

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS (FCM)

6th FCM Panel Plenary meeting – OPEN to observers

18-20 March 2025

14:00-19:00 / 09:00-17:00 / 09:00-13:00

MINUTES (Agreed on 01 April 2025)



Location: EFSA, Parma / Teleconference

Attendees:

- FCM Panel Members:
Riccardo Crebelli, Maria da Silva, Konrad Grob, Claude Lambré (Chair), Evgenia Lampi, Maria Rosaria Milana (vice Chair), Marja Pronk, Gilles Rivière, Mario Ščetar, Georgios Theodoridis, Nadia Waegeneers
- European Commission: Bastiaan Schupp, Jonathan Briggs, Sabine Pelsser, Dielleza Gashi, Clelia Antico, Martinus Nagtzaam
- Hearing experts: Emma Di Consiglio, Claudia Bolognesi
- EFSA:
Food Ingredients and Packaging (FIP) Unit: Zainab Al Harraq, Eric Barthélémy, Roberta Bazzacco, Cristina Croera, Valeriu-Georghe Curtui, Marta Gallicet, Blanka Halamoda-Kenzaoui, Thomas Hemy-Dumas, Alexandros Lioupis, Remigio Marano, Sandra Rainieri, Vasiliki Sfika, Emmanouil Tsochatzis, Katharina Volk.

CLOSED SESSION

1. Welcome and apologies for absence

The Chair welcomed the participants and thanked them for their commitment towards EFSA. Apologies were received from Els Van Hoeck who did not participate to the Plenary meeting.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 5th Panel Plenary meeting held on 28 to 29 January 2025

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



The [minutes of the 5th FCM Panel meeting](#) were agreed by written procedure on 7 February 2025.

5. Report on written procedure

None.

6. Scientific topics for information/discussion

6.1. Application for the authorisation of N,N'-(2-)-4-(2-aminobenzamido) butyl)pentane-1,5-diyl)bis(2-aminobenzamide) as a new substance to be used in plastic for food contact uses ([EFSA-Q-2023-00721](#))

The FCM Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

OPEN SESSION

a. Welcome to observers

The Chair welcomed the observers and explained to the observers the structure of the Scientific Panels and Committee, the workflow of the safety assessment of regulated products, and gave an overview of the registered observers' affiliation and geographic distribution.

b. Presentation of Guidelines for observers

The FCM Panel coordinator introduced the rules for observers to be followed during and after the open Plenary meeting as well as some tips for the smooth running of the virtual meeting, including the rules on recording and transcribing the meeting. Observers were given the possibility to send questions when submitting their registration and these questions would be answered in a dedicated session at the meeting. Observers were also informed about the opportunity to submit additional questions during the meeting through the dedicated channel.

6.2. Re-assessment of the risks to public health related to the presence of styrene in plastic materials and articles intended to come into contact with food ([EFSA-Q-2023-00365](#))

The FCM Panel was presented with the results of the public consultation on the EFSA draft opinion that terminated on 28 January 2025. The Panel discussed the responses to the comments received and the changes made to the draft opinion as a result of some of the comments. The opinion was unanimously endorsed, subject to the incorporation of changes as suggested during the meeting and editorial changes. The adoption is pending further clarification between EFSA and the Dutch Health Council that recently addressed the classification for hazardous properties of styrene in the context of occupational setting.



6.3. Request to update the “Guidance on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin” ([EFSA-Q-2024-00020](#))

The FCM Panel was presented with the results of the public consultation that terminated on 5 February 2025.

7. Feedback from the Scientific Committee/ Scientific Panels/ EFSA/ EC

7.1. Feedback from Scientific Committee

The Chair reported the main points discussed during the 123rd Scientific Committee Plenary, held from 19 to 20 February in Parma.

7.2. Feedback from EFSA

7.2.1 Safety assessment of substances present in FCM intended for use in foods for infants

The potential application of the “Guidance on the risk assessment of substances in food intended for infants below 16 weeks of age” (EFSA Scientific Committee, 2017) to the assessment of food contact materials was presented to the Panel.

7.3. Feedback from WGs

7.3.1 FCM WG on Food Contact Materials

The major achievements, ongoing work and future challenges of the WG were presented to the Panel. The progress on dossier evaluation is recorded in [the minutes of the WG](#).

7.3.2 FCM WG on Recycling Plastic

The major achievements, ongoing work and future challenges of the WG were presented to the Panel. The progress on dossier evaluation is recorded in the [minutes of the WG](#).

7.3.3 FCM WG on Extraction Solvents

The major achievements, ongoing work and future challenges of the WG were presented to the Panel. The progress on dossier evaluation is recorded in the [minutes of the WG](#).

7.3.5 FCM WG on Preparation for re-evaluation of phthalates, structurally similar substances and replacement substances

The major achievements, ongoing work and future challenges of the WG were presented to the Panel. The progress on the work is recorded in the [minutes of the WG](#).

8. Questions from and answers to Observers (in application of the guidelines for Observers)

The following questions were collected from the online registration form, and answered by EFSA during the plenary meeting.



No	Question and Answer
1.	<p>Q: Has it been assessed whether the current Migration Limit for Styrene is safe?</p> <p>A: There is no restriction measure or a Specific Migration Limit (SML) currently established for the use of styrene in FCMs. The EC mandated EFSA to assess whether styrene is genotoxic in FCMs up to a provisional SML of 40 µg/kg food. EFSA concluded that there is no scientific evidence that styrene is genotoxic following oral exposure up to that SML. The scientific opinion is submitted today for discussion and possible adoption by the EFSA FCM Panel.</p>
2.	<p>Q: Do we need to test extractable and leachable test in food?</p> <p>A: Please refer to EU Regulation 10/2011 on plastics, in particular Art. 18 on rules for assessing compliance with migration limits. Please note Art. 18(2) stating "For materials and articles not yet in contact with food verification of compliance with specific migration limits shall be carried out in food or in food simulants set out in Annex III in accordance with the rules set out in Chapter 2, Section 2.1 of Annex V" and Art. 18(6) stating "The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches".</p>
3.	<p>Q: Could the hazards of recycled plastic become a future problem when it comes in contact with food?</p> <p>A: In order to address environmental concerns related to plastic waste, the European strategy for plastics in a circular economy has set specific goals for the increase of the use of recycled plastic, including in food contact applications. To this end, the Commission produced Regulation (EU) 2022/1616, which sets the rules for the risk management of different types of recycling and different types of plastics intended to be used for contact with food. EFSA performs risk assessment of such recycling processes and provides its scientific advice to the Commission and Member States. Recycling applications may receive positive, inconclusive or negative evaluations from EFSA, depending on whether it is demonstrated that these processes produce recycled plastic that is of no safety concern to the consumer. Future developments and challenges related to the increase of recycling of plastic FCM will be addressed by EFSA and the Commission under the current regulatory framework.</p>
4.	<p>Q: Safety assessment in FCM intended for use in food for infants - We request that the risk assessment include the obligation to use rPET in beverage and natural mineral water packaging, including "water suitable for preparing baby food" according to Directive 2009/54/EC and national regulations. In order to reduce the risk and increase the safety of packaging for infant food, it is necessary to abandon the obligation to use rPET in packaging for infant and child food, taking into account: NIAS, up to 5% non-food material addition in recycling (2022/1616/EC), possibility of genotoxicity, non-EU origin of rPET (lack of consistency between EU and non-EU FCM regulations), lack of harmonise analytical techniques for contaminants quantification.</p>



	<p>A: EFSA has recently produced its Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food (https://doi.org/10.2903/j.efsa.2024.8879). The criteria set allow to assess whether the migration of a potential unknown contaminant from rPET into food exceeds a level of dietary exposure below which the risk to human health would be negligible. The exposure scenario for infants consuming water and baby bottle contents - such as reconstituted milk formula - has been specifically considered in the abovementioned Guidance document. It should also be noted that, in European legislation, there is no "obligation to use rPET in packaging for infant and child food".</p>
5.	<p>Q: When will EU food safety authorities allow Nannochloropsis gaditana to be used as food or dietary supplements?</p> <p>A: This question is out of the remit of the FCM Panel. In any case, please note that EFSA does not authorise foods or food supplements, but performs risk assessment on the basis of dossiers submitted. This topic is under the remit of the Panel on Nutrition, Novel Foods and Food Allergens.</p>

The following questions were collected through the dedicated channel of the open session and answered by EFSA during the plenary meeting.

No	Questions and Answers
6.	<p>Q: Will the new appendix regarding the DHC discussion be open to further public comment, as there are some scientifically debatable points in this text?</p> <p>A: The Public consultation for the EFSA draft opinion was concluded on 28 January 2025. As the text related to DHC was prepared afterwards, it will not be available for further consultation with the public.</p>
7a.	<p>Q: Regulation 10/2011/EC refers to "Infant and young children" as defined by Directive 2006/125/EC.</p> <p>As per that directive, 'Infants' means children under the age of 12 months.</p> <p>"Infant below the age of 16 weeks" is a subgroup of "Infant" as defined by Directive 2006/125/EC.</p> <p>What is the reason for addressing only the subgroup? will there be an effect on Regulation 10/2011?</p>
7b	<p>Q: When EFSA refers to "infant food" (as for example in point 7.1 of today's agenda), is EFSA referring to children below 16 weeks or to the definition of infant as per Regulation 609/2013?</p> <p>A: EFSA Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age identifies this sub-population and explains the reasons for considering this sub-population (e.g. nutrition habits up to that age, specific toxicokinetics, organ developments). Infants as a population group should be considered as reported in the EFSA CEF Opinion 2016.</p> <p>Possible effects on the Regulations are restrictions.</p>



No	Questions and Answers
8.	<p>Q: Will the WG on Default Values work also on the topic of surface-to-volume ratios to use for FCMs? This was a highly discussed topic during the last amendment to Regulation 10/2011</p> <p>A: We understand this refers to compliance testing. Regarding risk assessment, please consult EFSA CEF Panel Opinion on Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials (2016), especially section 6.2.2. There, it is explained why the default value of 6 dm²/kg food is still an appropriate conversion factor to represent the surface to mass ratio of packaged foodstuffs in the context of applications.</p>

CLOSED SESSION

9. Feedback from European Commission

Regulations relative to FCM were presented to the Panel and discussed.

10. New mandates

1. New questions received: 1

Food Sector	EFSA-Q-Number	Subject	Reception date
FCM	EFSA-Q-2025-00164	Application for the extension of use of the substance phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly [oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters to be used in plastic for food contact uses	24-Feb-2025

2. Valid questions: 1

Food Sector	EFSA-Q-Number	Subject	Validity date
FCM	EFSA-Q-2024-00536	Application for the authorisation of potassium salicylate as a new substance to be used in plastic for food contact uses	31-Jan-2025

3. Withdrawn questions: None

9. AoB

The next FCM Panel meeting will take place online, on 21 May 2025.



Annex I: List of Observers

Online:

151 observers registered, 72 attended

Observer	Organization
Afghan Abdul	Health Canada
Aldasheva Nariné	Fleishman Hillard
Andreotti Grazia	Polynt SpA
Azens Jean-Jacques	Carton Ondulé de France and Association Club MCAS - Member of CEFIC food contact
Bankoglu Eylül	German Federal Institute for Risk Assessment
Braido Lusso Anna	
Bravo Lobo David	
Bronson Roni	Health Canada
BUSTOS JUANA	Spanish Agency for Food Safety and Nutrition
Cisneros Miluska	Chelab
Colombo Gianluca	
Dawkins Gordon	Plastics Europe
de Oude Wim	Eastman Chemical Company
Eisert Ralf	BASF
Fontán Vela Julia	CIBERESP
Genovese Jessica	DNV
Gibbons Daire	Anses
Guzatto Rafael	Videolar-Innova S/A
Hajjar Kalila	FEDIOL
Hamarneh Asal	AOC

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Hartmann Georg	WACKER CHEMIE AG
Haskan Artman Fatma	KT-ALCHEMY
Heath Ester	Jožef Stefan Institute
Herranz Nuria	Nuria Herranz Solana
Hoppe Maria	BASF SE
Islam Md Mazedul	Mosa Meat
Jaramillo Garcia Javier	Dow Chemical Ibérica S.L.
Johansson Caisa	Billerud AB
Joosen Rob	ExxonMobil
Joppen Sara	Alberdingk Boley GmbH
Kelly Craig	ACRE Consultancy
Kontonikola Katerina	Alpha Plan
Kurtek Pisanski Sanja	Molson Coors Beverage Company
Kurti Alesia	
La Grutta Francesco Paolo	
Lalić Anita	University of Mostar
Lamberti Alma	Plastics Europe
Lasimon Yohanes	Universita Cattolica del Sacro Cuore
Lee Sooryeon	Braskem Europe
Lindner Sabine	Plastics Europe
Lingqi Kong	Kraton
Luan Fang	German Association for Plastics Packagings and Films
Lunde Ingeborg	ADS Insight
Mahdiani Maryam	Tetra Pak

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Maidra Marian	Agriculture and Food Board
Martin Ana	Cefic
Marzolla Roberta	Basell Poliolefine Italia Srl
Massardo Nicolas	PETFUTURES SARL
Meiszner Agnes	HACO AG
Mendez Paula	MosaMeat
Michalak Michal	Berry Supefos
Mostardini Francesca	Francesca.Mostardini
Neto Leandra	BRASMAR
Nigdeli Yuksel Deniz	H&M Puls
Operato Luigi	DNV Business Assurance Italy S.r.l.
Rovida Costanza	ecopa
Ruckman Stephen	TSG Consulting Ltd
Schmahl Pascal	Cefic
Schmidt Natalie	INEOS Styrolution Group GmbH
Scholten Arend-Jan	Covestro
Sguazzin Alessia	
Simenon Maurice	SABIC Europe BV
Slimani Kahina	Anses
Sobocińska Maria	Nałęczów Zdrój sp. z o.o.
Stadler Nicolas	Südpack
Sui Haixia	China national center for food safety risk assessment
Taglieber Andreas	Zott SE & Co. KG
Tańska Izabela	IGI FOOD LAW

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van der Slot Saskia	Covestro
Wittenberg Nils	INEOS Styrolution Group GmbH
Woods Bethany	BASF
Wylin Franky	Plastics Europe