are currently considered by industry to replace BPA. Finally, (iv) there was the need to involve ECHA in view of the industrial applications of other bisphenols.

25. European Commission SANTE activities

[23] https://www.efsa.europa.eu/en/efsajournal/pub/6857.

EC SANTE presented the EC SANTE activities with a focus on the ongoing revision of the Framework Regulation (EU) No 1935/2004 on FCM. The abstract provided by the speaker is reported below.

"The European Commission is currently accelerating its work on the revision of FCM legislation, based initially on targeted consultation of experts in the field of FCM, with more formal consultations planned further on in the process. The primary objectives of the revision are to achieve appropriate harmonisation across all materials, improve certainty over food safety and functioning of the EU market, simplification and improve competitiveness and legal certainty. The core principles of revised rules will include requirements to share information throughout supply chain, transparency on composition of final articles and on migratable substances as well as clarity on accountability of business operators' responsibilities. The revision also aims to drive common approaches for risk assessment, prioritise the most harmful substances, improve use of GMP and ensure improved compliance and enforcement. The European Commission is also continuing work on implementation of current FCM legislation, including a recent amendment to Commission Regulation (EU) No 10/2011 with the authorisation of six new substances and further substances to be authorised following favourable EFSA opinions. Commission Regulation (EU) 2022/1616 on plastic recycling is being amended with the aim of providing better procedural support for the EU Register and clarification of declarations of compliance. Audits of registered installations are being carried out with improvements to the online register. Concerning BPA, a correcting Regulation will be adopted in the coming months, mostly to correct issues related to the transitional provisions. An official guidance document for Regulation 2024/3190 in the form of a Q&A will also soon be adopted."

The speaker (EC SANTE) clarified that the revision should apply to all types of FCM and will consider specifications when they are needed.

It was noted that a considerable share of FCM used in the EU are imported from third countries; therefore, the revision should also consider how the rules should be applied to FCMs imported into the EU.

26. Welcome and practical information (Day 3)

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

27. Belgium Working Group regarding the SciCom 2024/05 on Microplastics

Olga Rojo Poveda (Ad'hoc Expert) presented the approach of the Belgium Federal Agency for the Safety of the Food Chain (FASFC) Working Group on the safety assessment of microplastics in the food chain. The abstract provided by the speaker is reported below. "The Federal Agency for the Safety of the

Food Chain (FASFC) is responsible in Belgium for the assessment and management of risks that may be harmful to the health of consumers, as well as to the health of animals and plants. The Scientific Committee (SciCom) is a consultative body established within the FASFC. It plays a central role in the assessment of the risks in the food chain. Its main task is to provide independent scientific opinions on risk assessment and options for risk management in matters related to the competencies of the FASFC. The SciCom has recently tasked itself with a dossier on the risks of micro and nanoplastics (MNP) in the food chain, with the objective of publishing a scientific report on this topic. In recent years, several competent authorities have concentrated their efforts on different scientific opinions concerning MNP. However, the outcomes of these opinions have generally been inconclusive due to a lack of relevant data and analytical capabilities. Consequently, a classical risk assessment or the establishment of a health-based guidance value is not yet possible for this type of contaminant. The working group (WG) has therefore proposed a different approach for its scientific opinion on MNP. Instead of attempting a conventional risk assessment, the WG will evaluate the necessary criteria required to make such an assessment possible. To this end, it is proposed to develop a multi-criteria scoring system. This scoring system is intended as a tool to support the risk assessment of MNP by integrating toxicological potential, co-contaminant interactions, and exposure relevance. It should also help to prioritize research, regulatory actions, and monitoring needs."

The speaker clarified that the activity resulted in the development of an approach to observe and estimate data gaps related to MNP research and human exposure. Based on this, the BE WG is currently working on estimating the magnitude of the risk due to exposure to MNP. One of the largest hurdles is the estimation of the exposure due to the various sources of MNP. It was noted that there is increasing evidence on the uptake of nanoparticles by plants (e.g. from pesticide use), hence some of the exposure may come directly from food. In the next steps, it is being considered to use case studies to test the scoring system developed in this work and to focus on Human biomonitoring studies to estimate the internal exposure to microplastics.

EFSA reported that it received a draft mandate from the European Parliament in consultation with the Commission on the safety of the exposure to micro- and nanoplastics in the food chain. The Opinion will fall under the lead of the EFSA CONTAM Panel. It should 'update' and complement the EFSA statement published in 2016 on the "presence of microplastics and nanoplastics in food, with particular focus on seafood"[24].

[24] https://www.efsa.europa.eu/en/efsajournal/pub/4501.

28. EFSA draft Technical report on micro- and nano-plastics released by Food Contact Materials during their uses

Thomas Hemy-Dumas (EFSA) presented the EFSA draft Technical report on micro- and nano-plastics released by Food Contact Materials[25]. The abstract of the Report is reported below.

"To search for evidence of micro- and nanoplastics (MNP) release during the uses of food contact materials (FCM), a structured literature review was carried out on studies published between 2015 and 20th January 2025. It identified 1711 publications of which 122 were selected for data extraction. Eight additional publications were added to provide more context. Most studies concern microplastics, while data on nanoplastics are almost entirely absent. Most publications use water or aqueous food simulants as FCM contact medium for suspension and subsequent isolation of released MNP. Foods other than mineral water were tested in only few cases. Despite the large number of publications investigating the release of MNP from FCM, the available evidence concerning the characteristics and quantities of released MNP from FCM remains limited. Many publications are affected by methodological shortcomings in test conditions, in sample preparation, and by deficiencies in the reliability of analytical data, with the consequence of frequent misidentification and miscounting. Based on the findings on release mechanisms, contaminations, mimicking substances, particle numbers and masses generated during the use of FCMs, it is concluded that (i) there is evidence of microplastics released during the uses of FCM, (ii) this release is due to mechanical stress, such as abrasion or friction, or due to materials with open or fibrous structures, (iii) despite the uncertainties, the actual release is much lower than the results presented in many publications. In view of all this, there is no sufficient basis at this stage to estimate MNP exposure from FCM during their uses. This review identifies methodological shortcomings and data gaps, and makes recommendations on related future research needs."

The Network welcomed this work considering the attention given to the contamination by microplastics and the upcoming EFSA CONTAM evaluation. The discussion continued under the Q&A common session on MNP (item 29 below).

29. Q&A on micro- and nano-plastics released by Food Contact Materials during their uses

Laurence Castle summed up the conclusion of the report, pointing out that most of the results from the literature are misleading because of inadequate methods of particle analysis. For example, often the detected particles were artifacts – i.e. not truly plastic particles coming from the FCM. It is possible

[25] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2025.EN-9733.

that the same issues are limitations in studies carried out on environmental and human samples. He noted that these issues seem to have been overcome in most recent works; hence it is reasonable to revisit the matter within a relative short timeframe (a time of 5 years is suggested in the report).

It was highlighted that the reports in the literature of number-based without mass-based concentrations might have led to a misleading perception of the risk: a very high number-based concentration value usually results in a very low mass-based value, hence in a very low exposure to consumers. Without disregarding a potential hazard, it was noted that for many of the works considered, the mass-based values were in the range of µg/kg food and below.

Considering the mechanical mechanism of generation of microplastics from FCM, PT noted that the majority of the studies are using liquid simulants/water, while solid food would be more pertinent.

On the source of contaminations of foodstuffs by nanoparticles and as mentioned under the above item 27, A Raijkovic (FASFC) reminded that nanoparticles are also reported as present in plant tissues.

PT noted that there is an increasing use of biobased materials (such as PLA, polyesters) and questioned as to whether the biodegradability add or not to the presence of microplastics in the environment.

A Raijkovic (FASFC) expressed appreciation to the thorough appraisal and to the quality of the scientific articles considered. The work done shows that most of the methods used in literature are not adequate, while particles should be characterised by using a triangulated analysis, i.e. by applying a combination of multiple suitable techniques (pyro-GC-MS, spectroscopy, etc.).

CoE asked why a 100 nm threshold was used to discriminate micro and nanoparticles. EFSA clarified that this threshold follows the recommendations from the EFSA SC, which is currently discussing its possible readjustment. Waiting for changes, if any, the threshold used in EFSA is 100 nm. It was noted that even if the report had used a different threshold, the outcome would not have changed as very little information was reported in the literature on particles below 1 µm.

30. Oligomers released from teabags made from PET, PLA, polyamide

DK presented a study on the release of oligomers from teabags made of PET, PLA, polyamide. The abstract provided by the speaker is reported below.

"Plastic teabags are largely replaced by biobased teabags. In this study, we tested teabags made from PET, PLA, polyamide in relation to the concentration of oligomers released from these teabags. The findings revealed that PET oligomers migrated from PET teabags, various lengths of PLA oligomers were detected from PLA teabags, and polyamide oligomers were found in polyamide teabags. The concentration of released oligomers was largest in polyamide teabags followed by PET and PLA teabags."

It was noted that migration of oligomers has been historically not addressed at the same extent as monomers or other substances. However, the trend of addressing them has increased.

It was observed that a large part of the oligomers migrating in water are cyclic. This is not an artefact, but it is expected as cyclic oligomers with molecular weight below 1000 Da are present in condensation polymers such as PET.

The observed migration is in the range of few µg/kg item, i.e. hinting to a low exposure to consumers.

31. BfR NIAS concept for their safety assessment

DE presented the draft 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 (EC) 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 draft concept was presented at the last network meeting and submitted to the members of the FIP network and industry stakeholders for comment. A summary of the comments will be provided."

The Network noted that the potential waiving of toxicological data for non-identified NIAS migrating from 0.15 to 50 µg/kg food is the main divergency between the BfR and the current EFSA approach. In the draft BfR proposal, waiving could be granted if the applicant demonstrates to have carried out an adequate and thorough chemical analysis and on the basis of expert judgement. Such expert judgement would be based on information on the manufacturing process, the extent of analytical efforts, the results from compositional or from the migration studies, etc.

The Network acknowledged the current analytical limitations to identify all potentially migrating NIAS detected from screening analysis. However, it was noted that the work of applicants should not be limited to prove that the screening was state-of-the art. Additional data should be provided including, for example, tentative identification, additional analysis to confirm or exclude the presence of aromatic structures or of certain elements (N, S, halogens).

It was noted that in its 2016 opinion[26], the EFSA CEF Panel reported the possible use of non-testing methods (in silico tools), read-across and the threshold of toxicological concern for DNA reactive substances to support the evaluation of NIAS. Testing on mixtures might be a tool to address genotoxicity potential bearing in mind the related limitations. The use of Cramer classes cannot be applied to non-identified NIAS (structure not fully elucidated). DE noted that – as opposed to EFSA – BfR generally does not use Cramer Classes as a risk assessment tool for NIAS from FCM. Other non-testing approaches like grouping, or in silico methods are, however, proposed in order to overcome practical issues of NIAS testing.

DE reported that if the migration of a degradation product exceeds 50 µg/kg food the requirements for toxicological data for the NIAS would be tier II. The Network Chair noted that this is in line with the EFSA CEF Panel Opinion (2016).

32. EFSA Guidance on the use of read-across for chemical safety assessment in food and feed

Lucian Farcal (EFSA) presented the EFSA Guidance on the use of read-across for chemical safety assessment in food and feed. The abstract provided by the speaker is reported below.

"The presentation provides an overview of the EFSA Scientific Committee guidance on the read-across approach for chemical safety assessment in food and feed. Read-across is a method used in chemical risk assessment to predict the toxicological properties of a target substance by using data from structurally and mechanistically similar substances, known as source substances. The guidance is applicable to both regulated and non-regulated substances, with flexibility to adapt to various risk assessment contexts. The read-across approach is intended to be complementary and inform the risk assessment, used as part of a weight-of-evidence (WoE) approach and not as a substitute of the whole risk assessment process. The presentation introduces the concept, regulatory context, and practical application of read-across, targeting EFSA risk assessors and applicants. It covers the workflow steps: problem formulation, target substance characterisation, source substance identification and evaluation, data gap filling, uncertainty assessment, and conclusion/reporting. Each step is associated with potential uncertainties, which must be transparently assessed and documented. The guidance encourages integration of data from new approach methodologies (NAMs) to strengthen scientific justification and reduce uncertainty. A theoretical example is included to illustrate these steps. Overall, the presentation highlights the importance of clarity, consistency, and scientific rigor in applying read-across, promoting its use as a robust tool to fill data gaps and support safety evaluations in the food and feed chain. Finally, the presentation outlines EFSA's activities to support implementation, including training and advisory services."

The Network Chair welcomed the finalisation of the cross-cutting guidance. Read-across is regularly used by applicants in the dossiers submitted for the

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

assessment of substances intended to be used in plastics. This requires a clear and harmonised Guidance. He encouraged the Network participants to read, share and promote the use of the Guidance notably to support harmonisation in that area.

33. 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 and proposed potential follow-up activities.

No major changes were observed with regards to the previous meetings regarding **cooperation** on risk assessment activities and harmonisation of risk assessment methodologies and substances. **Topics are well identified**, and the question is more how to progress on the cooperation and harmonisation of the related risk assessment. Cooperation is acknowledged to be essential. The topics are listed below.

1. A significant part of the meeting was dedicated to the assessment of **paper and boards**. The implementation of the EFSA technical report on natural compounds (2023) to P&B, their manufacture, migratables and assessment were presented and discussed, including the views from CITPA/CEFIC. Understanding must continue, notably with the considerations highlighted during the meeting and the sharing of data and information (such as examples of practical assessments and if possible dossiers on P&B materials and articles). This topic has currently no leader.
2. 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 by a **database of their mass spectra**. EC JRC clarified that it is not working on such a database that would requires considerable standardisation efforts. The shared European database of substances, IAS and NIAS, evaluated at EU and national levels must still be addressed. **Belgium** leads this activity.
3. The assessment of **NIAS** is being harmonised and related **multi-analytes screening analysis** are under permanent developing. In addition to GC-MS, screening methods with LC-MS are increasinly used routinely to complete the knowledge gap. Still, there are obstacles due to the lack of mass spectra libraries for LC-MS (cf. 2.), the scarcity of analytical standards on the market and the use of different analytical methodologies resulting in data of different quality. **Germany** leads the activity on the assessment of NIAS and reported on the comments received from stakeholders to their draft concept. This activity aligns generally to the EFSA Note for Guidance; however, several differences must be addressed.
4. No significant progress was made on **rubber/elastomers** and so no update was deemed necessary. It is crucial to agree on the methodology (tiered approach) and the migration testing in their details, so it is

harmonised. This activity is led by **France** in close collaboration with Germany and with the participation of The Netherlands to move from collaboration to harmonisation. Member States were invited in 2024 to share any list from legislation in order to ensure mutual acceptance. Lists were received from SP, IT, NL and DE. The work is ongoing.

5. The safety assessment of **biobased articles** stays of common interest. Member States will continue reporting their ongoing activities at the next meeting. In case of safety assessment, it is 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.
6. In addition to these five already identified topics, the possible use of bioassays and New Approach Methodologies (NAMs) was mentioned. The discussion should continue at the next meeting to define the frame (IAS, NIAS, mixture, etc.).

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

34. 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.

The Next Network meeting is scheduled to be held on **20-22/10/2026**. MS representatives are recommended to note the dates in their calendar.