



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 FOOD CONTACT MATERIALS 2018-2021

By teleconference, 30 September 2020

(Agreed on 21 October 2020)

Participants

■ Working Group Members:

Claudia Bolognesi, Laurence Castle, Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Claude Lambré, Evgenia Lampi, Maria Rosaria Milana and Gilles Rivière (Chair)

■ Hearing Experts¹:

- not applicable

■ European Commission and/or Member States representatives:

- DG SANTE: Bastiaan Schupp, Jonathan Briggs
- DG JRC: Eddo Hoekstra

■ EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Alexandros Lioupis, Stavroula Sampani, Ellen Van Haver and Katharina Volk

SCER Unit: Jose Tarazona

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>.



1. Welcome and apologies for absence

The Chair welcomed the participants. This meeting was organised as a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

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 Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 18th WG meeting

The minutes of the 18th WG meeting (held on 7-9 July 2020) were agreed by written procedure⁴.

5. Scientific topic(s) for discussion

There were no FCM applications for discussion. Additional information was foreseen to be received for several FCM-applications, but the applicants informed EFSA that they encountered a delay in obtaining the analytical data EFSA requested due to the Covid-situation. The deadline for submitting the additional information was therefore extended, and the applications remain in stop-the-clock awaiting the receipt of the additional information.

6. Other scientific topics for discussion

Scientific Committee draft guidance on nanomaterials

The "draft EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles", for which the [public consultation ended in September](#), was presented and discussed. The guidance follows a mandate from the European Commission (EC) addressing technical requirements for conventional materials (i.e. materials that do not meet the "engineered nanomaterials" definition of the Novel Food Regulation) in order to identify the presence of a fraction of small particles requiring assessment at the nanoscale. The Scientific Committee WG on Nanotechnology is currently addressing the comments received during the public consultation and, simultaneously, updating the SC Guidance on the risk assessment of nanomaterials published in 2018. Specific considerations for FCM are provided in an Annex of the 2018 guidance. EFSA explained the scope of both complementary guidance documents. The draft

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://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>



“Guidance document on Technical Requirements” is only applicable to conventional materials and provides applicants and other interested parties with the information to be submitted for confirming that the material does not require assessment at the nanoscale. The scope of the SC Guidance on the risk assessment of nanomaterials under update covers both nanomaterials covered by the legal definitions and conventional materials requiring assessment at the nanoscale (i.e. those identified according to the Guidance document on Technical Requirements).

FCM being currently excluded from the scope of the draft guidance on Technical Requirements, questions and options on its applicability to the FCM area were presented and discussed. The WG considered the need for addressing properly the specific considerations required for FCM in both guidance documents. Discussion will continue at the next WG meeting.

Re-evaluation of phthalates

The WG was informed about the receipt of a new mandate from the EC tasking EFSA with the re-evaluation of phthalates. Once the mandate is formally accepted, it will become publicly available in EFSA’s register of questions. In preparation of this opinion, the EC is requesting the collaboration with ECHA to work together, considering the screening and prioritisation exercise done by ECHA on groups of structurally similar substances that may be relevant as regards their use in FCMs.

7. Feedback from EFSA, CEP Panel and the European Commission

In the context of the 16th amendment of Regulation (EC) 10/2011, the EC asked the FCM WG for their considerations on the SML to be set for FCM substance n. 1080 ((triethanolamine-perchlorate, sodium salt) dimer ([opinion](#) adopted by the CEP Panel on 29 April 2020) and the possible implications for adding the substance to two group restrictions (SML(T)). The EC also asked the WG for their views on the possible implications of the classification by REACH of certain cobalt salts as CMRs, as the salts of authorised acids can be used in FCM (in accordance with Article 6(3)(a) of Reg. 10/2011), subject to an SML for cobalt of 50 ppb.

1) FCM substance n. 1080 ((triethanolamine-perchlorate, sodium salt) dimer:

In the context of the 16th amendment of Regulation (EC) 10/2011, FCM substance n. 1080 will need to be added to two group restrictions, for triethanolamine (FCM 793) and perchlorate (FCM 822). In the case of FCM 822, the SML was set to cover the acids and not necessarily the salts. As indicated in the EFSA opinion (2020), the SML for perchlorate is based on the health-based guidance value as set by the CONTAM Panel. The salts will instead dissociate (perchlorate and counter ions in the solution), which makes the salts obsolete in the current listed SML for FCM 822.

2) Cobalt salts:

Salts of authorised acids can be used in FCM on the basis of dissociation (Article 6(3)(a) of Reg. 10/2011). Some cobalt salts have been classified under REACH as CMRs (e.g. cobalt di(acetate) is carcinogenic by inhalation). In view of the REACH classifications, is there a reason to reconsider the SML of 50 ppb for cobalt currently limiting the migration of cobalt from plastic FCM?

For being able to answer this question, the FCM WG indicated that there is a need to first look at the available dataset (mechanisms of action, studies by oral exposure, etc.) to understand whether the carcinogenicity by inhalation also applies to oral exposure, as the REACH classification is based on studies on occupational exposure by inhalation. It was noted that the exposure to cobalt could come from different sources, including FCM, feed additives and contaminants.



8. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

The FCM WG members thanked Anna F. Castoldi, transferring from the FIP unit from October 2020 to another Unit in EFSA, for her support to the work of the FCM WG.

9. Next meeting(s)

The next meeting will take place 11 November 2020 by teleconference.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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

MINUTES OF THE 18TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 7-9 July 2020

(Agreed on 27 July 2020)

Participants

■ Working Group Members:

Claudia Bolognesi¹, Laurence Castle, Riccardo Crebelli¹, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Claude Lambré, Evgenia Lampi, Maria Rosaria Milana², Karla Pfaff and Gilles Rivière (Chair)

■ Hearing Experts³:

- not applicable

■ European Commission and/or Member States representatives:

- DG SANTE: Bastiaan Schupp, Jonathan Briggs, Martinus Nagtzaam, Ludovic Chatelin

■ EFSA:

FIP Unit: Eric Barthélémy, Mary Carfi, Anna F. Castoldi, Fatima Den Ouden, Alexandros Lioupis, Ellen Van Haver and Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants. This meeting was organised as a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

¹ Not present on 9 July

² Not present on 8 July pm

³ 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. Adoption of agenda

The agenda was adopted without changes.

3. 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, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 17th WG meeting

The minutes of the 17th WG meeting (held on 26-28 May 2020) were agreed by written procedure⁶.

5. Scientific topic(s) for discussion

5.1. Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks (FCM 93) (EFSA-Q-2018-00558)⁷

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.2. Styrene (FCM 193) (EFSA-Q-2019-00686)⁸

Subsequent to the discussions at the last meetings of the FCM WG and the cross-cutting WG on Genotoxicity, the draft opinion in response to the mandate EFSA received from the EC for re-assessing the safety of styrene for use in food contact materials, was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.3. 1,4-benzenedicarboxylic acid, 1,4-dibutyl ester (EFSA-Q-2019-00586)⁹

The dossier received from the applicant was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

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

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00558>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00586>



6. Feedback from EFSA, CEP Panel and the European Commission

Update of the EFSA guidance documents in the FCM area

The WG was informed about the need for EFSA to revise certain guidance documents in order to comply with the Regulation (EU) 2019/1381 which will enter into force on 27 March 2021. The new legal requirements introduced by this so-called Transparency Regulation will impact various areas of EFSA's work, including the handling of application dossiers in the context of regulated products, and therefore have to be correctly reflected in the guidance documents provided to applicants, so that both EFSA and the applicants can comply with the new requirements. Draft changes to the guidance documents which are pertinent to the WG's work, i.e. the plastic FCM Note for Guidance ([EFSA CEF Panel, 2008](#)) and the guidelines for active and intelligent materials ([EFSA CEF Panel, 2009](#)), were presented.

7. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

This meeting was the last FCM WG meeting for K. Pfaff given that she will resign from the FCM WG as of 31 July 2020. EFSA staff and the WG members expressed their appreciation for all her contributions to the FCM WG's work.

8. Next meeting(s)

The next meeting will take place 29 September – 1 October 2020 by teleconference (to be confirmed).



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹⁰ and the Decision of the Executive Director on Competing Interest Management¹¹, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹⁰ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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 FOOD CONTACT MATERIALS 2018-2021

By teleconference, 26-28 May 2020

(Agreed on 22 June 2020)

Participants

■ Working Group Members:

Claudia Bolognesi, Laurence Castle, Riccardo Crebelli¹, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Claude Lambré, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff and Gilles Rivière (Chair)

■ Hearing Experts²:

- not applicable

■ European Commission and/or Member States representatives:

- DG SANTE: Bastiaan Schupp

■ EFSA:

FIP Unit: Eric Barthélémy, Mary Carfi, Anna F. Castoldi, Fatima Den Ouden, Alexandros Lioupis, Ellen Van Haver, Katharina Volk and Francesca Werner

BIOCONTAM Unit: Winny Messens

¹ Not present on 28 May

² 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>.



1. Welcome and apologies for absence

The Chair welcomed the participants, and especially Claude Lambré as new member to the FCM WG. This meeting was organised as a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

2. Adoption of agenda³

The agenda was adopted without changes.

3. 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, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 14th (1-2 April 2020), 15th (5 May 2020) and 16th (11 May 2020) WG meetings

The minutes of the 14th (held on 1-2 April 2020), 15th WG meeting (held on 5 May 2020) and 16th (held on 11 May 2020) WG meetings were agreed by written procedure⁶.

5. Scientific topic(s) for discussion

5.1. Nonamethylenediamine (NMDA, EFSA-Q-2019-00533)⁷

The dossier received from the applicant was discussed together with the item 5.2, given that both dossiers were submitted by the same applicant and the substances are intended to be used jointly. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.2. 2-Methyl-1,8-octadecamine (MODA, EFSA-Q-2019-00534)⁸

The dossier received from the applicant was discussed together with the item 5.1, given that both dossiers were submitted by the same applicant and the substances are intended to be used jointly. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.3. Styrene (FCM 193) (EFSA-Q-2019-00686)⁹

³ Not present on 26 May

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

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00533>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00534>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686>



Subsequent to the discussions at the last FCM WG meeting, the WG continued with the evaluation of styrene in the frame of the mandate EFSA received from the EC for re-assessing the safety of styrene for use in food contact materials. The WG also took into account the advice from the cross-cutting WG on Genotoxicity with regard to the genotoxicity evaluation of styrene by the oral route.

5.4. Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters (EFSA-Q-2020-00014)¹⁰

The dossier received from the applicant was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

6. Feedback from EFSA, CEP Panel and the European Commission

Mandate on high pressure processing

The mandate from the European Commission was presented (EFSA-Q-2020-00380¹¹). It requests a scientific opinion on the efficacy and safety of high-pressure processing (HPP) of food. The first terms of reference cover the efficacy and the potential chemical and microbiological food safety risks in HPP-treated food compared to untreated food or to food submitted to treatments, routinely applied to these foods with the purpose to increase microbiological food safety. HPP is normally applied to pre-packed foods. Three members of the FCM Working Group agreed to join the *ad hoc* BIOHAZ Working Group on HPP of food in order to address the potential risks related to HPP-treated FCM compared to untreated FCM. The scientific opinion will be delivered by the BIOHAZ Panel and specific sections are to be endorsed by the CEP and CONTAM Panels for their respective areas.

7. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

After the last WG meeting, it was agreed with the Chair to enlarge the WG with an additional expert in the areas of general toxicology, immunotoxicology and nanotechnologies. Moreover, during this meeting it was also suggested to enlarge the WG with an additional expert in the area of chemistry of FCMS.

8. Next meeting(s)

The next meeting will take place 7-9 July 2020 by teleconference.

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00014>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00380>



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹² and the Decision of the Executive Director on Competing Interest Management¹³, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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

MINUTES OF THE 16TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 11 May 2020

(Agreed on 14 May 2020)

Participants

- Working Group Members:
Koni Grob and Evgenia Lampi
- Hearing Experts¹:
 - not applicable
- European Commission and/or Member States representatives:
 - not applicable
- EFSA:
FIP Unit: Anna F. Castoldi and Ellen Van Haver

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

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>.



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 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.

4. Scientific topic(s) for discussion

4.1. Styrene (FCM 193) (EFSA-Q-2019-00686)⁴

Subsequent to the discussions at last FCM WG meeting, the WG continued with the evaluation of styrene in the frame of the mandate EFSA received from the EC for re-assessing the safety of styrene for use in food contact materials. The WG also considered the additional information that EFSA requested from a consortium of industry operators under the auspices of PlasticsEurope.

5. AOB

There was no any other business.

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-2019-00686>

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

MINUTES OF THE 15TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

Subgroup on data collection

**By teleconference, 5 May 2020
(Agreed on 27 May 2020)**

Participants

■ Working Group Members:

Laurence Castle, Roland Franz, Koni Grob, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff and Gilles Rivière (Chair)

■ Hearing Experts¹:

- not applicable

■ European Commission and/or Member States representatives:

- DG SANTE: Greta Borg, Bastiaan Schupp
- JRC: Eddo Hoekstra

■ EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Fatima Den Ouden, Alexandros Lioupis, Ellen Van Haver, Katharina Volk and Francesca Werner

DATA Unit: Davide Arcella, Claudia Cascio, Davide Gibin

1. Welcome and apologies for absence

The Chair welcomed the participants. This meeting was organised as a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

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. 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 Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 14th (1-2 April 2020) WG meeting

The minutes of the 14th WG meeting (held on 1-2 April 2020) were agreed by written procedure⁴.

5. Scientific topic(s) for discussion

5.1. Data collection for food contact materials

As a follow-up to the Commission Monitoring Recommendation for food contact materials, the WG discussed the possibility to establish a data collection system which could allow Member States and/or other data providers to submit FCM-related data (e.g. results of migration tests) to EFSA via a harmonised electronic submission format. The usefulness of such data, e.g. of migration test results for exposure estimates, was discussed. Several parameters that would be of relevance for collection and interpretation of migration data were discussed, and the need to further refine them as well as the general concept for FCM data collection before a possible implementation was identified.

6. Other scientific topics for discussion

7. Feedback from EFSA, CEP Panel and the European Commission

8. AOB

9. Next meeting(s)

The next meeting will take place 26-28 May 2020 by 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://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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

MINUTES OF THE 14TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 1-2 April 2020

(Agreed on 23 April 2020)

Participants

■ Working Group Members:

Emilio Benfenati¹, Claudia Bolognesi², Laurence Castle³, Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Evgenia Lampi, Maria Rosaria Milana², Karla Pfaff and Gilles Rivière (Chair)

■ Hearing Experts⁴:

- not applicable

■ European Commission and/or Member States representatives:

- DG SANTE: Greta Borg, Jonathan Briggs, Bastiaan Schupp

■ EFSA:

FIP Unit: Eric Barthélémy, Mary Carfi, Anna F. Castoldi, Consuelo Civitella, Fatima Den Ouden, Alexandros Lioupis, Remigio Marano, Ellen Van Haver, Katharina Volk and Francesca Werner

FEED Unit: Fabiola Pizzo

SCER Unit: Georges Kass

¹ Present on 1 April am and 2 April pm

² Not present on 1 April

³ Not present on 2 April pm

⁴ 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>.



1. Welcome and apologies for absence

The Chair welcomed the participants. This meeting was organised as a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 12th (25-27 February 2020) and 13th (18-19 March 2020) WG meetings

The minutes of the 12th WG meeting (held on 25-27 January 2020) and of the 13th WG meeting (held on 18-19 March 2020) were agreed by written procedure⁷.

5. Scientific topic(s) for discussion

5.1. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150)⁸

Subsequent to the discussions at last FCM WG meeting, a revised draft opinion was presented to the WG, in particular as regards the results of the prioritisation exercise. The discussion focused on the list of substances that were clustered in the high priority group based on the agreed strategy. Each substance was presented to the WG and conclusions on each of them was discussed by the experts and agreed among the WG. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.2. Benzophenone-3,3'-4,4'-tetracarboxylic dianhydride (EFSA-Q-2018-01007)⁹

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01007>



5.3. Styrene (FCM 193) (EFSA-Q-2019-00686) ¹⁰

Subsequent to the discussions at last FCM WG meeting, the WG continued with the evaluation of styrene in the frame of the mandate EFSA received from the EC for re-assessing the safety of styrene for use in food contact materials.

6. Other scientific topics for discussion

G. Kass from the EFSA SCER Unit presented the Threshold of Toxicological Concern (TTC) approach, in particular the 2019 EFSA guidance on the use of the TTC approach in food safety assessment¹¹.

7. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

8. Next meeting(s)

The next meeting will take place 26-28 May 2020 by teleconference.

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686>

¹¹ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5708>



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹² and the Decision of the Executive Director on Competing Interest Management¹³, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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 FOOD CONTACT MATERIALS 2018-2021

TELE-conference, 18-19 March 2020

(Agreed on 19 March 2020)

Participants

- Working Group Members:
Emilio Benfenati¹, Laurence Castle, Riccardo Crebelli², Roland Franz, Nicole Hellwig and Gilles Rivi re (Chair)
- Hearing Experts:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
FIP Unit: Consuelo Civitella, Alexandros Lioupis, Francesca Werner
FEED Unit: Fabiola Pizzo
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ Not present on 18 March

² Not present on 19 March

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 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 members at the beginning of this meeting.

4. Agreement of the minutes of the 12th Working Group meeting held on 25-27 February 2020, TELE-conference.

The minutes of the 12th WG meeting held on 25-27 February 2020 were agreed by written procedure.⁵

5. Scientific topic(s) for discussion

5.1. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150)⁶

The results of the prioritisation exercise were presented to the WG, taking into account the last amendments made in the draft opinion. The discussion focused on the list of substances that were clustered in the high priority group based on the agreed strategy. Each substance was discussed by the experts and conclusions on each of them were agreed among the WG. Furthermore, the results on the *in silico* predictions on substances of the medium priority group were presented and discussed among the experts.

6. Any Other Business

None

7. Next meeting(s)

The next WG meeting will take place 1 – 2 April 2020 by teleconference.

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 <http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence⁷ and the Decision of the Executive Director on Competing Interest Management⁸, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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

MINUTES OF THE 12TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

Held on 25-27 February 2020, Parma

(Agreed on 18 March 2020)

Participants

■ Working Group Members:

Emilio Benfenati¹, Claudia Bolognesi², Laurence Castle, Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Evgenia Lampi, Maria Rosaria Milana², Karla Pfaff and Gilles Rivière (Chair), and Detlef Wölfle³

■ Hearing Experts⁴:

- not applicable

■ European Commission and/or Member States representatives:

- Not applicable

■ EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Consuelo Civitella, Alexandros Lioupis, Ellen Van Haver, Katharina Volk and Francesca Werner

¹ For agenda item 5.2 only

² Not present on 26 February

³ Present on 27 February only

⁴ 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>.



1. Welcome and apologies for absence

The Chair welcomed the participants. This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 11th WG meeting, held on 14-16 January 2020

The minutes of the 11th WG meeting held on 14-16 January 2020 were agreed by written procedure⁷.

5. Scientific topic(s) for discussion

5.1. Styrene (FCM 193) (EFSA-Q-2019-00686)⁸

Subsequent to the discussions at last FCM WG meeting, the WG continued with the evaluation of styrene in the frame of the mandate EFSA received from the EC for re-assessing the safety of styrene for use in food contact materials.

5.2. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150)⁹

A short report-back of the last CEP Panel meeting was provided to the WG and the points raised by the Panel were discussed. The on-going activities on the collection of chemical/toxicological information, the *in silico* prediction results and the draft opinion were presented and discussed. Regarding the prioritisation strategy, the methodology and the results of the prioritisation exercise were presented to the WG, taking into account the most recent amendments made in the draft opinion.

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>



6. Feedback from EFSA, CEP Panel and the European Commission

Drinking Water Directive (DWD)

Feedback was given on the ongoing collaboration with EC ENVI, EC SANTE, EC JRC and ECHA on the revision of the Drinking Water Directive on materials in contact with drinking water from source to tap water.

7. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

8. Next meeting(s)

The next meeting will take place 1 – 2 April 2020 by teleconference.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹⁰ and the Decision of the Executive Director on Competing Interest Management¹¹, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹⁰ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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

MINUTES OF THE 11TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

Held on 14-16 January 2020, Parma

(Agreed on 5 February 2020)

Participants

■ Working Group Members:

Emilio Benfenati¹, Claudia Bolognesi², Laurence Castle, Riccardo Crebelli, Emma Di Consiglio², Roland Franz, Koni Grob², Nicole Hellwig³, Evgenia Lampi², Maria Rosaria Milana^{2,3}, Karla Pfaff² and Gilles Rivi  re (Chair)

■ Hearing Experts⁴:

- not applicable

■ European Commission and/or Member States representatives:

- Not applicable

■ EFSA:

FIP Unit: Eric Barth  l  my, Anna F. Castoldi, Consuelo Civitella, Alexandros Lioupis, Ellen Van Haver and Katharina Volk

FEED Unit: Fabiola Pizzo

¹ For agenda item 5.1 only

² Not present on 14 January

³ By teleconference

⁴ 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>.



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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting.

For further details on the outcome of the screening of the Annual Declarations of Interest, as well as the Oral Declaration(s) of Interest at the beginning of the meeting, and for conflicts of interest identified therein, please refer to Annexes I and II, respectively.

4. Agreement of the minutes of the 10th WG meeting, held on 26-28 November 2019

The minutes of the 10th WG meeting held on 26-28 November 2019 were agreed by written procedure⁷.

5. Scientific topic(s) for discussion

5.1. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150)⁸

A short report-back of the last CEP Panel meeting was given to the WG. The on-going activities on the collection of chemical/toxicological information, the *in silico* predictions results and a preliminary draft opinion were presented and discussed. In addition, the working group examined the strategy for prioritisation of substances and decided to slightly revise the methodology.

5.2. Di(m-2,2',2''-nitrilotris(ethanol)-diperchlorato)dinatrium (TEAP) (EFSA-Q-2017-00444)⁹

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.3. Reaction product of stearyl-diethanol-amine with C18 saturated fatty acids (additive) – (EFSA-Q-2016-00510)¹⁰

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00444>



Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.4. Nano precipitated Calcium Carbonate (EFSA-Q-2019-00232) ¹¹

The dossier received from the applicant was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.5. Fatty acid-coated nano precipitated Calcium Carbonate (EFSA-Q-2019-00233) ¹²

The dossier received from the applicant was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.6. Styrene (FCM 193) (EFSA-Q-2019-00686) ¹³

Subsequent to the discussions at the last FCM WG meeting, the WG continued with the evaluation of styrene in the frame of the mandate EFSA received from the EC for re-assessing its safety for use in food contact materials.

5.7. Silver as nano material (EFSA-Q-2018-00640) ¹⁴

The dossier received from the applicant was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

6. Feedback from EFSA, CEP Panel and the European Commission

The FCM WG was informed about the ongoing call¹⁵ (deadline 20 April 2020) for technical and toxicological data on the substances N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine (FCM No 19) and N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides (FCM No 20) for their use in plastic materials and articles intended to come into contact with food, including in food for infants (EFSA-Q-2019-00763).

7. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

8. Next meeting(s)

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00510>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00232>

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00233>

¹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686>

¹⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00640>

¹⁵ <http://www.efsa.europa.eu/en/consultations/call/call-technical-and-toxicological-data-substances-nn-bis2>



The next meeting will take place 25-27 February 2020 in Parma.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹⁶ and the Decision of the Executive Director on Competing Interest Management¹⁷, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Annex II

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

With regard to this meeting, Dr. R Franz declared the following interest: in relation to agenda item 5.7 (Silver as nano material), the expert indicated that the applicant has used several of his publications on nano silver (which he co-authored) as well as the doctoral thesis of his co-worker to substantiate the information in the dossier, without the consent of the expert himself. In accordance with EFSA's Policy on Independence¹⁸ and the Decision of the Executive Director on Competing Interest Management¹⁹, and taking into account the specific matters discussed at the meeting in question, the interest above was however deemed to represent a Conflict of Interest (CoI) given that the review, assessment or rating by Experts of their own work is considered incompatible with the Experts' participation to the concerned activities on the agenda. This results in the exclusion of the expert from any discussion, voting or other processing of item 5.7 by the concerned scientific group.

¹⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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

MINUTES OF THE 10TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

Held on 26-28 November 2019, Parma

(Agreed on 16 December 2019)

Participants

■ Working Group Members:

Emilio Benfenati¹, Claudia Bolognesi², Laurence Castle, Riccardo Crebelli, Emma Di Consiglio², Roland Franz, Koni Grob², Nicole Hellwig, Evgenia Lampi², Maria Rosaria Milana^{2,3}, Karla Pfaff^{2,3} and Gilles Rivi  re (Chair)

■ Hearing Experts⁴:

- not applicable

■ European Commission and/or Member States representatives:

- Not applicable

■ EFSA:

FIP Unit: Eric Barth  l  my, Anna F. Castoldi, Consuelo Civitella, Alexandros Lioupis, Claudia Roncancio Pe  a, Ellen Van Haver and Katharina Volk

APDESK Unit: Remigio Marano

¹ For agenda item 5.1 only

² Not present on 26 November

³ By teleconference

⁴ 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>.



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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 9th WG meeting, held on 8-10 October 2019

The minutes of the 9th WG meeting held on 8-10 October 2019 were agreed by written procedure⁷.

5. Scientific topic(s) for discussion

5.1. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150)⁸

The terms of reference of the EU mandate for the priority setting of substances of the FCM Union list without an SML were presented together with the on-going activities on the collection of chemical/toxicological information, setting the relevant criteria for the use of information, the *in silico* predictions and the feedback received from the EU Member States on risk assessments at national level. The working group discussed on the methodology and the strategy to prioritise the substances.

5.2. 2-hydroxyethyl methacrylate phosphate (as a monomer) (EFSA-Q-2019-00390)⁹

The dossier received from the applicant was discussed. The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00390>



5.3. Bis(2-ethylhexyl)-cyclohexane-1,4-dicarboxylate (EFSA-Q-2018-00549)¹⁰

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.4. Milled carbonised PAN based carbon fibre (EFSA-Q-2018-00064)¹¹

Further to the receipt of the additional information requested from the applicant, the WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

6. Feedback from EFSA, CEP Panel and the European Commission

EFSA has received a mandate from the EC for re-assessing the safety of Styrene for use in food contact materials (EFSA-Q-2019-00686¹²) following the new information that became available after the publication of the [Monograph](#) of the International Agency for Research on Cancer (IARC). In accordance with Article 12(3) of Regulation (EC) No 1935/2004, the EC asks EFSA to evaluate whether the authorisation of styrene (FCM 193) is still in accordance with the requirements of Reg. (EC) No 1935/2004. The FCM WG discussed the extent of available data required for addressing this mandate following the discussions held by the cross-cutting WG of the Scientific Committee for addressing the genotoxicity by oral route.

7. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

8. Next meeting(s)

The next meeting will take place 14-16 January 2020 in Parma.

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00549>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00064>

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686>



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his former employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), from which he retired within a period of less than 2 years' time, he had responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This included e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹³ and the Decision of the Executive Director on Competing Interest Management¹⁴, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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

MINUTES OF THE 9TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

Held on 8-10 October 2019, Parma

(Agreed on 24 October 2019)

Participants

■ Working Group Members:

Emilio Benfenati^{1,2}, Claudia Bolognesi, Laurence Castle, Riccardo Crebelli^{1,3}, Emma Di Consiglio^{1,3}, Roland Franz, Koni Grob, Nicole Hellwig, Evgenia Lampi, Maria Rosaria Milana⁴, Karla Pfaff and Gilles Rivière (Chair)

■ Hearing Experts⁵:

- not applicable

■ European Commission and/or Member States representatives:

- Bastiaan Schupp (DG SANTE)

■ EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Consuelo Civitella, Alexandros Lioupis, Ellen Van Haver and Katharina Volk

APDESK Unit: Constanza Miranda

FEED Unit: Fabiola Pizzo

¹ By teleconference

² Present on 10 September only

³ Not present in the afternoons of 8 & 9 September

⁴ Present on 8 September only

⁵ 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>.



1. Welcome and apologies for absence

The Chair welcomed the participants and welcomed the new member E. Benfenati that joined the FCM WG for the Prioritisation exercise for substances without an SML (agenda item 5.5).

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 Independence⁶ and the Decision of the Executive Director on Competing Interest Management⁷, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting, please refer to Annexes I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 8th WG meeting, held on 3-5 September 2019

The minutes of the 8th WG meeting held on 3-5 September 2019 were agreed by written procedure⁸.

5. Scientific topic(s) for discussion

5.1. EC mandate: untreated wood flour and fibres (FCM No 96) (EFSA-Q-2019-00089)⁹

The WG continued the discussion on the mandate received from the European Commission to review whether the authorisation of untreated wood flour and fibres (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004. Following the discussions at the last WG meeting, the draft opinion was discussed further and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.2. 1,1,2,3,3-pentafluoro-3-(heptafluoro-propoxy)prop-1-ene for use as monomer in plastics (EFSA-Q-2019-00099)¹⁰

The dossier received from the applicant was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.3. Bis(2-ethylhexyl)-cyclohexane-1,4-dicarboxylate (EFSA-Q-2018-00549)¹¹

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁸ <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00089>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00099>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00549>



Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion at the next FCM WG meeting.

5.4. Cyclooctene homopolymer (PCOE) and Cobalt stearate (EFSA-Q-2019-00387)

The dossier received from the applicant was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.5. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150)¹²

The terms of reference of the EU mandate for the priority setting of substances of the FCM Union list without an SML were presented together with the on-going activities on the collection of chemical/toxicological information, setting the relevant criteria for the use of information, the *in silico* predictions and the feedback received from the EU Member States on risk assessments at national level. The working group discussed on the criteria, methodology and tools available to prioritise the substances.

6. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

7. Next meeting(s)

The next meeting will take place 26-28 November 2019 in Parma.

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), he has responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This includes e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹³ and the Decision of the Executive Director on Competing Interest Management¹⁴, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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

MINUTES OF THE 8TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

Held on 3-5 September 2019, Parma

(Agreed on 24 September 2019)

Participants

■ Working Group Members:

Laurence Castle, Riccardo Crebelli^{1,2}, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig^{1,3}, Evgenia Lampi, Maria Rosaria Milana^{1,2}, Karla Pfaff, Gilles Rivière (Chair) and Detlef Wölfe⁴

■ Hearing Experts⁵:

- not applicable

■ European Commission and/or Member States representatives:

- not applicable

■ EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Alexandros Lioupis, Ellen Van Haver and Katharina Volk

APDESK Unit: Remigio Marano, Constanza Miranda

¹ By teleconference

² Not present on 4 September PM

³ Not present on 5 September

⁴ For agenda point 5.1, by teleconference

⁵ 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>.



1. Welcome and apologies for absence

The Chair welcomed the participants and welcomed the two new members E. Di Consiglio and N. Hellwig that have joined the FCM WG. Apologies were received from Claudia Bognesi.

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 Independence⁶ and the Decision of the Executive Director on Competing Interest Management⁷, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting, please refer to Annexes I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 7th WG meeting, held on 18-19 June 2019

The minutes of the 7th WG meeting held on 18-19 June 2019 were agreed by written procedure⁸.

5. Scientific topic(s) for discussion

5.1. Tris (2-ethylhexyl) benzene-1,2,4-tricarboxylate (EFSA-Q-2017-00645)⁹

Following the discussions at the last WG meeting the draft opinion was discussed further and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.2. Cellulose pulp, bleached (EFSA-Q-2017-00740)¹⁰

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.3. Re-evaluation waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks (EFSA-Q-2018-00558)¹¹

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁸ <http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00645>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00740>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00558>



The dossier received from the applicant was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.4. EC mandate: untreated wood flour and fibres (FCM No 96) (EFSA-Q-2019-00089)¹²

The WG continued the discussion on the mandate received from the European Commission to review whether the authorisation of untreated wood flour and fibres (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004. A second draft of the opinion was discussed and changes were noted. A revised draft opinion will be scheduled for discussion at the October FCM WG meeting.

6. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

7. Next meeting(s)

The next meeting will take place 8-10 October 2019 in Parma.

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00089>



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), he has responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This includes e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹³ and the Decision of the Executive Director on Competing Interest Management¹⁴, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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

MINUTES OF THE 7TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

**Held on 18-19 June 2019, Zurich
(Agreed on 8 July 2019)**

Participants

■ Working Group Members:

Laurence Castle, Riccardo Crebelli¹, Roland Franz, Koni Grob, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff, Gilles Rivi  re (Chair) and Detlef W  lfle²

■ Hearing Experts³:

- not applicable

■ European Commission and/or Member States representatives:

- not applicable

■ EFSA:

FIP Unit: Eric Barth  l  my, Anna F. Castoldi, Alexandros Lioupis, Ellen Van Haver¹ and Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants and thanked the Kantonal Labor Zurich for hosting the meeting at their premises. Apologies were received from Claudia Bolognesi. The WG members were informed that Beat Johannes Br  schweiler resigned from the CEP Panel and its WGs.

¹ By teleconference

² For agenda point 5.1, by teleconference

³ 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. Adoption of agenda

The agenda was adopted without changes.

3. 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, please refer to Annexes I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 5th & 6th WG meeting, held on 7-8 May 2019 and 23 May 2019

The minutes of the 5th WG meeting held on 7-8 May 2019 and 6th WG meeting held on 23 May were agreed by written procedure⁶.

5. Scientific topic(s) for discussion

5.1. Tris (2-ethylhexyl) benzene-1,2,4-tricarboxylate (EFSA-Q-2017-00645)^{7 8}

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed, and changes were noted. The revised draft opinion will be scheduled for discussion at the next FCM WG meeting.

5.2. Benzophenone-3,3',4,4'-tetracarboxylic dianhydride (EFSA-2018-01007)⁹

The dossier received from the applicant was discussed. The draft opinion was discussed and changes were noted. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.3. EC mandate: untreated wood flour and fibres (FCM No 96) (EFSA-Q-2019-00089)¹⁰

The WG continued the discussion on the mandate received from the European Commission to review whether the authorisation of untreated wood flour and fibres (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004. A first draft of the opinion was discussed and

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

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wq-m.pdf>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00645>

⁸ This agenda item was chaired by Laurence Castle

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01007>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00089>



changes were noted. A revised draft opinion will be scheduled for discussion at the September FCM WG meeting.

6. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

7. Next meeting(s)

The next meeting will take place 3-5 September 2019 in Parma.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), he has responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This includes e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹¹ and the Decision of the Executive Director on Competing Interest Management¹², and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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 FOOD CONTACT MATERIALS 2018-2021

**Held on 23 May 2019, Parma (Italy)
(Agreed on 17 June 2019)**

Participants

- Working Group Members:
Beat Johannes Brüscheweiler, Laurence Castle, Riccardo Crebelli, Roland Franz, Gilles Rivière (Chair)
- Hearing Experts:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
FIP Unit: Eric Barthélémy, Anna F. Castoldi, , Alexandros Lioupis, Ellen Van Haver,
Repro Unit: Giovanni Bernasconi
Feed Unit: Fabiola Pizzo
- Others:
Not Applicable

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 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.

4. Agreement of the minutes of the 4th WG meeting, held on 11-12 March 2019, Parma.

The minutes of the 5th WG meeting held on 7 and 8 May 2019 will be agreed by written procedure³ and will be recorded in the minutes of a next WG meeting.

5. Scientific topic(s) for discussion

5.1 Mandate on the prioritisation of Union list FCM substances without an SML, EFSA-Q-2019-00150.⁴

The WG discussed the criteria and tools used to place the substances under low, medium and high priority groups, in the frame of the EU mandate for the priority setting of substances of the FCM Union list without an SML. The discussion focused on the retrieval of chemical and toxicological information available in databases and the use of predictive structure-activity tools.

6. Next meeting(s)

The next meeting will take place on 18-19 June 2019.

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

³ <http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>

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

MINUTES OF THE 5TH MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

Held on 7-8 May 2019, Parma

(Agreed on 27 May 2019)

Participants

- Working Group Members:
Claudia Bolognesi, Beat Johannes Brüscheiler, Laurence Castle, Riccardo Crebelli, Roland Franz, Koni Grob, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff and Gilles Rivière (Chair)
- Hearing Experts¹:
 - for item 6.3: Stefania Bencini (Sabo); Enrico Galfrè (Sabo); Omolola Akintoye (Intertek)
- European Commission and/or Member States representatives²:
Jonathan Briggs, Takis Daskaleros (DG SANTE)
- EFSA:
FIP Unit: Eric Barthélémy, Anna F. Castoldi, Cristina Croera, Alexandros Lioupis, Claudia Roncancio Peña, Ellen Van Haver and Katharina Volk
AMU Unit: Irene Munoz (item 6.2)
SCER Unit: Georges Kass (item 7.2)

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 By teleconference



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 Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, as well as the Oral Declaration(s) of Interest at the beginning of the meeting, and for conflicts of interest identified therein, please refer to Annexes I and II, respectively.

4. Agreement of the minutes of the 4th WG meeting, held on 12-14 March 2019

The minutes of the 4th WG meeting held on 12-14 March 2019 were agreed by written procedure⁵.

5. Hearing Expert (s)

Ms Omolola Akintoye, Ms Stefania Bencini and Mr Enrico Galfrè were invited to present their views for item 6.3 of the present meeting. They attended the meeting on 7 May 2019 from 14:00 till 15:15.

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, EFSA invited Ms Omolola Akintoye, Ms Stefania Bencini and Mr Enrico Galfrè to submit an Annual Declaration of Interest. Their participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e. not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

6. Scientific topic(s) for discussion

6.1. Titanium dioxide treated with fluoride modified alumina (EFSA-Q-2014-00300)⁶

Upon request from the CEP Panel at their last plenary meeting⁷, the cross cutting Working Group on nanotechnologies of the Scientific Committee was consulted for the characterisation of the additive.

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 <http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00300>

⁷ http://www.efsa.europa.eu/sites/default/files/event/190402-m_0.pdf



The draft opinion was slightly revised following this consultation and the revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

6.2. EC mandate: untreated wood flour and fibres (FCM No 96) (EFSA-Q-2019-00089)⁸

The WG continued the discussion on the mandate received from the European Commission to review whether the authorisation of untreated wood flour and fibres (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004.

6.3. Reaction product of stearyl-diethanol-amine with C18 saturated fatty acids (EFSA-Q-2016-00510)^{9, 10}

Upon request from EFSA, the interested parties were given the opportunity to clarify the additional data that the applicant provided following the request of the WG, as the data were not considered satisfactory to conclude on the risk assessment of the substance. Following the discussion during the hearing, EFSA has followed up by providing the interested parties with a written summary of the points discussed and with a letter requesting additional data. The scientific evaluation was suspended, awaiting submission of the additional information requested.

7. Other scientific topics for discussion

7.1. FCM evaluation of legislative framework

The FCM WG continued exchanging views on the evaluation of the legislative framework (Regulation (EU) No 1935/2004) on food contact materials and expressed its views as follows.

The European Commission is currently evaluating the framework Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food (called hereafter "the Regulation") in relation to its original objectives, the protection of food consumers and the functioning of the market (see [EC website](#)). In this context, the EFSA Food Contact Materials (FCM) Working Group (WG) discussed the functioning of the Regulation using, as a driver, the questionnaire sent to EFSA for its own interview. The FCM WG expresses views notably on the effectiveness of the Regulation in ensuring the safety of consumers, on the effectiveness of the positive list, on the definition of EFSA's role in the risk assessment procedure, on EFSA's tasks and resources, on the differences in the risk assessment for harmonised and non-harmonised material types and on the harmonisation for more material groups.

The FCM WG has the view that the Regulation partly achieves its objectives with regards to addressing human health and the interest of consumers. For regulated FCM types, such as plastics, it achieves the task for regulated intentionally added substances (IAS, i.e. monomers, other starting substances and additives), but does partly for non-regulated substances used and non-intentionally added substances (NIAS). For instance, in the current format of evaluation prior to authorisation, a specific application describing a particular production process and use may become converted to a rather generic listing of the substance open to all and with little or no specifications. In this way, much of the safety assessment (especially for NIAS) can be essentially invisible to users of that

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00089>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00510>

¹⁰ Agenda item 6.3 was chaired by L. Castle



substance. For non-EU regulated FCM types, neither the IAS nor the NIAS are clearly addressed in the Regulation, except under Art. 3, and specific measures foreseen for these FCM types have not been implemented. The Regulation also does not foresee the periodic revision of existing specific measures and provide a mechanism for doing it.

The WG considers the approach of having a list of authorised substances effective in ensuring the safety of the listed chemicals. However according to the current implementation of the Regulation, most authorised substances are listed without specification of the application and conditions of use, which hinders EFSA to apply more appropriate exposure scenarios. The present Union list for plastic encompasses a fraction of the migrating substances. It should be completed with other IAS not authorised/listed yet. In addition, results of the evaluation of NIAS by European and national Authorities should be reported. The safety of other/non-listed migrating chemicals should be addressed. For non-harmonised material types, it is desirable to follow the same approach, however the feasibility under the current system is questionable.

When it comes to considering new scientific knowledge and technological developments, the Regulation is not flexible with existing EU-regulated measures. As mentioned above, no revision and related mechanism is foreseen.

In reviewing the current functioning, other regulatory approaches, such as in the USA, Japan, China and South America (Mercosur) as well as REACH, should be considered to provide a robust and an enlightened evaluation.

The EFSA's role in the risk assessment procedure on regulated substances is defined, but limited to the application described by the petitioner. For instance, the tasks for the evaluation of NIAS and non-regulated IAS (used to manufacture harmonised and non-harmonised FCM types) are not clarified. If the Regulation should make the EFSA responsible for providing guidance for the safety evaluation (not only for applications), it is not the proper place for detailing the methodology. With regards to the evaluation of EU-regulated substances, the Regulation allows re-evaluation and consideration of new knowledge which might affect the safety assessment of authorised substance in relation to human health.

With regards to the applications on regulated substances evaluated by the FCM WG, the dossiers are usually complete, i.e. in accordance with the SCF guidelines and the [EFSA Note for Guidance](#). However, the quality and the amount of details is usually not sufficient to complete and finalise the scientific evaluation without asking for additional data. Requests to applicants for further information are normally met within set time limits.

In the current situation, EFSA would deserve more scientific staff to support the Working Groups and Panel in performing more scientific work. If the revision of the Regulation requires EFSA to do more tasks (such as more applications, more guidance, more coordination), more scientific staffs would be required. As part of new tasks, the WG believes that EFSA could support risk managers in providing guidance on the evaluation of potential risk further to non-compliance and analytical results showing potential concern.

According to the JRC report, there are differences in the restrictions set for non-harmonised and harmonised substances. This does not represent an issue *per se*, since when considering the same substance for different uses or for different material types, there may be important differences in exposure, reactions and fate, etc. However, for non-harmonised FCM types, it is an issue for compliance and mutual recognition when a substance used for the same applications in the same FCM type has different restrictions, such as limits. These problematic differences may originate from



using different testing conditions, different risk management approaches, lack of communication on the substances evaluated at national level and, of much importance, lack of harmonised risk assessment guidance.

The [EFSA FCM Network](#) is a useful platform for exchange of information between Member States, EFSA and other organisations in the area of FCM. The different approaches in the risk assessment, actual cases, new developments in the field and tools are presented and discussed. The Network aims to support and harmonise risk assessment practices in this area. However, as of today, the outcome of the FCM Network activities are more informative than binding. The Network should become a more active driver in regulatory implementation and improvement to increase its impact. It should provide draft guidance to unify risk assessment procedures, notably to facilitate mutual recognition among Member States.

Overall, the FCM WG believes that the Regulation achieves the objectives of food safety and functioning of the market better than a non-harmonised approach. The mixed approach currently operating does not work well, especially for non-EU harmonised FCM types. It notably creates different benchmarks for the safety requirement; a remarkable example is recycled plastics compared to recycled paper and board. More harmonisation is needed and the non-EU harmonised FCM types should be harmonised especially with regards to the safety requirements. The related specific measures should be implemented in priority, because e.g. of exposure to consumers and/or presence of contaminants, and/or NIAS, starting with for paper and board (including their recycling), printing inks, coatings, metals, multi-materials. This may require different approaches than the current one, and not all the assessments may be done by EFSA. However, safety evaluations should be clearly under the control of public institutions/ competent authorities.

Cooperation and coordination between EFSA and ECHA need to be strengthened to avoid duplication, to pool resources and to create synergies. European Reference Laboratory could be mandated to coordinate and harmonise the control of compliance (including document control and checking the safety assessment performed by producers) by National Reference Laboratories, promoting synergies with competence centres rather than duplication.

7.2. List of substances identified as emerging risks

G. Kass from the EFSA SCER Unit presented the procedure they applied for the identification of emerging chemical risks in the food and feed chain. The WG discussed the similarities and differences of this project with the EC mandate on the prioritisation of FCM substances without an SML¹¹.

8. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

The WG discussed the need for strengthening the WG with an additional expert in general toxicology and toxico-kinetics. There is also a need for an expert in toxicity and environmental modelling, computer chemistry and QSAR.

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>



9. Next meeting(s)

The next meeting will take place 18- 19 June 2019 in Zurich.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), he has responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This includes e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹² and the Decision of the Executive Director on Competing Interest Management¹³, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Annex II

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

With regard to this meeting, R Franz declared the following interest: his laboratory has done some experimental work in support of the application Titanium dioxide treated with fluoride modified alumina, under agenda item 6.1. In accordance with EFSA's Policy on Independence¹⁴ and the Decision of the Executive Director on Competing Interest Management¹⁵, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI) but it has been waived pursuant to the Decision of the Executive Director on Competing Interest Management. This means that the expert should not suffer from the exclusion from the meeting, but he may not be the chairman, vice-chairman or rapporteur of the WG.

G. Rivière declared the following interest in relation to agenda item 6.1: his employer ANSES has been involved in the assessment of published literature (between 2017 and 2019) on the toxicology of titanium dioxide as a food additive. In accordance with EFSA's Policy on Independence¹³ and the Decision of the Executive Director on Competing Interest Management¹⁴, 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, because this interest is in the context of the experts' employment with a public institution and considered to be of public interest duty and without risk management tasks. The assessment of the application under agenda item 6.1 does not cover the review of the ANSES evaluation.

¹⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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 FOOD CONTACT MATERIALS 2018-2021

Held on 12-14 March 2019, Parma

(Agreed on 3 April 2019)

Participants

■ Working Group Members:

Claudia Bolognesi¹, Beat Johannes Brüscheiler, Laurence Castle, Riccardo Crebelli, Roland Franz, Koni Grob, Evgenia Lampi, Karla Pfaff, Gilles Rivière (Chair) and Detlef Wölfle²

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Bastiaan Schupp (DG SANTE)

■ EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Cristina Croera, Alexandros Lioupis, Foteini Pantazi, Ellen Van Haver, Ana Rincon (item 5.2) and Katharina Volk

Apdesk Unit: Remigio Marano (items 5.4 & 5.5)

Feed Unit: Fabiola Pizzo (item 5.5)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Maria Rosaria Milana.

¹ Not present on 14 March

² Only for agenda point 5.1, by teleconference



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 Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, as well as the Oral Declaration(s) of Interest at the beginning of the meeting, and for conflicts of interest identified therein, please refer to Annexes I and II, respectively.

4. Agreement of the minutes of the 3rd WG meeting, held on 24&29 January 2019

The minutes of the 3rd WG meeting held on 24 & 29 January 2019 were agreed by written procedure⁵.

5. Scientific topic(s) for discussion

5.1. Phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters (EFSA-Q-2018-00411)⁶

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.2. Titanium dioxide treated with fluoride modified alumina (EFSA-Q-2014-00300)⁷

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.3. Reaction product of stearyl-diethanol-amine with C18 saturated fatty acids (additive) – Sabofog (EFSA-Q-2016-00510)⁸

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed. The WG requires clarification of the additional information provided in order to complete the risk assessment, possibly through a technical hearing.

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 <http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwg-wq-m.pdf>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00411>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00300>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00510>



5.4. EC mandate: untreated wood flour and fibres (FCM No 96) (EFSA-Q-2019-00089)⁹

EFSA received from the European Commission a mandate to review whether the authorisation of untreated wood flour and fibres (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004. The substance is presently authorised based on its inertness as an additive for the manufacture of plastic food contact materials, and listed in Annex I of Regulation (EU) No 10/2011, with no specific migration limit (SML). The WG started to identify possible criteria, not yet set out in the FCM Note for Guidance, for assessing the safety and support the use of wood and of similar materials from a plant origin, as plastic additives (art. 9 of Regulation (EC) No 1935/2004).

5.5. EC mandate: Prioritisation of substances without a specific migration limit (SML) (EFSA-Q-2019-00150)¹⁰

EFSA received from the European Commission a mandate for the priority setting of substances of the FCM Union list which have not been assigned an SML, for future risk assessment purposes. The WG discussed the criteria and tools that may be used in order to place the substances under low, medium and high priority groups.

6. Other scientific topics for discussion

The FCM WG continued exchanging views on the evaluation of the legislative framework (Regulation (EU) No 1935/2004) on food contact materials.

7. AOB

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

8. Next meeting(s)

The next meeting will take place 7-8 May 2019.

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00089>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150>



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his employment at Fraunhofer Institute for Process Engineering and Packaging (IVW), he has responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This includes e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence¹¹ and the Decision of the Executive Director on Competing Interest Management¹², and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

¹¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Annex II

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

With regard to this meeting, R Franz declared the following interest: his laboratory has done some experimental work in support of the application Titanium dioxide treated with fluoride modified alumina, under agenda item 5.2. In accordance with EFSA's Policy on Independence¹³ and the Decision of the Executive Director on Competing Interest Management¹⁴, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI) but it has been waived pursuant to the Decision of the Executive Director on Competing Interest Management. This means that the expert should not suffer from the exclusion from the meeting, but he may not be the chairmanship, vice-chairman or rapporteur of the WG.

G. Rivière declared the following interest in relation to agenda item 5.2: his employer ANSES has been involved in the assessment of published literature (between 2017 and 2019) on the toxicology of titanium dioxide as a food additive. In accordance with EFSA's Policy on Independence¹³ and the Decision of the Executive Director on Competing Interest Management¹⁴, 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, because this interest is in the context of the experts' employment with a public institution and considered to be of public interest duty and without risk management tasks. The assessment of the application under agenda item 5.2 does not cover the review of the ANSES evaluation.

¹³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Scientific Panel on Food Contact Materials, Enzymes and Processing Aids (CEP)

Minutes of the 3rd meeting of the Working Group on Food Contact Materials 2018-2021

**Held on 24 (4-6 pm) and 29 (2-4 pm) January 2019, by
teleconference**

(Agreed on 18 February 2019)¹

Participants

- **Working Group Members:**

Claudia Bolognesi², Beat Johannes Brüscheiler, Riccardo Crebelli, Roland Franz, Koni Grob, Evgenia Lampi, Maria Rosaria Milana², Karla Pfaff and Gilles Rivière (Chair)

- **European Commission and/or Member States representatives:**

DG SANTE: Takis Daskaleros and Bastiaan Schupp

- **EFSA:**

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Laurence Castle.

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 Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest,

¹ By written procedure

² Present on 24 January only

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

please refer to the Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 2nd WG meeting (14-15 November 2018)

The minutes of the 2nd WG meeting held on 14-15 November 2018 were agreed by written procedure⁵.

5. Scientific topic(s) for discussion

EFSA received end of December 2018 five mandates from the European Commission for updating the risk assessment of the FCM substances No 19 and 20, 96, 193, 220, and for prioritising the need for re-evaluating the substances without an SML as listed by Regulation (EU) No 10/2011 (following the removal of the Generic Specific Migration Limit (GML) of 60 mg/kg food).

The aim of this meeting was to discuss and identify possible issues in preparation to the CEP Plenary meeting (5-7 February) when the Panel will discuss the mandates before acceptance.

6. Next meeting(s)

The next meeting is scheduled for 12-14 March 2019.

⁵ <https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr. R Franz the following interest has been declared: in the context of his employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), he has responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This includes e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA FCM Working Group. In accordance with EFSA's Policy on Independence⁶ and the Decision of the Executive Director on Competing Interest Management⁷, and taking into account the specific matters discussed within the EFSA FCM Working Group, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr. Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁷

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

Scientific Panel on Food Contact Materials, Enzymes and Processing Aids (CEP)

Minutes of the 2nd meeting of the Working Group on Food Contact Materials 2018-2021

**Held on 14-15 November 2018, by teleconference
(Agreed on 29 November 2018)¹**

Participants

- **Working Group Members:**

Claudia Bolognesi, Beat Johannes Brüscheiler, Laurence Castle, Riccardo Crebelli, Koni Grob, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff, Gilles Rivière (Chair) and Detlef Wölflé²

- **European Commission and/or Member States representatives:**

DG SANTE: Takis Daskaleros

- **EFSA:**

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

Apdesk Unit: Remigio Marano

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 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

¹ By written procedure

² For agenda item 5.1 only

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

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 WG meeting (9-10 October 2018)

The minutes of the 1st WG meeting held on 9-10 October 2018 were agreed by written procedure⁵.

5. Scientific topic(s) for discussion

5.1 Phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters (EFSA-Q-2018-00411)⁶

The dossier received from the applicant was discussed. The draft opinion was discussed and changes were noted. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.2 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2017-00412 – all foods)⁷

Further to the discussions at the last WG meeting, the revised draft opinion was discussed and changes were noted. The draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.3 Bis(2-ethylhexyl) cyclohexane-1,4-dicarboxylate (EFSA-Q-2018-00549)⁸

The dossier received from the applicant was discussed. The draft opinion was discussed and changes were noted. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

6. Next meeting(s)

The next meeting is scheduled for 15-17 January 2019 (to be confirmed).

⁵ <https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00411>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00412>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00549>

Scientific Panel on Food Contact Materials, Enzymes and Processing Aids (CEP)

Minutes of the 1st meeting of the Working Group on Food Contact Materials 2018-2021

**Held on 9-10 October 2018, Parma (Italy)
(Minutes agreed on 26 October 2018)¹**

Participants

- **Working Group Members:**

Claudia Bolognesi, Beat Johannes Brüscheweiler, Laurence Castle, Koni Grob, Evgenia Lampi, Maria Rosaria Milana², Karla Pfaff, and Gilles Rivière (Chair)

- **European Commission and/or Member States representatives:**

DG SANTE: Takis Daskaleros

- **EFSA:**

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

Apdesk Unit: Remigio Marano

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from 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 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

¹ By written procedure

² Present on 9 October only

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

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

4. Working Group organisation

The Working Group members were informed about the status of ongoing applications (in stop-the-clock or evaluation ongoing). The applications were re-distributed among the current members as former FCM CEF WG members were previously appointed as rapporteurs for some of these applications. It was suggested to extend the WG with one additional expert with expertise in general toxicology in FCM to join the WG meetings on an *ad hoc* basis.

5. Scientific topic(s) for discussion

5.1 Montmorillonite organic clay (EFSA-Q-2013-00641)⁵

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption by the CEP Panel.

5.2 Cellulose pulp, bleached (EFSA-Q-2017-00740)⁶

The dossier received from the applicant was discussed. The draft opinion was discussed and changes were noted. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.3 Milled carbonised PAN based carbon fibre (EFSA-Q-2018-00064)⁷

The dossier received from the applicant was discussed. The draft opinion was discussed and changes were noted. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.4 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2017-00412 – all foods)⁸

Further to the receipt of the additional information requested from the applicant, the draft opinion was discussed and changes were noted. The WG identified issues for clarification to be further discussed at the next WG meeting.

6. Feedback from EFSA, CEP Panel and the European Commission

The WG members were informed about the draft statement on genotoxicity assessment of chemical mixtures that is currently under revision by the WG of the EFSA Scientific Committee. The WG briefly discussed the proposed approaches for assessing chemical mixtures in the context of FCMs.

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00641>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00740>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00064>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00412>

Some members of the WG attended the stakeholder workshop of the European Commission regarding the evaluation of the legislative framework on FCMs. More information on the Workshop can be found on the [dedicated webpage](#).

7. Other scientific topics for discussion

No other topics were discussed.

8. Any Other Business

The WG was informed about new mandates on food contact materials that were received by EFSA since the last WG meeting.

9. Next meeting(s)

The next meeting date will take place 14-15 November 2018 by teleconference.