

51st Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement substances
13 October 2025
09:00-18:00
MINUTES - Agreed on 28 October 2025

Location: EFSA - Parma (Meeting Room 04/B14)/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Marcel Mengelers, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers, Keyvin Darney
- Hearing Experts¹:
Not Applicable
- Applicants participating in a technical hearing²:
Not Applicable
- ECHA :
Stefano Frattini, Michaela Lucas, Niko Hellsten, Virpi Vaananen
- EFSA:
FIP Unit: Marta Gallicet, Blanka Halamoda, Katharina Volk (chair)
MESE Unit: Bruno Dujardin, Francesca Riolo, Laura Martino
- Others:
Violetta Costanzo as data entry analysis support to dietary exposure assessment of chemicals, nutrients and food ingredients contractor

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jean-Lou Dorne (CSO Team).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No conflicts of interest related to the issues discussed in this meeting have been identified during the screening

¹ As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups":
<https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf>

² As defined in the "EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products":
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6472>

³ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

⁴ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf



process, and no interests were declared orally by the Working Group members at the beginning of this meeting.

IV. Agreement of the minutes of the 50th Working Group meeting held on 09-10 September 2025, in Parma and via web-conference

The minutes of the 50th Working Group meeting were agreed by written procedure on 24 September 2025.

V. Feedback from the FCM Panel plenary meeting

Not applicable.

VI. Feedback from the European Commission

Not applicable.

VII. Update on applications, new mandates

Not applicable.

VIII. Scientific topic(s) for discussion

The working group (WG) was presented with an overview of the cleaned data from the Plasticisers_FCM data collection, showing the number of positive results by substance, FCM material, and format for compositional and migration data. In addition, a summary of information retrieved from different data sources was presented, with the aim of identifying in which FCMs the prioritised substances under study occur and what are the possible sources of their presence. Furthermore, the use conditions and food chain steps where FCMs are applied were reviewed, and the current FCM–food mapping was presented and discussed.

An update on the availability of occurrence data from the ChemMon data collection was given to the WG and the need for some clarifications were identified in relation to the food packaging.

Furthermore, the WG was updated on the progress of the work on non-dietary exposure estimation, and the need to verify which information can be disseminated, due to confidentiality issues, was highlighted.

Summary tables providing an overview of the HBM data were presented to the WG, and a preliminary discussion was held to identify data gaps related to overall exposure, also considering the information necessary for the conversion of metabolite concentrations into the exposure to parental compounds.

The next steps were agreed, and tasks were distributed.



IX. Any Other Business

Not applicable.

X. Preparatory Meeting/s

Not applicable.

XI. Next meeting

The next WG meeting will be held on the 2-3 December 2025, via teleconference.

50th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement substances
09-10 September 2025
09:00-18:00 / 09:00-13.00
MINUTES - Agreed on 24 September 2025

Location: EFSA - Parma (Meeting Rooms 04/BOW, M06/B, 00/M04)/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Marcel Mengelers, Maria de Fatima Tavares Poças, Roland Franz¹, Nadia Waegeneers, Keyvin Darney¹
- Hearing Experts²:
Not Applicable
- Applicants participating in a technical hearing³:
Not Applicable
- European Commission and/or Member States representatives:
EC – DG SANTE: Jonathan Briggs
- ECHA :
Stefano Frattini, Michaela Lucas, Niko Hellsten
- EFSA:
FIP Unit: Sandra Rainieri, Marta Gallicet, Blanka Halamoda, Katharina Volk (chair), Pauline Le Gall
MESE Unit: Bruno Dujardin, Francesca Riolo, Laura Martino
CSO Team: Jean-Lou Dorne
- Others:
Gouda Bubnyte as data entry analysis support to dietary exposure assessment of chemicals, nutrients and food ingredients contractor

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Virpi Vaananen (ECHA).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No conflicts of interest

¹ Participated via teleconference

² As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups":
<https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf>

³ As defined in the "EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products":
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6472>

⁴ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

⁵ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf



related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the Working Group members at the beginning of this meeting.

IV. Agreement of the minutes of the 49th Working Group meeting held on 08 July 2025, via web-conference

The minutes of the 49th Working Group meeting were agreed by written procedure on 23 July 2025.

V. Feedback from the FCM Panel plenary meeting

Not applicable.

VI. Feedback from the European Commission

Not applicable.

VII. Update on applications, new mandates

Not applicable.

VIII. Scientific topic(s) for discussion

An overview of the cleaned compositional and migration data related to FCMs and collected via data collections was provided to the Working Group (WG). An initial comparison between compositional and migration data was carried out, with the aim of assessing the level of consistency between the two datasets. In addition to data collections, data extracted from literature on the migration and occurrence of plasticisers in FCM were presented.

The WG made initial considerations on the methodological steps needed to address the questions and sub-questions defined in the exposure assessment protocol, in relation to the contribution from FCMs.

An update on non-dietary exposure information, collected from the REACH database and extracted from the literature, was provided, highlighting the gaps in certain areas of exposure, including the dermal and oral exposure.

Furthermore, the WG was presented with an overview of the human biomonitoring (HBM) data on plasticisers, either available in the IPCHEM database or extracted from the scientific literature. The sufficiency and relevance of data were discussed and agreed upon.

Finally, a discussion was held on the methodological approaches that could be used to calculate overall exposure to the plasticisers, starting from the available HBM data related to their metabolites. The available PBK models and the TKPlate platform were presented to the WG.

The next steps were agreed, and tasks were distributed.

IX. Any Other Business



Not applicable.

X. Preparatory Meeting/s

Not applicable.

XI. Not applicable. Next meeting

The next WG meeting will be held on the 13th October 2025, via teleconference.

49th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement substances

08 July 2025

09:00-16:00

MINUTES - Agreed on 23 July 2025

Location: EFSA - Parma (Meeting Room 00/M04)/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Marcel Mengelers, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers
- Hearing Experts¹:
Not Applicable
- Applicants participating in a technical hearing²:
Not Applicable
- European Commission and/or Member States representatives:
EC – DG SANTE: Diellëza Gashi
- ECHA :
Stefano Frattini, Michaela Lucas
- EFSA:
FIP Unit: Marta Gallicet, Blanka Halamoda, Katharina Volk (chair), Pauline Le Gall
MESE Unit: Bruno Dujardin
- Others:
Gouda Bubnyte as data entry analysis support to dietary exposure assessment of chemicals,
nutrients and food ingredients contractor

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 Working Group members at the beginning of this meeting.

¹ As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups":
<https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf>

² As defined in the "EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products":
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6472>

³ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

⁴ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf



IV. Agreement of the minutes of the 48th Working Group meeting held on 23 June 2025, via web-conference

The minutes of the 48th Working Group meeting were agreed by written procedure on 4 July 2025.

V. Feedback from the FCM Panel plenary meeting

Not applicable.

VI. Feedback from the European Commission

Not applicable.

VII. Update on applications, new mandates

Not applicable.

VIII. Scientific topic(s) for discussion

The working group (WG) discussed the actions to be undertaken to continue the data cleaning procedure for the Plasticizers FCM_data. A recap of the decisions regarding the S/V ratios was provided, and overviews of the cleaned data were presented. At this stage of the data cleaning process, the main challenge is to harmonize all the data and group them into categories that enable meaningful comparison and analysis. Consequently, some considerations regarding specific entries were brought to the WG's attention to reach an agreement on the most appropriate terms to use for harmonisation. Afterwards, a discussion was held on the best way to summarise the data.

In addition, the meeting focused on data extraction from the literature, and the current status of the work was presented. The templates for basic data extraction (for the prioritized substances) and the information for detailed data extraction (for the pilot substance selected for the exposure assessment) were discussed, based on the feedback provided by the experts. Moreover, some examples of results generated by automated data extraction were presented to the WG.

The next steps were agreed, and tasks were distributed.

IX. Any Other Business

Not applicable.

X. Preparatory Meeting/s

Not applicable.

XI. Next meeting

MEETING MINUTES – 08 July 2025

49th Working Group meeting on Preparation for re-evaluation
of phthalates, structurally similar substances and replacement substances



The next WG meeting will be held on the 9-10th September 2025, as a physical WG meeting in Parma.

48th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances

23 June 2025, 09:00-16:00

MINUTES - Agreed on 4 July 2025

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Marcel Mengelers, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers
- EFSA:
FIP Unit: Marta Gallicet, Blanka Halamoda, Katharina Volk (chair)
MESE Unit: Guoda Bubnyte, Bruno Dujardin, Arnaud Molle
- European Commission:
Diellëza Gashi
- ECHA :
Niko Hellsten, Stefano Frattini, Michaela Lucas, Eleni Tsitsiou, Virpi Vaananen

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Claudia Cascio (MESE) and Jonathan Briggs (European Commission).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Agreement of the minutes of the 47th Working Group meeting held on 23 May 2025, via web-conference

The minutes of the 47th Working Group meeting were agreed on 12 June 2025.

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

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



V. Feedback from the FCM Panel plenary meeting

Not applicable.

VI. Feedback from the European Commission

Not applicable.

VII. Scientific topic(s) for discussion

An overview of surface-to-volume (S/V) ratios available for each food category and related food contact format and material was presented to the Working Group (WG). These parameters are necessary to convert the results reported by data providers (DP) in mg/dm² into mg/kg food. A discussion on the suitability of the values was held, and new values were proposed and agreed upon for those results that are reported in mg/dm².

Subsequently, the latest responses received from DPs following clarification requests related to the Plasticisers_FCM data collection were presented to the WG, and the results were accepted.

The experts provided their feedback on the plots representing the LODs/LOQs related to data reported in the Chemical Monitoring data collection. General observations were made and issues that require clarification from DPs were identified

Regarding the literature review, the current status of the work was presented, and the conflicting papers were discussed and resolved.

Moreover, proposals for templates for data extraction were presented to the WG. Experts provided feedback, and minor adjustments were agreed upon. The discussion will be continued at a forthcoming meeting.

The next steps were agreed, and tasks were distributed.

VIII. Any Other Business

Not applicable.

IX. Update on applications, new mandates

Not applicable.

X. Next meeting

The next WG meeting will be held on the 8th July 2025, via teleconference.

47th Working Group meeting on Preparation for re-evaluation of phthalates, structurally similar substances and replacement substances

23 May 2025, 09:00-12:00

MINUTES - Agreed on 12 June 2025

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers
- EFSA:
FIP Unit: Marta Gallicet, Blanka Halamoda, Katharina Volk (chair)
MESE Unit: Guoda Bubnyte, Bruno Dujardin, Arnaud Molle
- European Commission:
Diellëza Gashi

I. Welcome and apologies for absence

The Chair welcomed the participants and introduced the participants from the MESE Unit: Bruno Dujardin and Arnaud Molle. Apologies were received from Claudia Cascio (MESE) and Jonathan Briggs (European Commission - DG SANTE).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Agreement of the minutes of the 45th Working Group meeting held on 13-14 March 2025, via web-conference

The minutes of the 46th Working Group meeting were agreed on 14 May 2025.

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

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



V. Feedback from the FCM Panel plenary meeting

Not applicable.

VI. Feedback from the European Commission

Not applicable.

VII. Scientific topic(s) for discussion

The Working Group (WG) mainly focused on cleaning the collected data on plasticiser concentration and migration from food contact materials (FCMs). The results for which no decision had been recorded in previous meetings were reviewed. Subsequently, the data providers' (DPs) replies to clarification requests were presented to WG. Based on the previously established criteria, the data were ultimately either accepted or excluded.

A brief overview of the available surface-to-volume ratios of the measured samples, reported by DPs, was presented to the WG. These values are necessary to convert the results from mg/dm² to mg/kg food. The discussion regarding values to be applied for food/FCM categories where they are missing will be continued at the next WG meeting.

In addition, a short overview of the LOD/LOQ values related to data on occurrence in food from the Chemical Monitoring data collection was presented. Some general considerations were made and it was agreed to continue the discussion at the next WG meeting.

The next steps were agreed, and tasks were distributed.

VIII. Any Other Business

Not applicable.

IX. Update on applications, new mandates

Not applicable.

X. Next meeting

The next WG meeting will be held on the 23rd June 2025, via teleconference.

46th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances

28-29 April 2025, 14:00-18:00 / 09:00-18:00

MINUTES - Agreed on 14 May 2025

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers, Marcel Mengelers
- ECHA:
Niko Hellsten, Stefano Frattini, Michaela Lucas, Virpi Vaananen
- EFSA:
FIP Unit: Marta Gallicet, Blanka Halamoda, Katharina Volk (chair)
MESE Unit: Guoda Bubnyte, Claudia Cascio

I. Welcome and apologies for absence

The Chair welcomed the participants. Fatima Tavares Poças was absent for the entire Day 1, Nadia Wageeners from 15.00-18.00 of Day 1. Marcel Mengelers attended only Day 2 (14.00-18.00). Apologies were received from Laura Martino (MESE) and Diellëza Gashi (European Commission - DG SANTE).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Agreement of the minutes of the 45th Working Group meeting held on 13-14 March 2025, via web-conference

The minutes of the 45th Working Group meeting were agreed on 3 April 2025.

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

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



V. Feedback from the FCM Panel plenary meeting

Not applicable.

VI. Feedback from the European Commission

Not applicable.

VII. Scientific topic(s) for discussion

An update on the cleaning of the food data from the chemical monitoring data collection was presented to the working group (WG). The cleaning process focused on the analysed matrix and the identification of results to be excluded. The replies of data provider's (DP) to clarification requests were shown to WG and an overview of LODs and LOQs was presented. Further updates on the progress of the data cleaning will be provided at a forthcoming meeting.

The WG continued the discussion on the data from the data collection related to concentration and migration of plasticisers from food contact materials. Specific cases were discussed, and the replies already received from DP were presented and discussed. Decisions were made whether to exclude or include certain results, and cases requiring further clarification from data providers were identified.

In addition, ECHA presented an overview of information on use and exposure for the prioritised substances available in ECHA's database, and general considerations on the collected data were made.

Regarding the literature appraisal, the status of work was presented: the screening of the articles retrieved from the first literature search has now been completed and the results of the second search are prepared to be appraised.

The next steps were agreed and tasks were distributed.

VIII. Any Other Business

Not applicable.

IX. Update on applications, new mandates

Not applicable.

X. Next meeting

The next WG meeting will be held on the 23rd May 2025, via teleconference.

45th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances

13-14 March 2025, 09:00-18:00 / 09:00-13:00

MINUTES - Agreed on 3 April 2025

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers,
Marcel Mengelers
- ECHA:
Niko Hellsten
- EFSA:
FIP Unit: Marta Gallicet, Blanka Halamoda, Katharina Volk (chair)
MESE Unit: Guoda Bubnyte, Claudia Cascio
- European Commission:
Jonathan Briggs, Diellëza Gashi

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Stefano Frattini, Eleni Tsitsiou and Michaela Lucas (ECHA).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

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

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



IV. Agreement of the minutes of the 44th Working Group meeting held on 17-18 February 2025, via web-conference

The minutes of the 44th Working Group meeting were agreed on 5 March 2025.

V. Feedback from the FCM Panel plenary meeting

Not applicable.

VI. Feedback from the European Commission

Not applicable.

VII. Scientific topic(s) for discussion

An overview on the progress of the literature appraisal was presented to the working group (WG): the papers are now being processed for a basic data extraction in Distiller and the experts provided their feedback on this activity and the related forms in the tool. Some criteria for studies evaluation and implementations to be made to the tool were discussed and agreed.

Besides, some specific cases of conflict in the full-text screening were presented to the WG and resolved after discussion.

A proposal for information to be extracted from the papers identified as relevant was discussed. Templates to capture information on dietary and non-dietary exposure were presented to the WG and some initial considerations were made. The discussion will be continued at a forthcoming meeting.

Moreover, a proposal for substance classification, based on the quantity and type of data retrieved from both literature and data collections, was presented to the WG. This categorisation will help determine which substances to focus on for data extraction, provide an overview of the data gaps, and identify the substance for the pilot assessment.

In addition, the WG discussed the evaluation of the data received from data collections related to composition and migration of plasticisers from food contact materials. Based on the experts' feedback regarding the cleaning of the data, some common issues and specific cases were discussed. Decisions were made whether to exclude or include certain results, and cases requiring further clarification from data providers were identified.

The next steps were agreed and tasks were distributed.



VIII. Any Other Business

Not applicable.

IX. Update on applications, new mandates

Not applicable.

X. Next meeting

The next WG meeting will be held on the 28-29th April 2025, via teleconference.

44th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances

17-18 February 2025, 14:00-18:00 / 09:00-18:00

MINUTES - Agreed on 5 March 2025

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers, Marcel Mengelers
- ECHA:
Niko Hellsten, Stefano Frattini, Eleni Tsitsiou
- EFSA:
FIP Unit: Marta Gallicet, Blanka Halamoda, Katharina Volk (chair)
MESE Unit: Guoda Bubnyte, Claudia Cascio
- European Commission:
Jonathan Briggs

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Laura Martino (MESE) and Michaela Lucas (ECHA).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Feedback from the European Commission

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

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



Not applicable.

V. Scientific topic(s) for discussion

The Working Group (WG) discussed the evaluation of the data received from data collections related to migration of plasticisers from food contact materials. Based on the experts' feedback regarding the cleaning of the data, some common issues and specific cases were discussed. Decisions were made whether to exclude or include certain results, and cases requiring further clarification from data providers were identified.

An overview of the data on occurrence of plasticisers in food, collected via EFSA's annual collection of chemical monitoring data (ChemMon) was provided, and matters related to the initial data cleaning steps were discussed.

Regarding the literature review, observations related to the assessment of papers in Distiller were given and discussed with the experts. Besides, few further changes to be made to the tool were highlighted and agreed. Finally, some cases of conflicts between two reviewers in Distiller were presented to the WG and resolved after discussion.

The next steps were agreed and tasks were distributed.

VI. Any Other Business

Not applicable.

VII. Next meeting

The next WG meeting will be held on the 13-14th March 2025.

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS (FCM)

43rd Working Group meeting on Preparation for re-evaluation of phthalates, structurally similar substances and replacement substances



20 January 2025, 09:00-18:00
MINUTES - Agreed on 5 February 2025

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers, Marcel Mengelers
- ECHA:
Niko Hellsten, Stefano Frattini, Michaela Lucas, Eleni Tsitsiou
- EFSA:
FIP Unit: Marta Gallicet, Blanka Halamoda, Katharina Volk (chair)
MESE Unit: Guoda Bubnyte, Claudia Cascio, Laura Martino
- European Commission:
Jonathan Briggs

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.
The two new colleagues from ECHA who will follow the work of the Working Group — Michaela Lucas and Eleni Tsitsiou — introduced themselves and provided a brief overview of their backgrounds.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Agreement of the minutes of the 43rd Working Group meeting held on 20 January 2025, via web-conference

The minutes of the 43rd Working Group meeting were agreed on 5 February 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



V. Feedback from the European Commission

Not applicable.

VI. Scientific topics for discussion

The Working Group (WG) was informed that a new mandate (EFSA-Q-2025-00018³) from the European Commission was received in December 2024. EFSA, in collaboration with ECHA, is requested to produce a technical report related to consolidation of exposure data (e.g. literature as well as data collections) and related to the three steps laid down in the protocol for exposure assessment⁴ (i.e. dietary exposure, dietary exposure from FCMs, overall exposure). An overview of the tasks and deadlines was provided to the WG members.

The evaluation of data received in data collections related to migration of plasticisers from food contact materials was discussed. The WG was informed about feedback from data providers on clarification requests and agreed on specific cases that require further clarification from data providers. Decisions on derivation of new values for certain variables and exclusion of records were made, based on pre-established criteria.

Regarding the literature appraisal, the upgrade implemented in Distiller after the last WG meeting was presented to the experts. Final changes to be made to the assessment forms were discussed and agreed.

VII. Any Other Business

Not applicable.

VIII. Next meeting

The next meeting will be held on 17-18 February 2025, via web conference.

³ <https://open.efsa.europa.eu/questions/EFSA-Q-2025-00018>

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2022.EN-7288>

42nd Working Group meeting on Preparation for re-evaluation of phthalates, structurally similar substances and replacement substances

09 December 2024, 09:00-13:00

MINUTES - Agreed on 20 December 2024

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers, Marcel Mengelers
- ECHA:
Niko Hellsten
- EFSA:
FIP Unit: Marta Gallicet, Julia Fontán Vela, Blanka Halamoda, Katharina Volk (chair)
MESE Unit: Claudia Cascio

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.
The Working Group held a tour de table, introducing Marcel Mengelers as a new member of the WG's subgroup on exposure.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Feedback from the European Commission

Not applicable.

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



V. Scientific topic(s) for discussion

The WG discussed the literature appraisal trial performed by the experts in Distiller, providing feedback on the screening tool and making decisions on the questions proposed according to the criteria previously agreed.

An overview of the data collections for food and FCM was given and the way forward for the data cleaning was further discussed.

VI. Any Other Business

Not applicable.

VII. Next meeting

The next WG meeting will be held on the 20th January 2025.

19 November 2024, 09:00-13:00
MINUTES - Agreed on 6 December 2024

Location: EFSA – Parma/Webconference

Attendees:

○ **Working Group members:**

Laurence Castle, Maria de Fatima Tavares Poças, Nadia Waegeneers

○ **ECHA:**

Niko Hellsten

○ **EFSA:**

FIP Unit: Marta Gallicet, Julia Fontán Vela, Blanka Halamoda, Katharina Volk (chair)

MESE Unit: Claudia Cascio, Laura Martino

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Roland Franz. The participants were informed that the expert Francesca Romana Mancini resigned from the Working Group.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Feedback from the European Commission

Not applicable.

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



V. Scientific topic for discussion

The meeting focused on discussing a literature appraisal trial performed by the experts. An agreement on the criteria both for the evaluation of the literature and the data coming from data collections was reached. Furthermore, considerations for the mapping exercise were concluded.

VI. Any Other Business

Not applicable.

VII. Next meeting

The next Working Group meeting will be held on 9 December 2024.

40th Working Group meeting on Preparation for re-evaluation of phthalates, structurally similar substances and replacement substances

29 October 2024, 09:00-18:00

MINUTES - Agreed on 13 November 2024

Location: EFSA – Parma/Web conference

Attendees:

- Working Group members:
Laurence Castle, Maria de Fatima Tavares Poças, Roland Franz, Nadia Waegeneers,
Francesca Romana Mancini
- ECHA:
Niko Hellsten
- EFSA:
FIP Unit: Julia Fontan Vela, Blanka Halamoda, Sandra Rainieri, Katharina Volk (chair)
MESE Unit: Guoda Bubnyte, Claudia Cascio

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

Certain interests were declared orally by one member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

IV. Feedback from the European Commission

Not applicable.

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



V. Scientific topic for discussion

The outcome of the data cleaning trial carried out by the experts was presented and the respective evaluations were discussed. Based on these discussions, the evaluation criteria were further refined. Moreover, the criteria for the critical appraisal of the scientific literature were discussed. An update on the activities related to the mapping of food categories was provided.

VI. Any Other Business

Not applicable.

VII. Next meeting

The next Working Group meeting will be held on 19th November 2024.



Annex

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Dr Roland Franz declared the following interest: since his retirement, he has had several one-year-contracts with his previous employer. In the context of this work, the expert is screening research programmes, drafting scientific publications and supervising theses. The contract got prolonged for another year, until 30 September 2025. In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS (FCM)

39th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement substances



5 September 2024

09:00-16:00

MINUTES - Agreed on 25 September 2024

Location: EFSA - Parma /Webconference

Attendees:

- Working Group Members:
Laurence Castle, Maria de Fatima Tavares Pogas, Roland Franz, Nadia Waegeneers
- Hearing Experts¹:
Not Applicable
- European Commission:
EC: Jonathan Briggs
- EFSA:
FIP Unit: Julia Fontan Vela, Blanka Halamoda, Sandra Rainieri, Katharina Volk (chair)
MESE Unit: Guoda Bubnyte, Claudia Cascio

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.
The Working Group held a tour de table, introducing the new Working Group member Nadia Waegeneers, who is also a member of the Food Contact Materials Panel.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management,² EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

Certain interests were declared orally by one member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

¹ As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>



IV. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

V. Scientific topic for discussion

A workflow approach for the usage of Food Contact Materials related data (i.e. migration and compositional data) was presented and discussed. Furthermore, criteria for cleaning these types of data were discussed and agreed. An overview of the progress made with respect to mapping food categories listed in Regulation (EU) 10/2011 versus FoodEx categories was given.

VI. Next meeting

The next Working Group meeting will be held on 29 October 2024 via web conference.



Annex

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting.

With regard to this meeting, Dr Roland Franz declared the following interest: since his retirement, he has had several one-year-contracts with his previous employer. In the context of this work, the expert is screening research programmes, drafting scientific publications and supervising theses. The contract got prolonged for another year, until 30 September 2025. In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management", and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

**38th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances**

12 April 2024, 09:00-13:00

MINUTES - Agreed on 30 April 2024

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle (chair), Maria de Fatima Tavares Poças, Roland Franz
- European Commission:
Jonathan Briggs, Martinus Nagtzaam
- ECHA:
Niko Hellsten
- EFSA:
FIP Unit: Blanka Halamoda, Sandra Rainieri, Katharina Volk
MESE Unit: Guoda Bubnyte, Claudia Cascio, Bruno Dujardin

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups 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 Working Group 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.

IV. Feedback from the European Commission

Not applicable.

V. Scientific topic(s) for discussion

The aim of the WG meeting was to discuss the collected data to understand if and how they can be used to address the questions 1 and 2 from the [Protocol for the exposure assessment](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf). Specific

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

MEETING MINUTES – 12 April 2024

38th Working Group meeting on Preparation for re-evaluation of phthalates, structurally similar substances and replacement substances



focus was placed on the food categories covered in relation to the full diet and on the process of estimation of exposure coming from food contact materials.

VI. Any Other Business

Not applicable

VII. Next meeting

The date of the next meeting has not yet been fixed.

**37th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances**

02 February 2024, 09:00-13:00

MINUTES - Agreed on 19 February 2024

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle (chair), Maria de Fatima Tavares Poças, Roland Franz
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- ECHA:
Niko Hellsten
- EFSA:
FIP Unit: Julia Fontán Vela, Blanka Halamoda, Sandra Rainieri, Katharina Volk
MESE Unit: Guoda Bubnyte, Claudia Cascio

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups 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 Working Group 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.

IV. Feedback from the European Commission

Not applicable.

V. Scientific topic(s) for discussion

Preparatory work for exposure assessment: discussion on results of calls for data

The WG discussed the outcome of the examination of data submitted in the 2022 and the 2023 Chemical Monitoring data collection and Plasticisers_FCM data collection (including both

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

MEETING MINUTES – 02 February 2024

37th Working Group meeting on Preparation for re-evaluation of phthalates, structurally similar substances and replacement substances



information on occurrence in FCMs and migration from FCMs) and concluded on a list of substances for which an exposure assessment could be feasible based on the submitted data.

The approach for data processing and cleaning in EFSA's risk assessments was presented. The WG discussed possible acceptance criteria for the data originated from the Plasticisers_FCM data collections.

An update on the status of the review of scientific papers was provided.

The next steps were agreed and tasks were distributed.

VI. Any Other Business

Not applicable

VII. Next meeting

The next meeting will be held on 12 April 2024, via web conference.

**36th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances**

11 December 2023, 09:00-13:00

MINUTES - Agreed on 2 January 2024

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle (chair), Maria de Fatima Tavares Poças, Roland Franz
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- ECHA:
Niko Hellsten
- EFSA:
FIP Unit: Julia Fontán Vela, Blanka Halamoda, Sandra Rainieri, Katharina Volk
MESE Unit: Guoda Bubnyte, Claudia Cascio

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups 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 Working Group 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.

IV. Feedback from the European Commission

Not applicable.

V. Scientific topic(s) for discussion

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



Preparatory work for exposure assessment: discussion on results of calls for data

An overview of data collected in the context of the 2023 Chemical Monitoring data collection was provided to the Working Group, including distribution of results over food categories, sampling strategies and quantitative vs qualitative data. It was noted that for the majority of substances, the results were left-censored, and that only for few substances quantitative data on occurrence in food were available.

An update on the work done to map the food categories established in Regulation (EU) No 10/2011 with the food categories of the EFSA comprehensive Food Consumption Database was provided.

The WG provided feedback on the examination of data submitted in the 2022 and the 2023 Plasticisers_FCM data collection (including both information on occurrence in FCMs and migration from FCMs). Also, for this data collection, a high number of left-censored data was noted. Based on the results from the data collections and taking into account information/data available from the literature, the WG drew up a list of substances for which an exposure assessment could be possible.

The next steps were agreed and tasks were distributed.

VI. Any Other Business

Not applicable

VII. Next meeting

The next meeting will be held on 2 February 2024, via web conference.

**35th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances**

28 August 2023, 14:00-16:00
MINUTES - Agreed on 07 September 2023

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle (chair), Maria de Fatima Tavares Poças
- Hearing Experts¹:
Roland Franz
- European Commission and/or Member States representatives:
Not applicable
- ECHA:
Evelin Fabjan
- EFSA:
FIP Unit: Blanka Halamoda, Katharina Volk
MESE Unit: Claudia Cascio

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (European Commission – DG SANTE).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Feedback from the European Commission

Not applicable.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topic(s) for discussion

a. Preparatory work for exposure assessment: discussion on results of calls for data

An overview of data collected in the context of the 2022 Chemical Monitoring data collection was provided to the Working Group, including distribution of results over food categories, sampling strategies and quantitative vs qualitative data. It was noted that for the majority of substances, the results were left-censored, and that only for few substances quantitative data on occurrence in food were available.

The WG provided feedback on the examination of data submitted in the 2022 Plasticisers_FCM data collection, including both information on occurrence in FCMs and migration from FCMs. Also, for this data collection, a high number of left-censored data was noted. The WG agreed on the next steps for further examining and compiling the results.

VI. Any Other Business

Not applicable

VII. Next meeting

A date for the next meeting has not yet been fixed.

**34th Working Group meeting on Preparation for re-evaluation of
phthalates, structurally similar substances and replacement
substances**

06 July 2023, 09:00-13:00

MINUTES - Agreed on 21 July 2023

Location: EFSA – Parma/Webconference

Attendees:

- Working Group Members:
Laurence Castle (chair), Maria de Fatima Tavares Poças
- Hearing Experts¹:
Roland Franz
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
FIP Unit: Blanka Halamoda, Katharina Volk
MESE Unit: Claudia Cascio

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (European Commission – DG SANTE) and Evelin Fabjan (ECHA).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

IV. Feedback from the European Commission

Not applicable.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



V. Scientific topic(s) for discussion

a. Preparatory work for exposure assessment: discussion on results of calls for data

An overview of data collected in the context of the 2022 Chemical Monitoring data collection and the Plasticisers_FCM data collection were provided to the Working Group. In addition, a summary of the results gathered through the extensive literature review on plasticisers (Calvano et al., 2023⁴) was presented. Substances of interest were those phthalates, structurally similar substances and replacement substances, that had been prioritised as part of the identification and prioritisation for risk assessment of substances potentially used as plasticisers in food contact materials (EFSA CEP Panel, 2022⁵).

Based on considerations made in the protocol for exposure assessment of substances potentially used as plasticisers in food contact materials (EFSA et al, 2023⁶), the WG discussed which aspects and parameters should be taken into account when evaluating the quality of the data. A preliminary examination of the data quality should be conducted, which will inform discussions related to part 2 of the mandate, i.e. actual risk assessment(s).

VI. Any Other Business

Not applicable

VII. Next meeting

The next meeting will be held on 28 August 2023 (pm), via web conference.

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2023.EN-7988>

⁵ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7231>

⁶ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2022.EN-7288>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 33RD MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for hazard assessment'

**Held on 12 September 2022,
by TELE-conference**

(Agreed on 15 September 2022)

Participants

■ Working Group Members:

Laurence Castle (Chair), Claudia Bolognesi, Emanuela Corsini, Riccardo Crebelli, Rex FitzGerald, Claude Lambré, Francesca Mancini, Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölflé

■ Hearing Experts¹:

Not applicable

■ European Commission and/or Member States representatives:

Not applicable

■ EFSA:

FIP Unit: Matilde Benedettini, Chantra Eskes, Sandra Rainieri, Katharina Volk

MESE Unit: Irene Munoz Guajardo

■ Others:

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

ECHA: Evelin Fabjan (AM)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (DG SANTE), Marios Georgiadis (MESE Unit) and Vessela Vitcheva (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 32nd Working Group meeting held on 12 July 2022, by TELE-conference.

The minutes of the 32nd Working Group meeting were agreed via written procedure on 27 July 2022.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – hazard assessment protocol (EFSA-Q-2021-00593)⁵

Following the closure of the public consultation on the draft protocol on hazard assessment, the Working Group discussed the comments received (comments published here <https://open.efsa.europa.eu/consultations/a0c7U00000194PGQAY?search=2021-00593>) and agreed on the responses to the comments. In addition, amendments in the draft protocol were discussed and agreed. The revised draft protocol will be scheduled for discussion and possible endorsement by the CEP Panel during its Plenary meeting in October 2022.

6. Next meeting(s)

No further WG meeting is currently foreseen.

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 32ND MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for hazard assessment'

**Held on 12 July 2022,
by TELE-conference**

(Agreed on 27 July 2022)

Participants

■ Working Group Members:

Laurence Castle¹ (Chair), Claudia Bolognesi, Emanuela Corsini, Rex FitzGerald, Claude Lambré, Francesca Mancini, Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölfle

■ Hearing Experts²:

Not applicable

■ European Commission and/or Member States representatives:

Jonathan Briggs (DG SANTE)

■ EFSA:

FIP Unit: Matilde Benedettini, Chantra Eskes, Katharina Volk

■ Others:

ECHA: Vessela Vitcheva (am only)

¹ Participated on-site at EFSA premises

² As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Irene Munoz Guajardo (MESE), Marios Georgiadis (MESE), Evelin Fabjan (ECHA) and Riccardo Crebelli.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management,⁴ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 31st Working Group meeting held on 26-27 April 2022, by TELE-conference.

The minutes of the 31st Working Group meeting were agreed at the end of the meeting on 26-27 April 2022; for those participants not present anymore at the end of the meeting agreement via written procedure was reached on 4 May 2022.⁵

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – hazard assessment protocol (EFSA-Q-2021-00593)⁶

Following the closure of the public consultation on the draft protocol on hazard assessment, the Working Group discussed the comments received (comments published here <https://open.efsa.europa.eu/consultations/a0c7U00000194PGQAY?search=2021-00593>). Answers to the comments were proposed and discussed, along with possible amendments in the draft protocol. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 12 September 2022 via tele-conference.

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁵ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁶ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 31ST MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for hazard assessment'

**Held on 26-27 April 2022,
by TELE-conference**

(Agreed on 4 May 2022)

Participants

■ Working Group Members:

Laurence Castle (Chair), Claudia Bolognesi (26/04), Emanuela Corsini, Riccardo Crebelli (26/04), Rex FitzGerald, Claude Lambré (26/04), Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölflé

■ Hearing Experts¹:

Not applicable

■ European Commission and/or Member States representatives:

Not applicable

■ EFSA:

FIP Unit: Matilde Benedettini, Chantra Eskes, Sandra Rainieri, Katharina Volk

MESE Unit: Marios Georgiadis (27/04), Irene Munoz Guajardo

■ Others:

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Francesca Mancini and Jonathan Briggs (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 30th Working Group meeting held on 28-29 March 2022, by TELE-conference.

The minutes of the 30th Working Group meeting were agreed at the end of the meeting on 28-29 March 2022; for two participants not present anymore at the end of the meeting agreement via written procedure was reached on 5 April 2022.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – hazard assessment protocol (EFSA-Q-2021-00593)⁵

The Working Group exchanged views regarding different sections of the draft hazard assessment protocol for which comments have been received by the CEP Panel. In addition, revised text dealing with the appraisal of genotoxicity studies as well as weight of evidence was discussed and agreed. The draft protocol will be presented to the CEP Panel at its next meeting for possible endorsement for public consultation. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 12 July 2022 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 30TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for hazard assessment'

**Held on 28-29 March 2022,
by TELE-conference**

(Agreed on 5 April 2022)

Participants

- Working Group Members:
Laurence Castle (Chair), Rex FitzGerald, Claude Lambré, Francesca Mancini (28/03), Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölflé
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
FIP Unit: Matilde Benedettini, Chantra Eskes, Katharina Volk (28/03)
MESE Unit: Marios Georgiadis, Irene Munoz Guajardo (29/03)
- Others:
ECHA: Evelin Fabjan (28/03 AM)

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Emanuela Corsini.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 29th Working Group meeting held on 1-2 March 2022, by TELE-conference.

The minutes of the 29th Working Group meeting were agreed at the end of the meeting on 1-2 March 2022; for two participants not present anymore at the end of the meeting agreement via written procedure was reached on 8 March 2022.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – hazard assessment protocol (EFSA-Q-2021-00593)⁵

A short presentation regarding the general feedback on the draft hazard assessment protocol from the discussions at the 27th CEP Panel meeting was provided to the Working Group (WG). The WG exchanged views on how to address the comments from the CEP Panel, and further developed sections of the draft hazard assessment protocol that had not yet been presented to the Panel (e.g. weight of evidence, uncertainty analysis). Tasks were distributed.

6. AOB

In view of the development of the protocol for hazard assessment, the need for additional expertise on genotoxicity was identified.

7. Next meeting(s)

The next meeting will take place on 26-27 April 2022 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 29TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroups 'prioritisation' and 'protocol for exposure assessment'

**Held on 1-2 March 2022,
by TELE-conference**

(Agreed on 1-2 March 2022)

Participants – prioritisation subgroup

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Jonathan Briggs
- EFSA:
FIP Unit: Matilde Benedettini, Sandra Rainieri, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Ronan Nicolas

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

Participants – exposure protocol subgroup

- Working Group Members:
Laurence Castle (Chair), Francesca Mancini, Maria de Fátima Tavares Poças
- Hearing Experts²:
Roland Franz
- European Commission and/or Member States representatives:
Jonathan Briggs
- EFSA:
FIP Unit: Matilde Benedettini, Katharina Volk
MESE Unit: Claudia Cascio, Giulio Di Piazza, Marios Georgiadis, Irene Munoz Guajardo
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Niko Hellsten

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management,⁴ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 28th Working Group meeting held on 21-22 February 2022, by TELE-conference.

The minutes of the 28th Working Group meeting were agreed at the end of the meeting on 22 February 2022 for some participants; for some participants not present anymore at the end of the meeting agreement via written procedure was reached on 28 February.⁵

² As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁵ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wq-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.2 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – identification and prioritisation of substances (EFSA-Q-2020-00725)⁶

Following the discussion on comments received, and the related attachments, from the public consultation (comments published here: <https://open.efsa.europa.eu/consultation/a0c1v00000J9TRLAA3>), the WG discussed and agreed on the answers previously elaborated, along with amendments in the draft opinion. In addition, an update to the feedback received from the Netherlands on nationally authorised substances was discussed. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel during its next Plenary meeting.

6.2. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – exposure assessment protocol (EFSA-Q-2021-00592)⁷

Following the closure of the public consultation of the draft protocol on exposure assessment, the WG discussed the comments received and the related attachments, if any (comments published here: <https://open.efsa.europa.eu/consultation/a0c1v00000J9Uz5AAF>). Answers to the comments were proposed, discussed and drafted, along with amendments in the draft protocol. The revised draft protocol will be scheduled for discussion and possible adoption by the CEP Panel during its next Plenary meeting.

The instructions for the FCM data model were discussed in the context of a consultation with Member States.

7. Next meeting(s)

The next meeting will take place on 28-29 March 2022 (hazard assessment protocol subgroup) via tele-conference (due to the Covid-19 restrictions).

⁶ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00592>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 28TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for hazard assessment'

**Held on 21-22 February 2022,
by TELE-conference**

(Agreed on 22 February 2022)

Participants

- Working Group Members:
Laurence Castle (Chair), Emanuela Corsini, Rex FitzGerald, Claude Lambré, Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölfle
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
FIP Unit: Matilde Benedettini, Chantra Eskes, Sandra Ranieri
MESE Unit: Marios Georgiadis, Irene Munoz Guajardo
- Others:
ECHA: Evelin Fabjan (21/02), Vessela Vitcheva (22/02)

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (DG SANTE) and Katharina Volk (FIP Unit).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 27th Working Group meeting held on 7-9 February 2022, by TELE-conference.

The minutes of the 27th Working Group meeting were agreed at the end of the meeting on 9 February 2022; for one participant not present anymore at the end of the meeting agreement via written procedure was reached on 11 February 2022.⁴

5. Scientific topic(s) for discussion

5.1. **Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – hazard assessment protocol (EFSA-Q-2021-00593)**⁵

The Working Group (WG) exchanged views on the draft protocol for hazard assessment. Questions and sub-questions on hazard identification and on hazard characterisation were discussed as well as the approach to address them. Furthermore, the WG reviewed the draft protocol sections on study selection process, on evidence appraisal and on weighing the body of evidence. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 1-2 March 2022 (prioritisation subgroup and exposure subgroup) via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 27TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroups 'prioritisation' and 'protocol for exposure assessment'

**Held on 7-9 February 2022,
by TELE-conference**

(Agreed on 8-9 February 2022)

Participants – prioritisation subgroup

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
FIP Unit: Matilde Benedettini, Chantra Eskes, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Ronan Nicolas

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

Participants – exposure protocol subgroup

- Working Group Members:
Laurence Castle (Chair), Francesca Mancini, Maria de Fátima Tavares Poças
- Hearing Experts²:
Roland Franz
- European Commission and/or Member States representatives:
Jonathan Briggs (9/2)
- EFSA:
FIP Unit: Matilde Benedettini, Katharina Volk
MESE Unit: Claudia Cascio, Marios Georgiadis, Irene Munoz Guajardo
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Niko Hellsten, Evgenia Stoanova (8/2)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (DG SANTE) for item 6.1 and Giulio Di Piazza (MESE Unit) for item 6.2 of the present meeting.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management,⁴ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 26th Working Group meeting held on 20-21 January 2022, by TELE-conference.

² As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The minutes of the 26th Working Group meeting were agreed at the end of the meeting on 21 January 2022 for some participants; for one participant not present anymore at the end of the meeting agreement via written procedure was reached on 24 January.⁵

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.2 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – identification and prioritisation of substances (EFSA-Q-2020-00725)⁶

Following the discussion on comments received, and the related attachments, from the public consultation (comments published here: <https://open.efsa.europa.eu/consultation/a0c1v00000J9TRLAA3>), the WG discussed and agreed on the answers previously elaborated, along with possible amendments in the draft opinion. In addition, an update to the feedback received from the Netherlands on nationally authorised substances was discussed. Tasks were distributed.

6.2. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – exposure assessment protocol (EFSA-Q-2021-00592)⁷

Following the closure of the public consultation of the draft protocol on exposure assessment, the WG discussed the comments received and the related attachments, if any (comments published here: <https://open.efsa.europa.eu/consultation/a0c1v00000J9Uz5AAF>). Answers to the comments were proposed and discussed, along with possible amendments in the draft protocol.

7. Next meeting(s)

The next meeting will take place on 21-22 February 2022 (hazard assessment protocol subgroup) via tele-conference (due to the Covid-19 restrictions).

⁵ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wq-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁶ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00592>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 26TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for hazard assessment'

**Held on 20-21 January 2022,
by TELE-conference**

(Agreed on 24 January 2022)

Participants

- Working Group Members:
Laurence Castle (Chair), Emanuela Corsini, Rex FitzGerald, Claude Lambré, Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölfle
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
FIP Unit: Matilde Benedettini, Chantra Eskes, Katharina Volk
MESE Unit: Marios Georgiadis, Irene Munoz Guajardo
- Others:
ECHA: Evelin Fabjan, Vessela Vitcheva

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 25th Working Group meeting held on 17-18 January 2022, by TELE-conference.

The minutes of the 25th Working Group meeting were agreed by written procedure on 28 January 2022.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – hazard assessment protocol (EFSA-Q-2021-00593)⁵

The Working Group (WG) exchanged views on the draft protocol for hazard assessment. Questions and sub-questions on hazard identification and on hazard characterisation were discussed as well as the approach to address them by literature review. Furthermore, the WG reviewed the draft protocol sections on study selection process, on evidence appraisal, on weighing the body of evidence and on uncertainty analysis. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 7-8 February 2022 (prioritisation subgroup) via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 25TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 17-18 January 2022,
by TELE-conference**

(Agreed on 28 January 2022)

Participants

- Working Group Members:
Laurence Castle (Chair), Francesca Mancini, Maria de Fátima Tavares Poças
- Hearing Experts¹:
Roland Franz
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
FIP Unit: Matilde Benedettini, Katharina Volk
MESE Unit: Claudia Cascio, Marios Georgiadis, Irene Munoz Guajardo
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Niko Hellsten

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs, Stella D'Amore (DG SANTE), Evgenia Stoyanova (ECHA) and Giulio di Piazza (MESE Unit).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 24th Working Group meeting held on 13-14 January 2022, by TELE-conference.

The minutes of the 24th Working Group meeting were agreed at the end of the meeting on 14 January 2022.⁴

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2021-00592)⁵

Following the closure of the public consultation of the draft protocol on exposure assessment, the WG discussed the comments received and the related attachments, if any (comments published here: <https://open.efsa.europa.eu/consultation/a0c1v00000J9Uz5AAF>). Answers to the comments were proposed and discussed, along with possible amendments in the draft protocol. In addition, an update to the feedback received during the Member State consultation on nationally authorised substances was discussed. Tasks were distributed.

7. Next meeting(s)

The next meeting will take place on 20-21 January 2022 (hazard assessment protocol subgroup) via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00592>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 24TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'prioritisation'

**Held on 13-14 January 2022,
by TELE-conference**

(Agreed on 14 January 2022)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
FIP Unit: Matilde Benedettini, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Ronan Nicolas

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs and Stella D'Amore (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 23rd Working Group meeting held on 13 December 2021, by TELE-conference.

The minutes of the 23rd Working Group meeting were agreed at the end of the meeting on 13 December 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

Following the closure of the public consultation of the draft opinion on prioritisation, the WG discussed the comments received and the related attachments, if any (comments published here: <https://open.efsa.europa.eu/consultation/a0c1v00000J9TRLAA3>). Answers to the comments were proposed and discussed, along with possible amendments in the draft opinion. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 17-18 January 2022 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wq-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 23RD MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for hazard assessment'

**Held on 13 December 2021,
by TELE-conference**

(Agreed on 13 December 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Emanuela Corsini, Rex FitzGerald, Claude Lambré, Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölfe
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
FIP Unit: Katleen Baert, Matilde Benedettini, Chantra Eskes, Katharina Volk
DATA Unit: Marios Georgiadis, Irene Munoz Guajardo
- Others:
ECHA: Evelin Fabjan, Vessela Vitcheva

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 22nd Working Group meeting held on 15 November 2021, by TELE-conference.

The minutes of the 22nd Working Group meeting were agreed at the end of the meeting on 15 November 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – hazard assessment protocol (EFSA-Q-2021-00593)⁵

The Working Group (WG) exchanged views on the draft protocol for hazard assessment. Questions and sub-questions on hazard identification and on hazard characterisation were discussed as well as the approach to address them by literature review. Furthermore, the WG reviewed the draft protocol sections on study selection process, on evidence appraisal and on weighing the body of evidence. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 13-14 January 2022 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 22ND MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for hazard assessment'

**Held on 15 November 2021,
by TELE-conference**

(Agreed on 15 November 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Emanuela Corsini, Rex FitzGerald, Claude Lambré, Marcel Mengelers, Gilles Rivière, Emanuela Testai, Detlef Wölfe
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
FIP Unit: Katleen Baert, Matilde Benedettini, Cristina Croera, Chantra Eskes, Katharina Volk
DATA Unit: Marios Georgiadis
- Others:
ECHA: Evelin Fabjan, Vessela Vitcheva

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 21st Working Group meeting held on 8 November 2021, by TELE-conference.

The minutes of the 21st Working Group meeting were agreed at the end of the meeting on 8 November 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) – hazard assessment protocol (EFSA-Q-2021-00593)⁵

The tasks requested in the mandate were presented to the experts along with background information on the status of the work conducted so far (i.e. identification and prioritisation of substances; protocol for exposure assessment). A general introduction to protocol development was provided, followed by the discussion of an example of a previously developed hazard assessment protocol. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 13 December 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 21st MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 8 November 2021,
by TELE-conference**

(Agreed on 8 November 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Maria de Fátima Tavares Poças
- Hearing Experts¹:
Roland Franz
- European Commission and/or Member States representatives:
Eddo Hoekstra (JRC)
- EFSA:
DATA Unit: Claudia Cascio, Giulio Di Piazza
FIP Unit: Matilde Benedettini, Katharina Volk
- Others:
Not applicable

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 20th Working Group meeting held on 25 October 2021, by TELE-conference.

The minutes of the 20th Working Group meeting were agreed by written procedure on 4 November 2021.⁴

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group (WG) exchanged views regarding the draft guidance for the ad-hoc call for data on migration from and concentration in FCM in support of the exposure assessment, and discussed the different sections. Tasks were distributed.

7. Next meeting(s)

The next meeting will take place on 15 November 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 20TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 25 October 2021,
by TELE-conference**

(Agreed on 4 November 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Maria de Fátima Tavares Poças
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Eddo Hoekstra (JRC)
- EFSA:
DATA Unit: Claudia Cascio, Giulio Di Piazza
FIP Unit: Matilde Benedettini, Katharina Volk
- Others:
Not applicable

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Roland Franz (hearing expert) and Jonathan Briggs (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 19th Working Group meeting held on 11-12 October 2021, by TELE-conference.

The minutes of the 19th Working Group meeting were agreed by written procedure on 21 October 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group (WG) exchanged views regarding the draft guidance for the ad-hoc call for data on migration from and concentration in FCM in support of the exposure assessment, and discussed the different sections. The draft catalogues for the data model parameters were presented and revised. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 8 November 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 19TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 11-12 October 2021,
by TELE-conference**

(Agreed on 21 October 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Maria de Fátima Tavares Poças, Francesca Romana Mancini
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE), Eddo Hoekstra
- EFSA:
AMU Unit: Irene Munoz Guajardo
DATA Unit: Claudia Cascio, Giulio Di Piazza
FIP Unit: Katleen Baert, Matilde Benedettini, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Niko Hellsten, Evgenia Stoyanova

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Roland Franz and Marios Georgiadis (AMU Unit).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 18th Working Group meeting held on 4 October 2021, by TELE-conference.

The minutes of the 18th Working Group meeting were agreed at the end of the meeting on 4 October 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group (WG) exchanged views on the feedback received from the CEP Panel and on how to incorporate this feedback into the draft protocol for exposure assessment. Furthermore, the WG reviewed the questions, sub-questions and related methodologies to answer each sub-question as well as methodologies to integrate evidence across sub-questions. The draft protocol's sections on uncertainties related to the different questions were discussed. A revised version of the protocol for the literature reviews was presented. The draft protocol will be presented to the CEP Panel at its next meeting for possible endorsement for public consultation.

In addition, the draft guidance for the ad-hoc call for data on migration from and concentration in FCM was discussed and further progressed. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 25 October 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wq-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 18TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'prioritisation'

**Held on 4 October 2021,
by TELE-conference**

(Agreed on 4 October 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
FIP Unit: Katleen Baert, Matilde Benedettini, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Ronan Nicolas

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (DG SANTE), Marios Georgiadis, Irene Munoz (AMU), Letizia Polci, Evgenia Stoyanova (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 17th Working Group meeting held on 20 September 2021, by TELE-conference.

The minutes of the 17th Working Group meeting were agreed at the end of the meeting on 20 September 2021 for some participants; for one participant not present anymore at the end of the meeting agreement via written procedure was reached still on the same day.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft pool of substances, the draft prioritisation results and the draft opinion (incl. annex). The draft opinion will be presented to the CEP Panel at its next meeting for possible endorsement for public consultation. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 11-12 October 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wq-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 17TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 20 September 2021,
by TELE-conference**

(Agreed on 20 September 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Maria de Fátima Tavares Poças
- Hearing Experts¹:
Roland Franz
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
DATA Unit: Claudia Cascio, Giulio Di Piazza
FIP Unit: Matilde Benedettini, Katharina Volk
- Others:
Not applicable

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Marios Georgiadis and Irene Munoz (AMU).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 16th Working Group meeting held on 13+14 September 2021, by TELE-conference.

The minutes of the 16th Working Group meeting were agreed at the end of the meeting on 14 September 2021.⁴

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft data model for collection of FCM related data in support of the exposure assessment. Feedback received during a consultation with possible data providers was discussed. Tasks were distributed.

7. Next meeting(s)

The next meeting will take place on 4 October 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 16TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'prioritisation'

**Held on 13-14 September 2021,
by TELE-conference**

(Agreed on 14 September 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
FIP Unit: Katleen Baert, Matilde Benedettini, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Ronan Nicolas

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (DG SANTE), Marios Georgiadis, Irene Munoz (AMU), Letizia Polci, Evgenia Stoyanova (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 15th Working Group meeting held on 9 September 2021, by TELE-conference.

The minutes of the 15th Working Group meeting were agreed via written procedure on 21 September 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group discussed the feedback from the MS consultation. Furthermore, views were exchanged regarding the draft pool of substances, the draft prioritisation results and the draft opinion (incl. annex). Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 20 September 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 15TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 9 September 2021,
by TELE-conference**

(Agreed on 21 September 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Maria de Fátima Tavares Poças, Francesca Romana Manini
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
AMU Unit: Marios Georgiadis, Irene Munoz
DATA Unit: Claudia Cascio, Giulio Di Piazza
FIP Unit: Katleen Baert, Matilde Benedettini, Katharina Volk
- Others:
ECHA: Stefano Frattini, Niko Hellsten, Evgenia Stoyanova

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Roland Franz (hearing expert), Jonathan Briggs (DG SANTE) and Evelin Fabjan (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 14th Working Group meeting held on 6-7 September 2021, by TELE-conference.

The minutes of the 14th Working Group meeting were agreed at the end of the meeting on 7 September 2021 for some participants; for those participants not present anymore at the end of the meeting, agreement via written procedure was requested by 16 September 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft protocol for the literature review for addressing sub-questions via systematic or narrative review. Inclusion/exclusion criteria were discussed, as well as aspects related to searching and selecting studies, extracting data, appraising and synthesising evidence. Uncertainties related to the different questions and sub-questions were discussed. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 13-14 September 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wq-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 14TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 6 and 7 September 2021,
by TELE-conference**

(Agreed on 16 September 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Maria de Fátima Tavares Poças, Francesca Romana Mancini
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
AMU Unit: Marios Georgiadis, Irene Munoz
DATA Unit: Claudia Cascio, Giulio Di Piazza
FIP Unit: Katleen Baert, Matilde Benedettini, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Evgenia Stoyanova, Niko Hellsten

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Roland Franz (hearing expert), Greta Borg, Bastiaan Schupp, Jonathan Briggs (DG SANTE) and Davide Arcella (DATA Unit).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 13th Working Group meeting held on 14 July 2021, by TELE-conference.

The minutes of the 13th Working Group meeting were agreed at the end of the meeting on 14 July 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft questions and sub-questions for the draft protocol on exposure assessment. Evidence needs and related methodologies were discussed. Parts of the draft protocol will be presented to the CEP Panel at its September meeting for a first reading and possible endorsement. Tasks were distributed.

6. AOB

In view of the next steps of the mandate related to the development of the protocol for hazard assessment, the need for additional expertise on toxicology (general toxicology, neurotoxicology, reproductive toxicology, immunotoxicology, epidemiology and toxicokinetics) was identified.

7. Next meeting(s)

The next meeting will take place on 9 September 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 13TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 14 July 2021,
by TELE-conference**

(Agreed on 14 July 2021)

Participants

- Working Group Members:
Laurence Castle (Chair)
- Hearing Experts¹:
Roland Franz
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
DATA Unit: Claudia Cascio, Giulio Di Piazza
FIP Unit: Matilde Benedettini, Katharina Volk
- Others:
Not applicable

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Maria de Fátima Tavares Poças.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 12th Working Group meeting held on 9 July 2021, by TELE-conference.

The minutes of the 12th Working Group meeting were agreed at the end of the meeting on 9 July 2021.⁴

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft data model for collection of data for the exposure assessment. A questionnaire for gathering feedback from possible data providers was discussed and progressed. Tasks were distributed.

7. Next meeting(s)

The next meeting will take place on 6-7 September 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wq-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 12TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'prioritisation'

**Held on 9 July 2021,
by TELE-conference**

(Agreed on 9 July 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
FIP Unit: Katleen Baert, Matilde Benedettini, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Letizia Polci

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Birgit Ahrens, Ronan Nicolas, Evgenia Stoyanova (ECHA); Marios Georgiadis, Irene Munoz (AMU).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 11th Working Group meeting held on 5-6 July 2021, by TELE-conference.

The minutes of the 11th Working Group meeting were agreed at the end of the meeting for some participants; for those participants not present anymore at the end of the meeting, agreement via written procedure will be requested by 13 July 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group discussed the feedback received from the CEP Panel (6-8 July) on the progress of the work and the draft opinion. Furthermore, views were exchanged regarding the draft pool of substances, the draft prioritisation results and the draft opinion. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 14 July 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wq-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 11TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 5 and 6 July 2021,
by TELE-conference**

(Agreed on 13 July 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Maria de Fátima Tavares Poças
- Hearing Experts¹:
Roland Franz
- European Commission and/or Member States representatives:
Greta Borg, Bastiaan Schupp (DG SANTE)
- EFSA:
AMU Unit: Marios Georgiadis, Irene Munoz
DATA Unit: Davide Arcella, Claudia Cascio, Giulio Di Piazza
FIP Unit: Katleen Baert, Matilde Benedettini, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Evgenia Stoyanova

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Francesca Romana Mancini (WG member), Jonathan Briggs (DG SANTE), and Niko Hellsten (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 10th Working Group meeting held on 14-15 June 2021, by TELE-conference.

The minutes of the 10th Working Group meeting were agreed at the end of the meeting on 15 June 2021.⁴

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft questions and sub-questions for the draft protocol on exposure assessment. Evidence needs and related methodologies (incl. call for data) were discussed. Parts of the draft protocol will be presented to the CEP Panel at its September meeting for a first reading and possible endorsement. Tasks were distributed.

7. Next meeting(s)

The next meeting will take place on 9 July 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 10TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'prioritisation'

**Held on 14 and 15 June 2021,
by TELE-conference**

(Agreed on 15 June 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
FIP Unit: Katleen Baert, Stavroula Sampani, Katharina Volk
- Others:
ECHA: Birgit Ahrens, Evelin Fabjan, Ronan Nicolas, Letizia Polci

1. Welcome and apologies for absence

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

The Chair welcomed the participants. Apologies were received from Marios Georgiadis (AMU), Irene Munoz (AMU) and Evgenia Stoyanova (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 9th Working Group meeting held on 7-8 June 2021, by TELE-conference.

The minutes of the 9th Working Group meeting were agreed partly at the end of the meeting and partly via written procedure; both types of agreement were reached on 8 June 2021.⁴

5. Scientific topic(s) for discussion

5.1. **Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)**⁵

The Working Group further discussed the feedback from the MS consultation. Views were exchanged regarding the draft pool of substances, the draft prioritisation approach and the draft opinion. Parts of the draft opinion will be presented to the CEP Panel at its next meeting for a first reading and possible endorsement. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 5-6 July 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 9TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 7 and 8 June 2021,
by TELE-conference**

(Agreed on 8 June 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Francesca Romana Mancini, Maria de Fátima Tavares Poças
- Hearing Experts¹:
Roland Franz²
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
AMU Unit: Marios Georgiadis, Irene Munoz
DATA Unit: Davide Arcella, Claudia Cascio, Giulio Di Piazza
FIP Unit: Katleen Baert, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Niko Hellsten, Evgenia Stoyanova

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:

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

² Participated only on 7 June 2021.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jonathan Briggs (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management,⁴ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 8th Working Group meeting held on 28 May 2021, by TELE-conference.

The minutes of the 8th Working Group meeting were agreed at the end of the meeting on 28 May 2021.⁵

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁶

The Working Group exchanged views regarding the draft questions and sub-questions for the draft protocol on exposure assessment. Evidence needs and related methodologies (incl. call for data) were discussed. Tasks were distributed.

7. Next meeting(s)

The next meeting will take place on 14-15 June 2021 via tele-conference (due to the Covid-19 restrictions).

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁵ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁶ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 8TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'prioritisation'

**Held on 28 May 2021,
by TELE-conference**

(Agreed on 28 May 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
FIP Unit: Katleen Baert, Stavroula Sampani, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Ronan Nicolas, Evgenia Stoyanova

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Marios Georgiadis (AMU), Irene Munoz (AMU), Letizia Polci (ECHA) and Birgit Ahrens (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 7th Working Group meeting held on 12 May 2021, by TELE-conference.

The minutes of the 7th Working Group meeting were agreed at the end of the meeting on 12 May 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group further discussed the feedback from the MS consultation. Views were exchanged regarding the draft pool of substances, the draft prioritisation approach and sections of the draft opinion. In addition, the WG proposed some changes to the 'Background and Terms of Reference as provided by the requestor', which were agreed with the European Commission at the WG meeting. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 7-8 June 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 7TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'prioritisation'

**Held on 12 May 2021,
by TELE-conference**

(Agreed on 12 May 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
FIP Unit: Katleen Baert, Stavroula Sampani, Katharina Volk
AMU Unit: Irene Munoz
- Others:
ECHA: Birgit Ahrens, Evelin Fabjan, Ronan Nicolas, Letizia Polci, Evgenia Stoyanova

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Marios Georgiadis (AMU).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 6th Working Group meeting held on 11 May 2021, by TELE-conference.

The minutes of the 6th Working Group meeting will be agreed by written procedure on 24 May 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft pool of substances and draft prioritisation approach. Feedback from the MS consultation was discussed. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 28 May 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 6TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 11 May 2021,
by TELE-conference**

(Agreed on 24 May 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Francesca Romana Mancini, Maria de Fátima Tavares Poças
- Hearing Experts¹:
Roland Franz
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
AMU Unit: Marios Georgiadis, Irene Munoz
DATA Unit: Davide Arcella, Claudia Cascio, Giulio Di Piazza
FIP Unit: Katleen Baert, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Niko Hellsten, Evgenia Stoyanova

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 Working Group meeting held on 22 April 2021, by TELE-conference.

The minutes of the 5th Working Group meeting were agreed at the end of the meeting on 22 April 2021.⁴

5. Hearing Expert(s)

Dr. Roland Franz was invited to present his views for item 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft questions and sub-questions for the draft protocol on exposure assessment. Evidence needs and related methodologies were discussed. Tasks were distributed.

7. Next meeting(s)

The next meeting will take place on 12 May 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 5TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

Subgroup 'protocol for exposure assessment'

**Held on 22 April 2021,
by TELE-conference**

(Agreed on 22 April 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Francesca Romana Mancini, Maria de Fátima Tavares Poças
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
AMU Unit: Marios Georgiadis, Irene Munoz
DATA Unit: Davide Arcella, Claudia Cascio, Giulio Di Piazza
FIP Unit: Katleen Baert, Katharina Volk
- Others:
ECHA: Evelin Fabjan, Stefano Frattini, Niko Hellsten

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 4th Working Group meeting held on 12 April 2021, by TELE-conference.

The minutes of the 4th Working Group meeting were agreed at the end of the meeting on 12 April 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft questions and sub-questions for the protocol on exposure assessment. Timelines of the workplan were discussed. Tasks were distributed.

6. Next meeting(s)

The next meetings will take place on 11 and 12 May 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 4TH MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

**Held on 12 April 2021,
by TELE-conference**

(Agreed on 12 April 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not applicable.
- EFSA:
FIP Unit: Katleen Baert, Stavroula Sampani, Katharina Volk
- Others:
ECHA: Birgit Ahrens, Evelin Fabjan, Letizia Polci

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ronan Nicolas (ECHA), Marios Georgiadis (AMU), Irene Munoz (AMU) and Jonathan Briggs (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 3rd Working Group meeting held on 10 March 2021, by TELE-conference.

The minutes of the 3rd Working Group meeting were agreed by written procedure on 12 March 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft pool of substances and draft prioritisation approach, as well as a template for the table of contents for the draft opinion Timelines of the workplan were discussed. Tasks were distributed.

6. Next meeting(s)

The next meeting will take place on 22 April 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 3RD MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

**Held on 10 March 2021,
by TELE-conference**

(Agreed on 12 March 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
FIP Unit: Katleen Baert, Stavroula Sampani, Katharina Volk
AMU Unit: Marios Georgiadis, Irene Munoz
- Others:
ECHA: Birgit Ahrens, Evelin Fabjan, Elina Karhu, Ronan Nicolas, Letizia Polci

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 2nd Working Group meeting held on 12 February 2021, by TELE-conference.

The minutes of the 2nd Working Group meeting were agreed by written procedure on 18 February 2021.⁴

5. Scientific topic(s) for discussion

5.1. **Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)**⁵

The Working Group exchanged views regarding the draft pool of substances and draft prioritisation approach. Timelines of the workplan were discussed. Tasks were distributed.

6. Any Other Business

In view of the next steps of the mandate related to the call for data and development of the protocol for exposure assessment, the need for additional expertise on exposure assessment and food contact materials/migration was identified.

7. Next meeting(s)

The next meeting will take place on 12 April 2021 via tele-conference (due to the Covid-19 restrictions).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-02/wg-wg-preparation-re-evaluation-phthalates-structurally-similar-substances-and-replacement.pdf>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 2ND MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

**Held on 12 February 2021,
by TELE-conference**

(Agreed on 18 February 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Jonathan Briggs (DG SANTE)
- EFSA:
FIP Unit: Katleen Baert, Claudia Roncancio Peña, Stavroula Sampani, Katharina Volk
- Others:
ECHA: Birgit Ahrens, Evelin Fabjan, Elina Karhu, Ronan Nicolas, Letizia Polci

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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 1st Working Group meeting held on 09 February 2021, by TELE-conference.

The minutes of the 1st Working Group meeting were agreed by written procedure on 18 February 2021.⁴

5. Scientific topic(s) for discussion

5.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁵

The Working Group exchanged views regarding the draft pool of substances and draft prioritisation approach. Timelines of the workplan was discussed. Tasks were distributed.

6. Any Other Business

Not Applicable

7. Next meeting(s)

The date for the next meeting has still to be defined.

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://www.efsa.europa.eu/en/food-ingredients-and-packaging/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00725>



FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP)

MINUTES OF THE 1ST MEETING OF THE WORKING GROUP ON PREPARATION FOR RE-EVALUATION OF PHTHALATES, STRUCTURALLY SIMILAR SUBSTANCES AND REPLACEMENT SUBSTANCES

**Held on 09 February 2021,
by TELE-conference**

(Agreed on 18 February 2021)

Participants

- Working Group Members:
Laurence Castle (Chair), Claude Lambré, Gilles Rivière
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
FIP Unit: Katleen Baert, Stavroula Sampani, Katharina Volk
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group 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. Scientific topic(s) for discussion

4.1. Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs) (EFSA-Q-2020-00725)⁴

The tasks related to the mandate and the background on the status of the preparatory work was presented to the experts. The Working Group exchanged views regarding the draft pool of substances and draft prioritisation approach.

5. Any Other Business

Not Applicable

6. Next meeting(s)

The next meeting is scheduled for 12 February 2021, via teleconference.

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00725>