

#### FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS

44<sup>th</sup> Working Group meeting on Food Contact Materials 23-25 January 2024, 14:00-18:00 / 09:00-18:00 / 09:00-16:00



**Location**: EFSA - Parma/web conference

#### Participants:

- Working Group Members:

Claudia Bolognesi, Ronan Cariou, Laurence Castle, Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Konrad Grob, Claude Lambré, Evgenia Lampi, Maria Rosaria Milana, Gilles Rivière (Chair) and Detlef Wölfle

- Hearing Experts<sup>1</sup>: none
- European Commission and/or Member States representatives:
  - DG SANTE: none
- EFSA:
  - FIP Unit: Eric Barthélémy (coordinator), Marianna Ciccone, Daniele Comandella, Remigio Marano, Sandra Rainieri

#### 1. Welcome and Apologies for absence

The Chair welcomed the participants. D Wölfle was invited and participated only to item 5.3. Apologies were received from N Hellwig (whole meeting) and R Franz (first day).

#### 2. Adoption of the agenda

The agenda was adopted without changes.

#### 3. Declarations of interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.

 $<sup>{\</sup>tiny \frac{2}{h}} \underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf}$ 

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf



issues discussed in this meeting have been identified during the screening process. No interests were declared orally by the members before the beginning of the meeting.

#### 4. Agreement of the minutes of the 43rd WG meeting

The minutes of the  $43^{rd}$  WG meeting held on 21-23 November 2023 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

5.1 Nonamethylenediamine & 2-methyl-1,8-octadiamine (EFSA-Q-2019-00533 and -00534)<sup>5</sup>

Further to the receipt of the additional information requested from the applicant, the Working Group finalised the draft opinion. The draft opinion will be scheduled for discussion and possible adoption at a forthcoming meeting of the CEP Panel.

#### 5.2 Calcium tert-butylphosphonate (EFSA-Q-2022-00526)<sup>6</sup>

Further to the receipt of the additional information requested from the applicant, the Working Group finalised the draft opinion. The draft opinion will be scheduled for discussion and possible adoption at a forthcoming meeting of the CEP Panel.

5.3 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) (EFSA-Q-2019-00483 and -00484)<sup>7</sup>

Further to the receipt of part of the additional information requested from the business operators, the draft opinion was discussed and changes were noted. The scientific evaluation is currently suspended, awaiting submission of additional information requested.

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00533 and https://open.efsa.europa.eu/questions/EFSA-Q-2019-00534

<sup>&</sup>lt;sup>6</sup> https://open.efsa.europa.eu/dossier/FCM-2022-8691

<sup>&</sup>lt;sup>7</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00483 and https://open.efsa.europa.eu/questions/EFSA-Q-2019-00484



#### 6. Other scientific topics for discussion

#### 6.1 Possible EC mandates

The Working Group continued the discussion on the possible draft mandates shared by the European Commission.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from the EC

None

#### 7.2 Feedback from EFSA

None

#### 8. Any other business

The progress of the activities carried out within an EFSA guest program associated with a PhD project on microbial biopolymers for innovative packaging to increase food shelf-life and safety was presented. The activities are considering the recently published EFSA report on 'Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials'.

#### Next meeting

The next meeting is scheduled to take place on 5-7 March as web conference.



#### FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS

43<sup>rd</sup> Working Group meeting on Food Contact Materials 21-22 November 2023, 14:00-18:00 / 09:00-18:30



**Location**: EFSA - Parma/web conference

#### Participants:

- Working Group Members:

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

- Hearing Experts<sup>1</sup>: none
- European Commission and/or Member States representatives:
  - DG SANTE: Martinus Nagtzaam
- EFSA:
  - FIP Unit: Zainab Al Harraq, Eric Barthélémy (coordinator), Marianna Ciccone, Daniele Comandella, Julia Fontan Vela

#### 1. Welcome and Apologies for absence

The Chair welcomed the participants. For item 5.3 scheduled on 22 November, only C Bolognesi, R Crebelli, E Di Consiglio, C Lambré, M Mengelers (invited for this item only) and G Rivière were invited. D Wölfle was invited and participated only to item 5.2. Apologies were received from Nicole Hellwig (whole meeting), Claude Lambré (whole meeting) and E Di Consiglio (from 14:00 to 14:30 on second day).

#### 2. Adoption of the agenda

The agenda was adopted without changes.

#### 3. Declarations of interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

# MINUTES 43<sup>rd</sup> Working Group meeting on Food Contact Materials



issues discussed in this meeting have been identified during the screening process. No interests were declared orally by the members before the beginning of the meeting.

#### 4. Agreement of the minutes of the 42<sup>nd</sup> WG meeting

The minutes of the 42<sup>nd</sup> WG meeting held on 9 November 2023 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

5.1 Triphenyl phosphite, polymer with CHDM and polypropylene glycol, C10-16 alkyl esters (EFSA-Q-2022-00613)<sup>5</sup>

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

5.2 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) (EFSA-Q-2019-00483 and -00484)<sup>6</sup>

Further to the receipt of part of the additional information requested from the applicants, the WG revised parts of the draft opinion. The scientific evaluation is currently suspended, awaiting submission of additional information requested.

5.3 Re-evaluation of Styrene safety of use in FCMs (EFSA-Q-2023-00365)<sup>7</sup>

The WG discussed sections of the draft opinion based on recently added data.

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/dossier/FCM-2022-6990

<sup>&</sup>lt;sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00483 https://open.efsa.europa.eu/questions/EFSA-Q-2019-00484

<sup>&</sup>lt;sup>7</sup> https://open.efsa.europa.eu/guestions/EFSA-O-2023-00365



#### 6. Other scientific topics for discussion

#### 6.1 Possible EC mandates

The Working Group continued the discussion on the possible draft mandates shared by the European Commission.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from the EC

None

#### 7.2 Feedback from EFSA

None

#### 8. Any other business

A PhD project on microbial biopolymers for innovative packaging to increase food shelf-life and safety was presented, together with related potential activities to be carried out in the context of the recently published EFSA report on 'Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials'.

#### Next meeting

The next meeting is scheduled to take place on 23-25 January as web conference.



Location: EFSA - Parma / Web conference

#### Participants:

- Working Group Members:
   Claudia Bolognesi, Riccardo Crebelli, Emma di Consiglio, Claude Lambré, Marcel Mengelers,
   Gilles Rivière (Chair).
- European Commission and/or Member States representatives:
  - o DG SANTE: Bastiaan Schupp, Jonathan Briggs.
- o EFSA:
  - FIP Unit: Zainab Al Harrag, Julia Fontan Vela, Sandra Rainieri.

#### 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. 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 41<sup>st</sup> Working Group meeting held on 19-20 September 2023 via web-conference

The minutes of the 41<sup>st</sup> Working Group meeting held on 19-20 September 2023 were agreed by written procedure on 06 October 2023.

## 5. Scientific topic(s) for discussion Re-evaluation of Styrene safety of use in FCMs

The WG discussed the feedback from PE/SIRC on the additional data requested and went through the comments received at the FCM Network meeting held on 17 October 2023.

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf



### **6. Any other business**

#### **Next meeting:**

The next FCM WG meeting is scheduled to take place on 21-22 November, by web conference.





41<sup>st</sup> Working Group meeting on Food Contact Materials 19-20 September 2023, 14:00-18:00 / 09:00-12:30



Location: EFSA - Parma/Web conference

#### Participants:

- Working Group Members:

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

- Hearing Experts1: none
- European Commission and/or Member States representatives:
  - DG SANTE: Martinus Nagtzaam
- EFSA:
  - FIP Unit: Zainab Al Harraq, Eric Barthélémy (coordinator), Daniele Comandella, Remigio Marano, Sandra Rainieri

#### 1. Welcome and Apologies for absence

The Chair welcomed the participants. For item 5.2 scheduled on 20 September, only C Bolognesi, R Crebelli, E Di Consiglio, C Lambré, M Mengelers (invited for this item only) and G Rivière were invited. Apologies were received from Emma Di Consiglio (from 14:00 to 15:00 on the first day), from Claude Lambré (whole second day), Maria Rosaria Milana (from 14:00 to 14:30 on the first day, and whole second day) and from Nicole Hellwig (for the whole meeting).

#### 2. Adoption of the agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.

## MINUTES and SECRETARY NOTES 41st Working Group meeting on Food Contact Materials



#### 3. Declarations of interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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. No interests were declared orally by the members before the beginning of the meeting.

#### 4. Agreement of the minutes of the 40th WG meeting

The minutes of the 40<sup>th</sup> WG meeting held on 27-29 June were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

### 5.1 Safety assessment of compounds and mixtures of natural origin (EFSA-Q-2023-00256)<sup>5</sup>

Following the presentation and discussion of the draft EFSA Technical report at the CEP Panel plenary meeting in July, the Working Group reviewed the proposed changes and comments. The Working Group endorsed the report that will be validated by EFSA before publication.

### 5.2 Re-evaluation of Styrene safety of use in FCMs (EFSA-Q-2023-00365)<sup>6</sup>

The Working Group discussed the first draft of the Styrene opinion and addressed the pending comments. Feedback on the 37<sup>th</sup> CEP Panel Plenary meeting was given in relation to the questions received on the preliminary evaluation and conclusions. The Working Group discussed the literature search update performed in July.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2023-00256

<sup>&</sup>lt;sup>6</sup> https://open.efsa.europa.eu/guestions/EFSA-Q-2023-00365



#### 6. Other scientific topics for discussion

### 6.1 Advance aggregated exposure to Chemicals in EU (ExpoAdvance)

The Working Group was informed on and discussed the ExpoAdvance project, which is based on the 2022 EFSA Technical Report "Theme (concept) paper - Advancing Aggregate Exposure to Chemicals in EU (ExpoAdvance)". The project aims at defining a roadmap for building a framework on the determination of aggregate exposure to chemicals (i.e., exposure to a single chemical from multiple routes of exposure). This one-year project is coordinated by EFSA and carried out by a consortium made of experts from universities and institutions from Europe and North America.

#### **6.2 Possible EC mandates**

The Working Group continued the discussion on the possible draft mandates shared by the European Commission.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from the EC

M Nagtzaam reported the ongoing EC activities related to plastic food contact materials and the upcoming amendment of the Regulation (EC) 10/2011.

#### 7.2 Feedback from EFSA

None

#### 8. Any other business

#### Next meeting

The next meeting is scheduled to take place on 21-23 November as web conference.

<sup>&</sup>lt;sup>7</sup> https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2022.e201001



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Location: EFSA - Parma

#### Participants:

- Working Group Members:

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

- Hearing Experts1: none
- European Commission and/or Member States representatives:
  - DG SANTE: Jonathan Briggs, Martinus Nagtzaam
- EFSA:
  - FIP Unit: Zainab Al Harraq, Eric Barthélémy (coordinator), Daniele Comandella, Remigio Marano, Sandra Rainieri

#### 1. Welcome and Apologies for absence

The Chair welcomed the participants. Apologies were received from Nicole Hellwig and Stefan Merkel (for the whole meeting), from Maria Rosaria Milana (on 28 June from 09:00 to 11:00) and from C Lambré (on 28 June from 09:00 to 17:00, on 29 June from 09:00 to 11:00).

Only C Bolognesi, R Crebelli, E Di Consiglio, C Lambré, M Mengelers (invited for this item only) and G Rivière participated to the discussion on item 5.4 on 29 June afternoon.

#### 2. Adoption of the agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.



#### 3. Declarations of interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

#### 4. Agreement of the minutes of the 39th WG meeting

The minutes of the 39th WG meeting held on 20 June were agreed by written procedure4.

#### 5. Scientific outputs submitted for discussion

### 5.1 Amendment to the SML(T) applicable to Crotonic Acid as a NIAS related to FCM 1059 (PHBH)(EFSA-Q-2023-00022)<sup>5</sup>

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.

### 5.2 Mixture of CHDM, Ether-Dimer and Ester-Dimer (EFSA-Q-2023-00021)<sup>6</sup>

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.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/dossier/FCM-2022-12110

<sup>&</sup>lt;sup>6</sup> https://open.efsa.europa.eu/dossier/FCM-2022-11011



### 5.3 Safety assessment of mixtures of natural origin to manufacture food contact materials

Following the presentation at the CEP Panel in June, the WG further discussed the principles that could be used in the safety assessment of mixtures of natural origin to manufacture FCMs.

#### 5.4 Re-evaluation of Styrene safety of use in FCMs

The WG discussed the comments on the preliminary findings received during the consultation of the cross cutting WG on Genotoxicity. The requests for additional data to be made to the applicant were discussed and finalized.

#### 6. Other scientific topics for discussion

#### 6.1 Possible mandates from EC

The working group continued the discussion started at the 35<sup>th</sup> meeting on the possible draft mandates shared by the European Commission.

# 6.2 Use of International Uniform Chemical Information Database (IUCLID) software for Drinking Water applications and possible use for FCM applications

An update on the use of IUCLID for submitting and assessing data in the context of Art. 11 of the drinking water directive was given.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from the EC

The item was deferred to a next meeting due to lack of time.

#### 7.2 Feedback from EFSA

None



#### 8. Any other business

#### Next meeting

The next meeting is scheduled to take place on 19-21 September as web conference.

#### **Annex**

#### Interests and actions resulting from the Oral Declaration of Interest

With regard to this meeting, Claude Lambré declared the following interest: "Participation to a Working Group on tobacco at the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), which could potentially assess formaldehyde". In accordance with EFSA's Policy on Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

 $<sup>^{7} \; \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate}} \; \; \underline{\text{publications/files/policy}} \; \; \underline{\text{independence.pdf}} \; \\$ 

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 39<sup>th</sup> Working Group meeting on Food Contact Materials 20 June 2023, 10:00 – 11:45

**Location**: EFSA – Parma /Web conference

#### Participants:

- Working Group Members:
   Claudia Bolognesi, Riccardo Crebelli, Emma di Consiglio, Claude Lambré, Marcel Mengelers,
   Gilles Rivière (Chair).
- o EFSA:
  - FIP Unit: Zainab Al Harraq, Marta Lopez Villegas, Sandra Rainieri

#### 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. 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 38<sup>th</sup> Working Group meeting held on 01 June 2023 via web-conference

The minutes of the 38<sup>th</sup> Working Group meeting held on 01 June 2023 were agreed by written procedure on 12 June 2023.

#### 5. Scientific topic(s) for discussion

#### Re-evaluation of Styrene safety of use in FCMs

The WG discussed the evidence on the intestinal metabolism of Styrene identified by the literature search and addressed all the pending issues left from the previous meeting.

#### 6. Next meetings

The next FCM WG meeting is scheduled to take place on 27-28-29 June in Parma.

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

# SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS 38<sup>th</sup> Working Group meeting on Food Contact Materials 01 June 2023, 10:00 – 13:00

EUROPEAN OOD SAFETY AUTHORITY

**Location**: EFSA – Parma /Web conference

#### Participants:

 Working Group Members:
 Riccardo Crebelli, Emma di Consiglio, Claude Lambré, Marcel Mengelers, Gilles Rivière (Chair).

o EFSA:

- FIP Unit: Zainab Al Harraq, Marta Lopez Villegas, Sandra Rainieri

MESE Unit: Jean-Lou Dorne

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received by Claudia Bolognesi.

#### 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. 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 37<sup>th</sup> Working Group meeting held on 03-04 May 2023 via web-conference

The minutes of the 37<sup>th</sup> Working Group meeting held on 03-04 May were agreed by written procedure on 23<sup>rd</sup> May 2023.

#### 5. Scientific topic(s) for discussion

#### Styrene safety re-evaluation

The WG finalized the evaluation of the literature on Toxicokinetics (Tks) and human biomonitoring (HBM) of Styrene, published in the last five years.

#### 6. Next meetings

The next FCM WG meeting is scheduled to take place on 20th June (web conference).

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf



Location: EFSA - Parma / Web conference

#### Participants:

- Working Group Members:

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

- Hearing Experts1: none
- European Commission and/or Member States representatives:
  - DG SANTE: Jonathan Briggs, Silvia Costante, Bastiaan Schupp
- EFSA:
  - FIP Unit: Zainab Al Harraq, Eric Barthélémy, Daniele Comandella, Remigio Marano, Sandra Rainieri

#### 1. Welcome and Apologies for absence

The Chair welcomed the participants. Apologies were received from R Crebelli (from 15:45 to the end of the day on 3 May) and E Lampi (from 12:15 to the end of the meeting on 4 May).

Only C Bolognesi, R Crebelli, E Di Consiglio, C Lambré, M Mengelers and G Rivière participated to the discussion on item 5.4.

#### 2. Adoption of the agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.

## MINUTES and SECRETARY NOTES 37<sup>th</sup> Working Group meeting on Food Contact Materials



#### 3. Declarations of interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

#### 4. Agreement of the minutes of the 36th WG meeting

The minutes of the 36<sup>th</sup> WG meeting held on 12 April 2023 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

#### 5.1 OLA8 Oligomeric Lactic Acid (EFSA-Q-2021-00179)<sup>5</sup>

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

#### 5.2 Calcium tert-butylphosphonate (EFSA-Q-2022-00526)<sup>6</sup>

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.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00179?search=EFSA-Q-2021-00179

<sup>&</sup>lt;sup>6</sup> https://open.efsa.europa.eu/guestions/EFSA-O-2022-00526?search=Calcium+tert-butylphosphonate



### 5.3 Safety assessment of mixtures of natural origin to manufacture food contact materials

Following the feedback received from the FIP FCM Network in April, the WG further discussed the principles that could be used in the safety assessment of mixtures of natural origin to manufacture FCMs.

#### 5.4 Styrene

The WG progressed on the safety assessment of styrene and discussed the comments raised at the 9<sup>th</sup> FCM Network held on 20 April in which the ongoing work on the assessment was presented (see Minutes, agenda item 4).

#### 6. Other scientific topics for discussion

#### 6.1 Possible mandates from EC

The discussion was deferred to a next WG meeting, due to lack of time.

# 6.2 Use of International Uniform Chemical Information Database (IUCLID) software for Drinking Water applications and possible use for FCM applications

The discussion was deferred to a next WG meeting, due to lack of time.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

None

#### 7.2 Feedback from the EC

The EC provided feedback on the draft  $17^{th}$  amendment to Reg. (EU) 10/2011.

# MINUTES and SECRETARY NOTES 37<sup>th</sup> Working Group meeting on Food Contact Materials



#### 7.3 Feedback from EFSA

Feedback was given on the  $9^{th}$  FCM Network meeting held on 20 April. The Minutes are published on EFSA Website <u>there</u>.

#### 8. Any other business

#### Next meeting

The next meeting is scheduled to take place on  $1^{\text{st}}$  June (web conference).

## MINUTES and SECRETARY NOTES 37<sup>th</sup> Working Group meeting on Food Contact Materials



#### **Annex**

#### Interests and actions resulting from the Oral Declaration of Interest

With regard to this meeting, Nicole Hellwig and Stefan Merkel declared the following interest: "Contribution to the assessment of a 'Wax, rice bran, oxidized and wax, rice bran, partially saponified' for its inclusion in the German positive list of FCM printing inks at the German Federal Institute for Risk Assessment (BfR)". In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a Conflict of Interest for the experts concerned.

Nicole Hellwig and Stefan Merkel also declared the following interest: "Involvement in the preparation of the opinion on formaldehyde in FCM at German Federal Institute for Risk Assessment (BfR)". In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a Conflict of Interest for the experts concerned.

Claude Lambré declared the following interest: "Participation to a Working Group on tobacco at the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), which could potentially assess formaldehyde". In accordance with EFSA's Policy on Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

<sup>&</sup>lt;sup>7</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 36<sup>th</sup> Working Group meeting on Food Contact Materials 12 April 2023

Location: EFSA - Parma / Web conference

#### **Participants:**

Working Group Members:
 Claudia Bolognesi, Riccardo Crebelli, Emma di Consiglio, Claude Lambré, Marcel Mengelers,
 Gilles Rivière (Chair).

o EFSA:

-FIP Unit: Zainab Al Harraq, Upeksha Alwis.

#### 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. 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 35<sup>th</sup> Working Group meeting held on 29 April 2023 via web-conference

The minutes of the  $35^{th}$  Working Group meeting were agreed by written procedure on  $18^{th}$  April 2023.

#### 5. Scientific topic(s) for discussion

The WG thoroughly discussed the preliminary conclusions of the evaluation of the Genotoxicity evidence as well as the toxicokinetics (Tks) aspects related to Styrene and Styrene 7,8-oxide.

The full text screening of the literature on Tks and human biomonitoring (HBM) was initiated and will be finalized and discussed at the next FCM WG meetings.

#### 6. Next meeting(s)

The next meeting is scheduled to take place on 3-4 May 2023 by teleconference.

<sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> 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 35th Working Group meeting on Food Contact Materials 28-30 March 2023

Location: EFSA - Parma / Web conference

#### Participants:

- Working Group Members:

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

- Hearing Experts1: none
- European Commission and/or Member States representatives:
  - DG SANTE: Jonathan Briggs, Silvia Costante, Bastiaan Schupp
- EFSA:
  - FIP Unit: Zainab Al Harraq, Eric Barthélémy, Daniele Comandella, Remigio Marano, Sandra Rainieri, Alwis Upeksha
  - MESE unit: Jane Richardson
- Other participants: Dorota Burchard-Sosnowska, Panagiotis Zarogiannis (ECHA)

#### 1. Welcome and Apologies for absence

The Chair welcomed the participants. Apologies were received from Laurence Castle (14:00-16:00 on 29 March) and E Di Consiglio (for 29 March afternoon and the whole of 30 March). Only R Crebelli, C Bolognesi, E di Consiglio, C Lambré and M Mengelers participated to the discussion on item 5.2.

#### 2. Adoption of the agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.



#### 3. Declarations of interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

#### 4. Agreement of the minutes of the 34th WG meeting

The minutes of the 34<sup>th</sup> WG meeting held on 8-9 February 2023 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

5.1 Triphenyl phosphite, polymer with 1,4cyclohexanedimethanol and polypropylene glycol, C10-16 alkyl ester (EFSA-Q-2022-00613)<sup>5</sup>

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. Other scientific topics for discussion

#### 6.1 Possible mandates from EC

The working group continued the discussion started at the 34<sup>th</sup> meeting on the possible draft mandates shared by the European Commission.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/dossier/FCM-2022-6990



### 6.2 Safety assessment of mixtures of natural origin to manufacture food contact materials

Following the feedback received from the CEP Panel at the March Plenary, the WG further discussed the principles that could be used in the safety assessment of mixtures of natural origin to manufacture FCMs.

#### 6.3 Level of safety

The working group discussed the challenges posed by current capabilities of compositional analyses to the risk assessment of compounds and mixtures of natural origin in FCM.

# 6.4 Use of International Uniform Chemical Information Database (IUCLID) software for Drinking Water applications and possible use for FCM applications

An update on the use of IUCLID for submitting and assessing data in the context of Art. 11 of the drinking water directive was given.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

None

#### 7.2 Feedback from the EC

The EC provided feedback on the revision of the FCM legislation.

#### 8. Any other business

#### Next meetings

The next meeting is scheduled to take place on 12 April 2023 by teleconference.

## MINUTES 35<sup>th</sup> Working Group meeting on Food Contact Materials



#### **Annex**

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

With regard to this meeting, Nicole Hellwig and Stefan Merkel declared the following interest: "Involvement in the preparation of the opinion on formaldehyde in FCM at the German Federal Institute for Risk Assessment (BfR)". In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a Conflict of Interest for the experts concerned.

Claude Lambré declared the following interest: "Participation to a Working Group on tobacco at the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), which could potentially assess formaldehyde". In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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.

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf



Location: EFSA - Parma / Web conference

#### Participants:

- Working Group Members:

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

- Hearing Experts<sup>1</sup>: none

- European Commission and/or Member States representatives:

- DG SANTE: Stella d'Amore

- EFSA:

- FEEDCO Unit: Paola Manini

- FIP Unit: Zainab Al Harraq, Eric Barthélémy, Daniele Comandella, Remigio Marano Carla Martino, Sandra Rainieri

KNOW Unit: Bernard Bottex
 MESE Unit: Jean-Lou Dorne
 NIF Unit: Eirini Kouloura

Other participants: none

#### 1. Welcome and Apologies for absence

The Chair welcomed the participants. Apologies were received from C Bolognesi (afternoon on 8 February and whole 9 February) E Di Consiglio (from 15:00 to 16:00 on 8 February) and S Merkel (whole 9 February).

#### 2. Adoption of the agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.



#### 3. Declarations of interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

#### 4. Agreement of the minutes of the 33rd WG meeting

The minutes of the  $33^{rd}$  WG meeting held on 14-15 December 2022 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

### 5.1 Wax, rice bran, oxidized and wax, rice bran, partially saponified (EFSA- Q-2022-00452)<sup>5</sup>

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 the submission of the additional information requested.

#### **6. Other scientific topics for discussion**

#### 6.1 EC possible mandates

EFSA presented and discussed possible mandates from the European Commission.

### 6.2 Safety assessment of compounds and mixtures of natural origin

Following the discussions at previous WG meetings, the working group further discussed principles that can be potentially used in the safety assessment of compounds and mixtures of natural origin in FCM substances.

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<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/dossier/FCM-2022-4638



#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

None

#### 7.2 Feedback from the EC

None

#### 8. Any other business

The working group was informed of the upcoming call for Expressions of Interest for Membership of the Scientific Panels (including the CEP Panel) and the Scientific Committee of EFSA 2023.

The next meeting is scheduled to take place on 28-30 March 2023 by teleconference.



#### **Annex**

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

With regard to this meeting, Nicole Hellwig and Stefan Merkel declared the following interest: "Contribution to the assessment of a 'Wax, rice bran, oxidized and wax, rice bran, partially saponified' for its inclusion in the German positive list of FCM printing inks at the German Federal Institute for Risk Assessment (BfR)". In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a Conflict of Interest for the experts concerned.

Nicole Hellwig and Stefan Merkel also declared the following interest: "Involvement in the preparation of the opinion on formaldehyde in FCM at German Federal Institute for Risk Assessment (BfR)". In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a Conflict of Interest for the experts concerned.

Claude Lambré declared the following interest: "Participation to a Working Group on tobacco at the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), which could potentially assess formaldehyde". In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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.

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf





Food Ingredients and Packaging Unit

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

MINUTES OF THE 33<sup>rd</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2024

by teleconference, 14 - 15 December 2022

(agreed on 03 January 2023)

#### **Participants**

Working Group Members:

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

- Hearing Experts<sup>1</sup>: none
- European Commission and/or Member States representatives:
  - DG SANTE: Stella d'Amore
- EFSA:

- FIP Unit: Zainab Al Harrag, Eric Barthélémy, Daniele Comandella, Sandra Rainieri

Other participants: none

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from C Bolognesi (from 14:00 to 18:00 on 14 December), R Crebelli (from 14:00 to 17:00 on 15 December), S Merkel (from 14:00 to 18:00 on 15 December) and D Wölfle (whole 15 December).

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 32<sup>nd</sup> WG meeting

The minutes of the 32<sup>nd</sup> WG meeting held on 18-20 October 2022 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

5.1 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) (Q-2019-00483 and -00484)<sup>5</sup>

The WG revised parts of the draft opinion based on the discussion at the previous WG meeting. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

#### 6. Other scientific topics for discussion

#### 6.1 Safety assessment of compounds and mixtures of natural origin

Following the discussions at previous WG meetings, the working group further discussed principles that can be potentially used in the safety assessment of compounds and mixtures of natural origin in FCM substances.

 $<sup>^2\ \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate}\ \ \underline{\text{publications/files/policy}\ \ independence.pdf}$ 

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00483





#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

EFSA presented the draft mandate on styrene received from the EC. The draft mandate is currently under discussion within EFSA and with the European Commission.

#### 7.2 Feedback from the EC

None.

#### 8. AoB

#### Next meetings

The next meeting is scheduled to take place on 7-9 February 2023 by teleconference.





Food Ingredients and Packaging Unit

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

MINUTES OF THE 32<sup>nd</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2024

by teleconference, 18 – 20 October 2022 (agreed on 07 November 2022)

#### **Participants**

Working Group Members:

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

- Hearing Experts¹: James Kevin Chapman (CONTAM Panel)
- European Commission and/or Member States representatives:
  - DG SANTE: Jonathan Briggs and Bastiaan Schupp
- EFSA:

 FIP Unit: Zainab Al Harraq, Eric Barthélémy, Daniele Comandella, Remigio Marano and Sandra Rainieri

MESE Unit: Jane RichardsonPREV Unit: Marco Binaglia

Other participants: Dorota Burchard-Sosnowska, Evelin Fabjan and Ronan Nicolas (ECHA)

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from C Lambré (from 14:30 to 15:30 on 18 October), MR Milana (whole 18 October), N Hellwig and C Bolognesi (from 16:00 to 18:00 on 19 October), L Castle (whole 20 October) and D Wölfle (whole 18 and 20 October, from 17:00 to 18:00 on 19 October). JK Chipman and M Binaglia participated to item 5.1 (from 14:00 on 18 October to 10:00 on 19 October).

#### 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

#### 4. Agreement of the minutes of the 31st WG meeting

The minutes of the 31st WG meeting held on 21-23 September 2022 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

### 5.1 Re-evaluation of Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks - FCM N. 93

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

# 5.2 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) (Q-2019-00483 and -00484)<sup>5</sup>

The WG discussed changes in the draft opinion that were made following the discussion at the previous WG meeting. The WG concluded on the additional information to be requested to complete the risk

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<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00483





assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

### 6. Other scientific topics for discussion

# 6.1 Use of the International Uniform Chemical Information Database (IUCLID) software for Drinking Water applications and possible use for FCM applications

A presentation was given by ECHA on the use of IUCLID for submitting and assessing data in the context of Art. 11 of the drinking water directive (DWD).

#### 6.2 Safety assessment of compounds and mixtures of natural origin

Following the discussions at previous WG meetings, the working group further discussed principles that can be potentially used in the safety assessment of compounds and mixtures of natural origin in FCM substances.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

None

#### 7.2 Feedback from the EC

The safety of styrene (FCM No. 193), for which there is currently no restriction in the Union list for its use in FCM, was questioned in the 2020 EFSA opinion on "the assessment of the impact of the IARC Monograph Vol. 121 on the safety of the substance styrene (FCM No 193) for its use in plastic food contact materials" (EFSA CEP Panel, 2020, question number EFSA-Q-2019-00686). The opinion concluded that, based on the data provided in the IARC Monograph and by the industry, a concern for genotoxicity associated with oral exposure to styrene cannot be excluded. The EC provided feedback on their intention to follow up the assessment made by EFSA and to set a specific migration limit (SML).

#### 8. AoB

#### Next meetings

The next meeting is scheduled to take place on 14-16 December 2022 by teleconference.





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

MINUTES OF THE 31<sup>st</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2024

by teleconference, 21 September - 23 September 2022

(Agreed on 13 October 2022)

#### **Participants**

Working Group Members:

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

- Hearing Experts<sup>1</sup>: none
- European Commission and/or Member States representatives:

DG SANTE: Jonathan Briggs and Bastiaan Schupp

■ EFSA:

FIP Unit: Eric Barthélémy, Daniele Comandella, Remigio Marano, Sandra Rainieri

Other participants: none

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from C. Lambré for the whole meeting, from S. Merkel (on 22/09 from 9:00 to 9:30), from MR. Milana (on 22/09 from 11:30 to 13:00), from C. Bolognesi (on 22/09, from 9:00 to 15:30) and from K. Grob and D. Wölfle (on 23/09 from 10:45 to the end of the meeting).

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

#### 4. Agreement of the minutes of the 30th WG meeting

The minutes of the 30<sup>th</sup> WG meeting held on 13-15 July 2022 were agreed by written procedure<sup>4</sup>.

### 5. Scientific outputs submitted for discussion

5.1 N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine (FCM no 19), and N,Nbis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides (FCM No 20) (Q-2019-00483 and -00484)5

The WG discussed sections of the draft opinion based on the data available at the end of the call for data. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00483





# 6. Other scientific topics for discussion

#### 6.1. Safety assessment of compounds and mixtures of natural origin

Following the discussions at previous WG meetings, the working group further discussed principles that can be potentially used in the safety assessment of compounds and mixtures of natural origin in FCM substances.

### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

None

#### 7.2 Feedback from the EC

None

#### 8. AoB

### Next meetings

The next meeting is scheduled to take place on 18-20 October 2022 by teleconference.





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

MINUTES OF THE 30<sup>th</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2024

Parma, 13 July - 15 July 2022

(Agreed on 28 July 2022)

#### **Participants**

Working Group Members:

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

- Hearing Experts¹: not applicable
- European Commission and/or Member States representatives:

DG SANTE: Sandra Borg, Jonathan Briggs, Stella d'Amore, Apostolis Kapsalis

■ EFSA:

FIP Unit: Eric Barthélémy, Daniele Comandella, Remigio Marano, Sandra Rainieri

Other participants: none

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from C. Bolognesi (on 14/07 afternoon and 15/07 morning), from E Lampi (on 14/07 from 15:15 to the end of the day) and from D Wölfle (on the last day of the meeting).

#### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 4. Agreement of the minutes of the 28th WG meeting

The minutes of the 29th WG meeting held on 31 May 2022 were agreed by written procedure4.

# 5. Scientific outputs submitted for discussion

#### 5.1 OLA8 Oligomeric Lactic Acid (EFSA-Q-2021-00179)<sup>5</sup>

Further to the receipt of the additional information requested from the applicant, the WG identified the need for further questions to the applicant. Once the additional information is received, the draft opinion will be discussed at a future WG meeting.

2

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00179





# 5.2 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) (Q-2019-00483 and -00484)<sup>6</sup>

The working group was updated on the extent of data received from business operators and other interested parties at the end of the corresponding call for data (31 June 2022)<sup>7</sup>. The WG discussed sections of the draft opinion based on the available data. The revised draft opinion will be scheduled for discussion at the next FCM WG meeting.

#### 6. Other scientific topics for discussion

#### 6.1. Discussion on the revision of the FCM legislation

Building on the discussion that take place at the previous FCM WG meeting, the working group further discussed European Commission's thoughts aimed at an improved harmonisation of the safety assessment of all types of FCMs.

#### 6.2. Safety assessment of compounds and mixtures of natural origin

Following the discussion at the previous WG meeting, the working group further discussed principles that can be potentially used in the safety assessment of compounds and mixtures of natural origin in FCM substances.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

An update on the use of the tools implemented by EFSA following the entry into force of the Transparency Regulation was given.

#### 7.1 Feedback from the EC

None

#### 8. AoB

#### Next meetings

The next meeting is scheduled to take place on 21-23 September 2022 by teleconference.

<sup>&</sup>lt;sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00483

https://www.efsa.europa.eu/en/consultations/call/call-technical-and-toxicological-data-substances-nn-bis2





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

MINUTES OF THE 29<sup>th</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2024

By teleconference, 31 May 2022

(Agreed on 9 June 2022)

#### **Participants**

Working Group Members:

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

- Hearing Experts¹: not applicable
- European Commission and/or Member States representatives:

DG SANTE: Sandra Borg, Jonathan Briggs, Stella d'Amore, Apostolis Kapsalis, Baastian Schupp

EFSA:

FIP Unit: Eric Barthélémy, Daniele Comandella, Remigio Marano, Sandra Rainieri

Other participants: none

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<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 1. Welcome and apologies for absence

The Chair welcomed the participants. Detlef Wölfle was present only for the agenda item 5.1.

#### 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 28th WG meeting

The minutes of the 28th WG meeting held on 6-7 April 2022 were agreed by written procedure4.

#### 5. Scientific outputs submitted for discussion

5.1 N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine (FCM no 19), and N,Nbis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides (FCM No 20) (O-2019-00483 and -00484)5

The working group discussed the information received from business operators following the corresponding call for data<sup>6</sup>. The draft opinion on the available data will be scheduled for discussion at the next FCM WG meeting.

#### 6. Other scientific topics for discussion

#### 6.1 Safety assessment of compounds and mixtures of natural origin

Following the discussion at the last WG meeting, a summary of the approaches used in EFSA for the safety assessment of complex mixtures of natural origin was presented. The potential use of these approaches in the safety assessment of FCM substances was considered. Examples of materials of natural origin used in FCMs (cups made using coffee bean shells and plastic FCMs with ground sunflower seed hulls) were also discussed.

<sup>6</sup> https://www.efsa.europa.eu/en/consultations/call/call-technical-and-toxicological-data-substances-nn-bis2

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>5</sup> https://open.efsa.europa.eu/guestions/EFSA-Q-2019-00483





## 6.2 Discussion on the revision of the FCM legislation

The working group discussed various approaches for the safety assessment of FCM, under consideration by the European Commission in its ongoing revision of the FCM legislation. The potential impact of these approaches on the EFSA's safety assessment was considered and debated. Moreover, the working group presented and discussed with European Commission's representatives its own proposals aimed at an improved harmonisation of the safety assessment of all types of FCMs.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

Postponed to the next meeting.

#### 7.2 Feedback from the EC

Feedback was given during discussion of item 6.2.

#### 8. AoB

#### Next meetings

The next meeting is scheduled to take place on 13-15 July 2022 at the EFSA premises in Parma.





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

MINUTES OF THE 28<sup>th</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2024

By teleconference, 6-7 April 2022

(agreed on 25 April 2022)

#### **Participants**

Working Group Members:

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

- Hearing Experts¹: not applicable
- European Commission and/or Member States representatives:

DG SANTE: Sandra Borg, Jonathan Briggs, Stella d'Amore, Apostolis Kapsalis, Baastian Schupp

- EFSA:
  - FIP Unit: Eric Barthélémy, Daniele Comandella, Yi Liu, Remigio Marano, Carla Martino, Sandra Rainieri

FEED Unit: Paola ManiniKNOW Unit: Bernard Bottex

Other participants:

Sciensano: Birgit Mertens, Els van HoeckIstituto Mario Negri: Emilio Benfenati

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





### 1. Welcome and apologies for absence

The Chair welcomed the participants. Sandra Rainieri, the new team leader of the FCM team in the FIP Unit since 1<sup>st</sup> March 2022, introduced herself to the WG. Apologies were received from Claude Lambré (absent on 7 April, from 10:00 to 13:00) and from Claudia Bolognesi (absent on 7 April, from 14:00 to the end of the meeting).

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 4. Agreement of the minutes of the 27th WG meeting

The minutes of the 27<sup>th</sup> WG meeting held on 12 January 2022 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

#### 5.1 Cyclooctene homopolymer (PCOE) and Cobalt stearate (Q-2019-00387)<sup>5</sup>

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

#### 5.2 Amines, di-C14-C18-alkyl, oxidized (Q-2021-00555)<sup>6</sup>

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.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00387

<sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00555





### 6. Other scientific topics for discussion

#### 6.1. Safety assessment of compounds and mixtures of natural origin

The methodologies to address the assessment of substances and mixtures of natural origin in EFSA-relevant fields of novel foods, food enzymes, feed additives and (smoke) flavourings were presented and discussed. The EFSA guidance on the "Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements" (2009) was also discussed.

#### 6.2. Migration Testing of GPPS and HIPS Polymers

The WG discussed the scientific article "Migration Testing of GPPS and HIPS Polymers: Swelling Effect Caused by Food Simulants Compared to Real Foods" (2002), Guazzotti et al., Molecules 2022, 27(3), 823.

#### 7. Feedback from EFSA, EC

#### 7.1 Feedback from EFSA

Postponed to the next meeting.

#### 7.1 Feedback from the EC

A feedback on the revision of the FCM legislation was given.

#### 8. AoB

The <u>VERMEER FCM</u> tool was presented and discussed. The VERMEER FCM tool, developed within the EC-funded Life-VERMEER project, is a software which estimates the migration of chemicals into food and can predict different hazards relevant to FCM compounds.

#### Next meeting

The next meeting is scheduled to take place on 31 May 2022 by teleconference.





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

MINUTES OF THE 27<sup>th</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2024

By teleconference, 12 January 2022

(Agreed on 25 January 2022)

#### **Participants**

Working Group Members:

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

- Hearing Experts¹: not applicable
- European Commission and/or Member States representatives:
  - DG SANTE: Sandra Borg, Stella d'Amore, Apostolis Kapsalis, Baastian Schupp
- EFSA:

FIP Unit: Katleen Baert, Eric Barthélémy, Daniele Comandella, Valeriu Curtui, Remigio Marano

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Nicole Hellwig for absence from 12:20 to the end of the meeting.

#### 2. Adoption of agenda

The agenda was adopted without changes.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 26th WG meeting

The minutes of the 26<sup>th</sup> WG meeting held on 16-18 November 2021 were agreed by written procedure<sup>4</sup>.

#### 5. Scientific outputs submitted for discussion

# 5.1 Diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate, FCM No 1007 (Irgamod) (EFSA-Q-2020-00615)<sup>5</sup>

The dossier received from the applicant was discussed. The draft opinion was discussed and changes were noted. The draft opinion will be scheduled for discussion and possible adoption at a forthcoming meeting of the CEP Panel.

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

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

# 5.3 N,N-bis(2- hydroxyethyl)stearylamine, partially or fully esterified with saturated C16/C18 fatty acids (Sabofog F1) (EFSA-Q-2021-00233)<sup>7</sup>

Further to the receipt of the additional information requested from the applicant, the WG identified the need for further questions to the applicant. Once the additional information is received, the draft opinion will be discussed at a future WG meeting.

### 5.4 Nano precipitated Calcium Carbonate (EFSA-Q-2019-00232)8

The draft opinion was discussed and changes were noted. The draft opinion will be scheduled for discussion and possible adoption at a forthcoming meeting of the CEP Panel.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2020-00615

<sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2017-00740

<sup>&</sup>lt;sup>7</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00233

<sup>8</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00232





## 6. Other scientific topics for discussion

None.

## 7. Feedback from EFSA, EC

Valeriu Curtui, the new Head of the EFSA FIP Unit since 1<sup>st</sup> January 2022, introduced himself to the WG. Katleen Baert, FCM Team leader, will leave EFSA in March to join the European Commission. In replacement of Ellen Van Haver, who moved to the new EFSA Front Desk and workforce Planning (FDP) Unit on 1<sup>st</sup> January, Eric Barthélémy will act as FCM WG coordinator.

#### 8. AoB

#### Next meetings

The next meeting that was scheduled for 14-16 February 2022 by teleconference is cancelled. The next meeting is scheduled to take place on 6-8 April 2022.





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

MINUTES OF THE 26<sup>th</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 16-18 November 2021

(Agreed on 1 December 2021)

#### **Participants**

Working Group Members:

Claudia Bolognesi, Laurence Castle, Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig<sup>1</sup>, Claude Lambré<sup>2</sup>, Evgenia Lampi, Stefan Merkel, Maria Rosaria Milana and Gilles Rivière (Chair)

- Hearing Experts<sup>3</sup>:
  - not applicable
- European Commission and/or Member States representatives:
  - DG SANTE: Greta Borg, Stella d'Amore, Bastiaan Schupp
- EFSA:

- FIP Unit: Katleen Baert, Eric Barthélémy, Daniele Comandella, Emmanouil Tsochatzis, Ellen Van Haver

- Apdesk Unit: Remigio Marano

SCER Unit: Jose Tarazona

<sup>&</sup>lt;sup>1</sup> Not present on 17 November PM

<sup>&</sup>lt;sup>2</sup> Not present on 17-18 November

<sup>&</sup>lt;sup>3</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





## 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 25th WG meeting

The minutes of the 25<sup>th</sup> WG meeting (held on 21-23 September 2021) were agreed by written procedure<sup>6</sup>.

# 5. Scientific outputs submitted for discussion

#### 5.1 Chopped carbon fibre (EFSA-Q-2021-00006) 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.

# 5.2 Nano precipitated Calcium Carbonate (EFSA-Q-2019-00232)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 and possible adoption by the CEP Panel.

 $<sup>^{4} \ \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf}}$ 

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

 $<sup>^{6} \ \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf} \\$ 

<sup>&</sup>lt;sup>7</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00006

<sup>8</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00232





# 5.3 Fatty acid-coated nano precipitated Calcium Carbonate (EFSA-Q-2019-00233)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.

# 5.4 Cellulose pulp, bleached (EFSA-Q-2017-00740)<sup>10</sup>

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.

# 5.5 re-evaluation of Diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate, FCM No 1007 (EFSA-Q-2020-00615)<sup>11</sup>

The dossier received from the applicant was discussed. The draft opinion will be scheduled for discussion at the next FCM WG meeting.

#### 6. Feedback from EFSA

The WG was informed about the process of applications submitted to EFSA after the implementation of the transparency Regulation, and in particular about the foreseen steps for launching the public consultation of the non-confidential version of the dossiers.

# 7. Next meeting(s)

The next meeting is scheduled for 12 January 2022 by teleconference.

<sup>9</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00233

<sup>10</sup> https://open.efsa.europa.eu/guestions/EFSA-Q-2017-00740

<sup>11</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2020-00615





#### **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 Independence<sup>12</sup> and the Decision of the Executive Director on Competing Interest Management<sup>13</sup>, 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.

<sup>12</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 25th MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 21-23 September 2021

(Agreed on 12 October 2021)

#### **Participants**

Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair<sup>1</sup>), Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Claude Lambré<sup>2</sup>, Evgenia Lampi, Stefan Merkel, Maria Rosaria Milana and Gilles Rivière

- Hearing Experts<sup>3</sup>:
  - not applicable
- European Commission and/or Member States representatives:
  - DG SANTE4: Jonathan Briggs, Greta Borg
- EFSA:
  - FIP Unit: Katleen Baert, Eric Barthélémy, Ellen Van Haver

## 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.

 $<sup>^{1}</sup>$  For this meeting, the vice-chair, Laurence Castle, chaired the meeting except for agenda item 5.1.

<sup>&</sup>lt;sup>2</sup> Not present on 22-23 September.

<sup>&</sup>lt;sup>3</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 24th WG meeting

The minutes of the 24<sup>th</sup> WG meeting (held on 29 June – 1 July 2021) were agreed by written procedure<sup>7</sup>.

# 5. Scientific outputs submitted for discussion

# 5.1 Cyclooctene homopolymer (PCOE) and Cobalt stearate (EFSA-Q-2019-00387) <sup>8</sup>

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 OLA8 Oligomeric Lactic Acid (EFSA-Q-2021-00179)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.

# 5.3 Alcohols, C8-16, reaction products with phosphorus oxide (EFSA-Q-2021-00202) $^{10}$

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.

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;sup>7</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>8</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2019-00387

<sup>9</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00179

<sup>10</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00202





## 5.4 a-Methylstyrene - styrene copolymer (EFSA-Q-2021-00189)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 re-evaluation of N,N-bis (2-hydroxyethyl) stearylamine partially esterified with saturated C16/C18 fatty acids (FCM N. 1081) (EFSA-Q-2021-00233)<sup>12</sup>

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

#### Recast of the Drinking Water Directive (DWD)

A presentation was given of the recast of the DWD with regards to its article 11 on the "Minimum hygiene requirements for materials that come into contact with water intended for human consumption" (<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020L2184&from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020L2184&from=EN</a>). The WG was informed on the new information related to the potential areas for building synergies such as the harmonisation of the methodology for assessing substances and the related data requirements.

#### **7. AOB**

The WG had some exchange of thoughts on the evaluation of so-called biobased, natural or sustainable food contact materials.

# 8. Next meeting(s)

The next meeting is scheduled for 16-18 November 2021 by teleconference.

<sup>11</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00189

<sup>12</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00233





#### **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 Independence<sup>13</sup> and the Decision of the Executive Director on Competing Interest Management<sup>14</sup>, 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.

<sup>13</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>14</sup> 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 24<sup>th</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 29 June – 1 July 2021

(Agreed on 19 July 2021)

#### **Participants**

Working Group Members:

Claudia Bolognesi, Laurence Castle, Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig<sup>1</sup>, Claude Lambré<sup>2</sup>, Evgenia Lampi, Stefan Merkel, Maria Rosaria Milana<sup>1</sup>, Gilles Rivière (Chair)

- Hearing Experts<sup>3</sup>:
  - for item 6.1: Rainer Brandsch, Sebastian Meyer
- European Commission and/or Member States representatives:
  - DG SANTE: Jonathan Briggs, Greta Borg, Stella D'Amore, Bastiaan Schupp
  - ECHA: Elina Karhu, Vessela Vitcheva, Stefano Frattini, Niko Hellsten, Letizia Polci, Panos Zarogiannis, Ofelia Bercaru
- EFSA:

- FIP Unit: Katleen Baert, Eric Barthélémy, Claudia Roncancio Peña, Ellen Van Haver

<sup>&</sup>lt;sup>1</sup> Not present on 1 July

<sup>&</sup>lt;sup>2</sup> Not present on 30 June & 1 July

<sup>&</sup>lt;sup>3</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 23<sup>rd</sup> WG meeting

The minutes of the 23<sup>rd</sup> WG meeting (held on 28-29 April 2021) were agreed by written procedure<sup>6</sup>.

# 5. Hearing Experts

Mr. Brandsch and Mr. Meyer were invited to present their views for item 6.1 of the present meeting. They attended the meeting on 30 June 2021 from 09:00 to 10:45.

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, EFSA invited Mr. Brandsch and Mr. Meyer 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<sup>7</sup>.

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>7</sup> Decision of the Executive Director on Competing Interest Management, Article 9: <a href="http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf">http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf</a>





# 6. Scientific outputs submitted for discussion

# 6.1 re-evaluation of Ground sunflower seed hulls, FCM No 1060 (EFSA-Q-2020-00561) <sup>8</sup>

Upon request from EFSA, the applicant was given the opportunity to clarify during the hearing any outstanding issues on the application. A number of points requiring further clarification were identified. After the hearing was finished, and the hearing experts left the teleconference, the WG concluded on the points for additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

EFSA will follow up by providing the applicant with a written summary of the points discussed and the next steps and relative timelines.

# 6.2 Cyclooctene homopolymer (PCOE) and Cobalt stearate (EFSA-Q-2019-00387)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 at the next FCM WG meeting.

# 6.3 Trimethylolpropane trisorbate (EFSA-Q-2021-00181)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.

# 6.4 Chopped carbon fibre (EFSA-Q-2021-00006)<sup>11</sup>

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.

# 7. Other scientific topics for discussion

#### Recast of the Drinking Water Directive (DWD)

A presentation was given of the recast of the DWD with regards to its article 11 on the "Minimum hygiene requirements for materials that come into contact with water intended for human consumption" (<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020L2184&from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020L2184&from=EN</a>). The WG was informed on the context, the objectives of the DWD and its implementation by ECHA. The ongoing cooperation with EFSA was underlined, as well as the challenges to avoid duplication and divergence, and the potential areas for building synergies such as the harmonisation of the methodology for assessing substances and the related data requirements.

<sup>8</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2020-00561

https://open.efsa.europa.eu/questions/EFSA-Q-2019-00387

<sup>10</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00181

<sup>11</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2021-00006





# **8. AOB**

The WG was informed about one application that was withdrawn (EFSA-Q-2019-00586; 1,4-benzenedicarboxylic acid, 1,4-dibutyl ester) since the last WG meeting.

# 9. Next meeting(s)

The next meeting is scheduled for 21-23 September 2021 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 Independence<sup>12</sup> and the Decision of the Executive Director on Competing Interest Management<sup>13</sup>, 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.

<sup>12</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 23<sup>rd</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 28-29 April 2021

(Agreed on 19 May 2021)

# **Participants**

Working Group Members:

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

- Hearing Experts<sup>1</sup>:
  - not applicable
- European Commission and/or Member States representatives:
  - DG SANTE: Jonathan Briggs, Greta Borg
- EFSA:

FIP Unit: Eric Barthélémy and Ellen Van Haver

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 22<sup>nd</sup> WG meeting

The minutes of the 22<sup>nd</sup> WG meeting (held on 3 March 2021) were agreed by written procedure<sup>4</sup>.

# 5. Scientific topic(s) for discussion

# 5.1 Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters (EFSA-Q-2020-00014)<sup>5</sup>

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

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> <a href="http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf">http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf</a>

<sup>&</sup>lt;sup>5</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2020-00014

<sup>6</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2018-00640





# 5.3 Re-evaluation of Ground sunflower seed hulls, FCM No 1060 (EFSA-Q-2020-00561)<sup>7</sup>

The dossier received from the applicant was discussed. The WG requires clarification of some outstanding issues in the dossier in order to complete the risk assessment, possibly through a technical hearing.

### 6. AOB

The WG was informed about one application that was withdrawn (EFSA-Q-2020-00455) since the last WG meeting.

# 7. Next meeting(s)

The next meeting is scheduled for 29 June – 1 July 2021 by teleconference.

3

<sup>7</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2020-00561





#### **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 Independence<sup>8</sup> and the Decision of the Executive Director on Competing Interest Management<sup>9</sup>, 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.

8 http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>9</sup> 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 5.2 (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 Independence<sup>10</sup> and the Decision of the Executive Director on Competing Interest Management<sup>11</sup>, 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 5.2 by the concerned scientific group.

<sup>10</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

<sup>11</sup> 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 22<sup>nd</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 3 March 2021

(Agreed on 15 March 2021)

#### **Participants**

Working Group Members:

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

- Hearing Experts<sup>1</sup>:
  - not applicable
- European Commission and/or Member States representatives:
  - DG SANTE: Jonathan Briggs, Bastiaan Schupp
- EFSA:

FIP Unit: Eric Barthélémy, Alexandros Lioupis and Ellen Van Haver

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Nicole Hellwig.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 21st WG meeting

The minutes of the 21st WG meeting (held on 20 January 2021) were agreed by written procedure<sup>4</sup>.

# 5. Scientific topic(s) for discussion

There were no FCM applications for discussion.

## 6. Other scientific topics for discussion

The FCM Working Group (WG) exchanged views on the <u>EC Inception Impact Assessment (IIA)</u>, also called the "EC Roadmap", on the revision of EU rules on food contact materials (FCMs). The IIA is part of the on-going evaluation of the framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (called hereafter "the Regulation") in relation to its original objectives, the protection of consumer health, protect the interests of consumers and ensure that the internal market functions effectively (see <u>EC website</u>).

The FCM WG noted that the IIA is a high-level document presenting 8 key issues and 5 options for the possible future Regulation. More details, especially on the implementation, are needed to comment on their feasibility, benefits, limitations and consequences. The FCM WG understands that those details will be provided via the Impact Assessment foreseen to be published in 2021-2022.

The FCM WG underlined that this discussion follows the discussions and views on the evaluation of the legislative framework (Regulation (EU) No 1935/2004) on FCMs that were published in the  $\underline{\text{Minutes}}$  of the 5<sup>th</sup> FCM WG meeting held on 7-8 May 2019 (item 7.1). The FCM WG reiterated those views and discussed the following:

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf





- 1. As part of new tasks triggered by the revision of the Regulation, the WG re-affirms 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".
- 2. The FCM WG acknowledges that the safety assessment of all migrating chemicals from final articles may require different approaches than the current one, and that not all the assessments may be done by EFSA and national risk assessment authorities. Involvement of notified/certified private bodies may be needed, but the WG emphasizes that their role would need to be clarified, bearing in mind that the safety evaluations should be clearly under the control of public institutions/competent authorities.
- 3. With regard to the "lack of focus on the final article", EFSA evaluates substances in the context of a product and the related reaction/degradation products. The evaluation of the reaction/degradation products may constitute a substantial part of the work, however, their safety assessment can be essentially invisible to users of that substance.
- 4. For assessing migrating chemicals, the FCM WG reiterates the need to harmonise risk assessment principles/guidance independently of the FCM types. As indicated in the EFSA CEP Panel Scientific opinion on "Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials" (EFSA CEP Panel, 2016), "the same scientific reasoning and risk assessment principles can apply to all migrating substances from all types of FCM...".
- 5. The FCM WG considers that the distinction between natural and organic/synthetic materials is not substantiated with regards to the safety assessment of migrating chemicals. What is important for the safety assessment is the identity and potential toxicity of migrating substances, as expressed above when referring to the EFSA CEP Panel Opinion (2016).
- 6. The multiple goals that are indicated (ensuring consumer safety; supporting sustainability, innovation, SMEs, compliance work; environmental considerations; facilitating recycling; etc.) may partly conflict. It would be important for risk managers to indicate what level of consumer protection would need to be aimed for. For instance, it may not be possible to implement the same level of consumer protection for recycled compared to virgin materials.
- 7. Options from the IIA refer to general principles, such as the reduction of complexity of materials (composites, multi-materials), a ban of the most hazardous substances and the related derogations, "more benign substances", migration at high and low amounts, etc.). More details on the implementation of these principles would be needed for the WG to comment. For instance, it is not clear how all the not-classified chemicals (including non-intentionally added substances (NIAS)) other than chemicals covered under tier 1 (most hazardous) would be assessed.
- 8. When referring to the prioritisation and the hazard properties for tier 1, the WG notes that the criteria for hazard identification need to be agreed between EFSA & ECHA and should not be specific to FCM. In fact, some of the criteria for hazard identification are established, e.g. for carcinogens, mutagens and reproductive toxicants (CMR) and for endocrine disrupting chemicals (ED, for biocidal products and plant protection products<sup>5</sup>).

<sup>&</sup>lt;sup>5</sup> <u>Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.</u> <u>EFSA Journal 2018;16(6):5311,135 pp. https://doi.org/10.2903/j.efsa.2018.5311. ECHA-18-G-01-EN.</u>





- 9. As expressed in May 2019, the FCM WG has the view that cooperation between ECHA and EFSA needs to be strengthened. The EU initiative from ECHA and EFSA on "One Substance One Assessment (OSOA)" is part of it and is crucial to create synergy and to avoid duplication of work and/or divergency. The principle of mutual recognition of assessments (hazard, safety, risk) should apply, so it benefits to all. This is true for instance for the work carried out on biocides under the Biocide Product Regulation (BPR, Regulation (EU) 528/2012) and the review of substances from the plastic Union list through the review of the drinking water directive (Directive (EU) 2020/2184 of the European Parliament and of the Council of 16/12/2020 on the quality of water intended for human consumption).
- 10. Along the same lines, the WG reiterates that cooperation between EFSA and the competent authorities of the Member States needs to be strengthened.

# 7. Next meeting(s)

The next meeting is scheduled for 27-29 April 2021 by teleconference.





## 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 Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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.

<sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

<sup>&</sup>lt;sup>7</sup> 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 21st MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 20 January 2021

(Agreed on 8 February 2021)

#### **Participants**

Working Group Members:

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

- Hearing Experts<sup>1</sup>:
  - not applicable
- European Commission and/or Member States representatives:
  - DG SANTE: Jonathan Briggs
- EFSA:

FIP Unit: Katleen Baert, Alexandros Lioupis, Ellen Van Haver and Katharina Volk

SCER Unit: Jose Tarazona<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> For agenda item 6





## 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 20th WG meeting

The minutes of the 20<sup>th</sup> WG meeting (held on 11 November 2020) were agreed by written procedure<sup>5</sup>.

#### 5. Scientific topic(s) for discussion

#### 5.1 Bis(2,2,6,6-tetramethyl-4-piperidyl)sebacate (EFSA-Q-2020-00455) 6

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. Other scientific topics for discussion

# Scientific Committee draft guidance on risk assessment of nanomaterials to be applied in the food and feed chain

The Scientific Committee WG on Nanotechnology is currently revising the EFSA guidance on the risk assessment of nanomaterials published in 2018, together with the new Technical requirements for nanoparticles (see previous minutes $^7$  of the  $19^{th}$  and  $20^{th}$  FCM WG meeting when the guidance on technical requirements was discussed). The revisions of the 2018 guidance were presented, in particular those sections that are of relevance to the FCM WG and on which the FCM WG is requested to comment on.

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>6</sup> http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00275

<sup>&</sup>lt;sup>7</sup> http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/fcmwq-wq-m.pdf





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

The European Commission informed the WG about the ongoing evaluation and revision of the EU rules on food contact materials<sup>8</sup> and the possible approaches for setting harmonised rules. The Inception Impact Assessment has been published on the EC website for <u>public consultation</u>. The EC foresees also after the closure date (29 January) to carry out additional consultations and counts on the expertise of EFSA and its WG experts in further developing the new legislation.

#### 8. AOB

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 is scheduled for 3-4 March 2021 by teleconference.

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<sup>&</sup>lt;sup>8</sup> https://ec.europa.eu/food/safety/chemical safety/food contact materials/specific-eu-policy-initiatives/evaluation-and-revision en





# 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 Independence<sup>9</sup> and the Decision of the Executive Director on Competing Interest Management<sup>10</sup>, 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.

<sup>9</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

<sup>10</sup> 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 20<sup>TH</sup> MEETING OF THE WORKING GROUP ON FOOD CONTACT MATERIALS 2018-2021

By teleconference, 11 November 2020

(Agreed on 20 November 2020)

#### **Participants**

Working Group Members:

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

- Hearing Experts<sup>1</sup>:
  - not applicable
- European Commission and/or Member States representatives:
  - DG SANTE: Bastiaan Schupp
- EFSA:

FIP Unit: Katleen Baert, Eric Barthélémy, Alexandros Lioupis, Ellen Van Haver and Katharina

Volk

SCER Unit: Jose Tarazona<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.

<sup>&</sup>lt;sup>2</sup> For agenda item 6.1





#### 1. Welcome and apologies for absence

The Chair welcomed the participants, and especially Stefan Merkel as new member to the FCM WG and Katleen Baert as new member to the EFSA FCM team. 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 19th WG meeting

The minutes of the 19<sup>th</sup> WG meeting (held on 30 September 2020) were agreed by written procedure<sup>5</sup>.

#### 5. Scientific topic(s) for discussion

# 5.1 Amines, bis (hydrogenated rape-oil alkyl) methyl, N-oxides (EFSA-Q-2020-00275) <sup>6</sup>

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. Other scientific topics for discussion

# 6.1 Scientific Committee draft guidance on Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles

The WG continued the discussion started at its previous meeting on 30<sup>th</sup> September on the applicability of the draft guidance to FCM. It is concluded that the draft guidance is applicable to FCM.

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

<sup>&</sup>lt;sup>6</sup> http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00275





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

The European Commission informed the WG about foreseen amendments of Regulation (EC) 10/2011 and other risk management matters in the area of food contact materials.

#### **8. AOB**

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 is scheduled for 19-21 January 2021 by teleconference.





# 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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>8</sup> 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 19<sup>TH</sup> 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 Experts<sup>1</sup>:
  - 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

<sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





## 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 procedure<sup>4</sup>.

#### 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 <u>public consultation</u> <u>ended in September</u>, 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

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/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 reevaluation 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.





# 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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.

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>6</sup> 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 18<sup>TH</sup> 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 Bolognesi<sup>1</sup>, Laurence Castle, Riccardo Crebelli<sup>1</sup>, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Claude Lambré, Evgenia Lampi, Maria Rosaria Milana<sup>2</sup>, Karla Pfaff and Gilles Rivière (Chair)

- Hearing Experts<sup>3</sup>:
  - 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

http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.

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.

<sup>&</sup>lt;sup>1</sup> Not present on 9 July

<sup>&</sup>lt;sup>2</sup> Not present on 8 July pm

<sup>&</sup>lt;sup>3</sup> 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:





#### 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 17<sup>th</sup> WG meeting (held on 26-28 May 2020) were agreed by written procedure<sup>6</sup>.

## 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)<sup>7</sup>

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)<sup>8</sup>

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.

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

 $<sup>^{6} \ \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf}$ 

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

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

<sup>9</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/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).





# 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 Independence<sup>10</sup> and the Decision of the Executive Director on Competing Interest Management<sup>11</sup>, 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.

<sup>10</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 17<sup>TH</sup> 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 Crebelli<sup>1</sup>, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Claude Lambré, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff and Gilles Rivière (Chair)

- Hearing Experts<sup>2</sup>:
  - 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** 

2 As defined in Article 17

<sup>&</sup>lt;sup>1</sup> Not present on 28 May

<sup>&</sup>lt;sup>2</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





# 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 agenda<sup>3</sup>

The agenda was adopted without changes.

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 14<sup>th</sup> (1-2 April 2020), 15<sup>th</sup> (5 May 2020) and 16<sup>th</sup> (11 May 2020) WG meetings

The minutes of the 14<sup>th</sup> (held on 1-2 April 2020), 15<sup>th</sup> WG meeting (held on 5 May 2020) and 16<sup>th</sup> (held on 11 May 2020) WG meetings were agreed by written procedure<sup>6</sup>.

## 5. Scientific topic(s) for discussion

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

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-octadiamine (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

<sup>&</sup>lt;sup>3</sup> Not present on 26 May

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

 $<sup>^{6}\ \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf}$ 

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

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

 $<sup>^{9}\ \</sup>underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686}$ 





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)<sup>10</sup>

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-2020-00380<sup>11</sup>). 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.

 $<sup>^{10} \ \</sup>underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00014}$ 

<sup>11</sup> http://registerofguestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2020-00380





# 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 Independence<sup>12</sup> and the Decision of the Executive Director on Competing Interest Management<sup>13</sup>, 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.

<sup>12</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 16<sup>TH</sup> 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 Experts<sup>1</sup>:
  - 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.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>4</sup> 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 15<sup>TH</sup> 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 Experts<sup>1</sup>:
  - 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.

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 procedure<sup>4</sup>.

## 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.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>4</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf





# 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 vicechairman or rapporteur of the Working Group.

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>6</sup> 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 14<sup>TH</sup> 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 Benfenati<sup>1</sup>, Claudia Bolognesi<sup>2</sup>, Laurence Castle<sup>3</sup>, Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Evgenia Lampi, Maria Rosaria Milana<sup>2</sup>, Karla Pfaff and Gilles Rivière (Chair)

- Hearing Experts<sup>4</sup>:
  - 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

<sup>&</sup>lt;sup>1</sup> Present on 1 April am and 2 April pm

<sup>&</sup>lt;sup>2</sup> Not present on 1 April

<sup>&</sup>lt;sup>3</sup> Not present on 2 April pm

<sup>&</sup>lt;sup>4</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





## 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 12<sup>th</sup> (25-27 February 2020) and 13<sup>th</sup> (18-19 March 2020) WG meetings

The minutes of the 12<sup>th</sup> WG meeting (held on 25-27 January 2020) and of the 13<sup>th</sup> WG meeting (held on 18-19 March 2020) were agreed by written procedure<sup>7</sup>.

## 5. Scientific topic(s) for discussion

# 5.1. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150) $^{\rm 8}$

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.

 $<sup>^{5}\ \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf}}$ 

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

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

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

<sup>9</sup> 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 assessment<sup>11</sup>.

#### **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.

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 $<sup>^{10}\ \</sup>underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00686}$ 

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





# 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 Independence<sup>12</sup> and the Decision of the Executive Director on Competing Interest Management<sup>13</sup>, 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.

<sup>12</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 13<sup>TH</sup> 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 Benfenati<sup>1</sup>, Laurence Castle, Riccardo Crebelli<sup>2</sup>, Roland Franz, Nicole Hellwig and Gilles Rivière (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.

<sup>&</sup>lt;sup>1</sup> Not present on 18 March

<sup>&</sup>lt;sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4,</sup> 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  $12^{th}$  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)<sup>6</sup>

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.

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00150

# 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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

<sup>&</sup>lt;sup>7</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 12<sup>TH</sup> 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 Benfenati<sup>1</sup>, Claudia Bolognesi<sup>2</sup>, Laurence Castle, Riccardo Crebelli, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig, Evgenia Lampi, Maria Rosaria Milana<sup>2</sup>, Karla Pfaff and Gilles Rivière (Chair), and Detlef Wölfle<sup>3</sup>

- Hearing Experts<sup>4</sup>:
  - 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

<sup>&</sup>lt;sup>1</sup> For agenda item 5.2 only

<sup>&</sup>lt;sup>2</sup> Not present on 26 February

<sup>&</sup>lt;sup>3</sup> Present on 27 February only

<sup>&</sup>lt;sup>4</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 11<sup>th</sup> WG meeting, held on 14-16 January 2020

The minutes of the 11<sup>th</sup> WG meeting held on 14-16 January 2020 were agreed by written procedure<sup>7</sup>.

#### 5. Scientific topic(s) for discussion

#### 5.1. Styrene (FCM 193) (EFSA-Q-2019-00686)<sup>8</sup>

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)<sup>9</sup>

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.

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

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

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

<sup>9</sup> 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 Independence<sup>10</sup> and the Decision of the Executive Director on Competing Interest Management<sup>11</sup>, 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.

<sup>10</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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  $11^{TH}$  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 Benfenati<sup>1</sup>, Claudia Bolognesi<sup>2</sup>, Laurence Castle, Riccardo Crebelli, Emma Di Consiglio<sup>2</sup>, Roland Franz, Koni Grob<sup>2</sup>, Nicole Hellwig<sup>3</sup>, Evgenia Lampi<sup>2</sup>, Maria Rosaria Milana<sup>2,3</sup>, Karla Pfaff<sup>2</sup> and Gilles Rivière (Chair)

- Hearing Experts<sup>4</sup>:
  - 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 and Katharina Volk

FEED Unit: Fabiola Pizzo

<sup>&</sup>lt;sup>1</sup> For agenda item 5.1 only

<sup>&</sup>lt;sup>2</sup> Not present on 14 January

<sup>&</sup>lt;sup>3</sup> By teleconference

<sup>&</sup>lt;sup>4</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 10<sup>th</sup> WG meeting, held on 26-28 November 2019

The minutes of the  $10^{th}$  WG meeting held on 26-28 November 2019 were agreed by written procedure<sup>7</sup>.

#### 5. Scientific topic(s) for discussion

### 5.1. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150) $^{\rm 8}$

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)<sup>9</sup>

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)<sup>10</sup>

 $<sup>^{5}\ \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate}\ \ \underline{\text{publications/files/policy}\ \ independence.pdf}$ 

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

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

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

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  $call^{15}$  (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)

 $<sup>^{10}\ \</sup>underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00510}$ 

 $<sup>^{11}\ \</sup>underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00232}$ 

<sup>12 &</sup>lt;a href="http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00233">http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00233</a>

http://registerofguestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2019-00686

<sup>14 &</sup>lt;a href="http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00640">http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00640</a>

<sup>15</sup> 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 Independence<sup>16</sup> and the Decision of the Executive Director on Competing Interest Management<sup>17</sup>, 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.

<sup>16</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 Independence<sup>18</sup> and the Decision of the Executive Director on Competing Interest Management<sup>19</sup>, 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

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 10<sup>TH</sup> 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 Benfenati<sup>1</sup>, Claudia Bolognesi<sup>2</sup>, Laurence Castle, Riccardo Crebelli, Emma Di Consiglio<sup>2</sup>, Roland Franz, Koni Grob<sup>2</sup>, Nicole Hellwig, Evgenia Lampi<sup>2</sup>, Maria Rosaria Milana<sup>2,3</sup>, Karla Pfaff<sup>2,3</sup> and Gilles Rivière (Chair)

- Hearing Experts<sup>4</sup>:
  - not applicable
- European Commission and/or Member States representatives:
  - Not applicable
- EFSA:

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

APDESK Unit: Remigio Marano

<sup>&</sup>lt;sup>1</sup> For agenda item 5.1 only

<sup>&</sup>lt;sup>2</sup> Not present on 26 November

<sup>&</sup>lt;sup>3</sup> By teleconference

<sup>&</sup>lt;sup>4</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 9<sup>th</sup> WG meeting, held on 8-10 October 2019

The minutes of the 9<sup>th</sup> WG meeting held on 8-10 October 2019 were agreed by written procedure<sup>7</sup>.

#### 5. Scientific topic(s) for discussion

### 5.1. Prioritisation exercise for substances without an SML (EFSA-Q-2019-00150)<sup>8</sup>

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)<sup>9</sup>

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.

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>7</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

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

<sup>9</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/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-2019-00686 $^{12}$ ) 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.

 $<sup>^{10}\ \</sup>underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00549}$ 

<sup>11</sup> http://registerofguestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2018-00064

<sup>12</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/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 Independence<sup>13</sup> and the Decision of the Executive Director on Competing Interest Management<sup>14</sup>, 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.

<sup>13</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>14</sup> 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 9<sup>TH</sup> 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<sup>1,2</sup>, Claudia Bolognesi, Laurence Castle, Riccardo Crebelli<sup>1,3</sup>, Emma Di Consiglio<sup>1,3</sup>, Roland Franz, Koni Grob, Nicole Hellwig, Evgenia Lampi, Maria Rosaria Milana<sup>4</sup>, Karla Pfaff and Gilles Rivière (Chair)

- Hearing Experts<sup>5</sup>:
  - 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

<sup>2</sup> Present on 10 September only

<sup>&</sup>lt;sup>1</sup> By teleconference

<sup>&</sup>lt;sup>3</sup> Not present in the afternoons of 8 & 9 September

<sup>&</sup>lt;sup>4</sup> Present on 8 September only

<sup>&</sup>lt;sup>5</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 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 Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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 8<sup>th</sup> WG meeting, held on 3-5 September 2019

The minutes of the 8<sup>th</sup> WG meeting held on 3-5 September 2019 were agreed by written procedure<sup>8</sup>.

#### 5. Scientific topic(s) for discussion

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

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)<sup>10</sup>

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

 $<sup>^{6}\ \</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate}}\ \underline{\text{publications/files/policy}}\ \underline{\text{independence.pdf}}$ 

<sup>&</sup>lt;sup>7</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

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

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

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

<sup>11</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/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.

 $<sup>\</sup>frac{12}{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00150}}$ 





#### **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 Independence<sup>13</sup> and the Decision of the Executive Director on Competing Interest Management<sup>14</sup>, 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.

<sup>13</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>14</sup> 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 8<sup>TH</sup> 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<sup>1,2</sup>, Emma Di Consiglio, Roland Franz, Koni Grob, Nicole Hellwig<sup>1,3</sup>, Evgenia Lampi, Maria Rosaria Milana<sup>1,2</sup>, Karla Pfaff, Gilles Rivière (Chair) and Detlef Wölfle<sup>4</sup>

- Hearing Experts<sup>5</sup>:
  - 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

<sup>2</sup> Not present on 4 September PM

<sup>&</sup>lt;sup>1</sup> By teleconference

<sup>&</sup>lt;sup>3</sup> Not present on 5 September

<sup>&</sup>lt;sup>4</sup> For agenda point 5.1, by teleconference

<sup>&</sup>lt;sup>5</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 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 Bolognesi.

#### 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 Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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 7<sup>th</sup> WG meeting, held on 18-19 June 2019

The minutes of the 7<sup>th</sup> WG meeting held on 18-19 June 2019 were agreed by written procedure<sup>8</sup>.

#### 5. Scientific topic(s) for discussion

### 5.1. Tris (2-ethylhexyl) benzene-1,2,4-tricarboxylate (EFSA-Q-2017-00645)<sup>9</sup>

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)<sup>10</sup>

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)<sup>11</sup>

<sup>&</sup>lt;sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

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

 $<sup>^{9}\ \</sup>underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00645}$ 

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

<sup>11</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/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)<sup>12</sup>

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.

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 $<sup>{\</sup>color{red}^{12}} \ \underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00089}$ 





#### **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 Independence<sup>13</sup> and the Decision of the Executive Director on Competing Interest Management<sup>14</sup>, 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.

<sup>13</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>14</sup> 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 7<sup>TH</sup> 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 Crebelli<sup>1</sup>, Roland Franz, Koni Grob, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff, Gilles Rivière (Chair) and Detlef Wölfle<sup>2</sup>

- Hearing Experts<sup>3</sup>:
  - not applicable
- European Commission and/or Member States representatives:
  - not applicable
- EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Alexandros Lioupis, Ellen Van Haver<sup>1</sup> and Katharina Volk

#### 1. Welcome and apologies for absence

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

<sup>2</sup> For agenda point 5.1, by teleconference

<sup>&</sup>lt;sup>1</sup> By teleconference

<sup>&</sup>lt;sup>3</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.





#### 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 5<sup>th</sup> & 6<sup>th</sup> WG meeting, held on 7-8 May 2019 and 23 May 2019

The minutes of the 5<sup>th</sup> WG meeting held on 7-8 May 2019 and 6<sup>th</sup> WG meeting held on 23 May were agreed by written procedure<sup>6</sup>.

#### 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)<sup>9</sup>

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)<sup>10</sup>

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

<sup>&</sup>lt;sup>4</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

 $<sup>^{6} \ \</sup>text{http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf}$ 

<sup>&</sup>lt;sup>7</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-Q-2017-00645

<sup>&</sup>lt;sup>8</sup> This agenda item was chaired by Laurence Castle

<sup>&</sup>lt;sup>9</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2018-01007

<sup>10</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/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 Independence<sup>11</sup> and the Decision of the Executive Director on Competing Interest Management<sup>12</sup>, 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.

<sup>11</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 6<sup>TH</sup> 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 Brüschweiler, 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2,</sup> 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 5<sup>th</sup> WG meeting held on 7 and 8 May 2019 will be agreed by written procedure<sup>3</sup> 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.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

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

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





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

MINUTES OF THE 5<sup>TH</sup> 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 Brüschweiler, Laurence Castle, Riccardo Crebelli, Roland Franz, Koni Grob, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff and Gilles Rivière (Chair)

- Hearing Experts<sup>1</sup>:
  - for item 6.3: Stefania Bencini (Sabo); Enrico Galfrè (Sabo); Omolola Akintoye (Intertek)
- European Commission and/or Member States representatives<sup>2</sup>:
   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)

<sup>&</sup>lt;sup>1</sup> 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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>.

<sup>&</sup>lt;sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 4<sup>th</sup> WG meeting, held on 12-14 March 2019

The minutes of the 4<sup>th</sup> WG meeting held on 12-14 March 2019 were agreed by written procedure<sup>5</sup>.

#### 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 meeting $^7$ , the cross cutting Working Group on nanotechnologies of the Scientific Committee was consulted for the characterisation of the additive.

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<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

<sup>&</sup>lt;sup>5</sup> http://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg-wg-m.pdf

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

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)<sup>8</sup>

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-O-2016-00510)<sup>9</sup>,<sup>10</sup>

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 <a href="EC website">EC website</a>). 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

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http://registerofquestions.efsa.europa.eu/rogFrontend/guestionLoader?question=EFSA-Q-2019-00089

 $<sup>\</sup>frac{9}{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00510}$ 

<sup>&</sup>lt;sup>10</sup> 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 <a href="EFSA Note for Guidance">EFSA Note for Guidance</a>. 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 <u>EFSA FCM Network</u> 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  $SML^{11}$ .

#### **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/rogFrontend/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 Independence<sup>12</sup> and the Decision of the Executive Director on Competing Interest Management<sup>13</sup>, 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

<sup>12</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

<sup>13</sup> 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 aluminia, under agenda item 6.1. In accordance with EFSA's Policy on Independence<sup>14</sup> and the Decision of the Executive Director on Competing Interest Management<sup>15</sup>, 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 Independence <sup>13</sup> and the Decision of the Executive Director on Competing Interest Management <sup>14</sup>, 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

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 4<sup>TH</sup> 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 Bolognesi<sup>1</sup>, Beat Johannes Brüschweiler, Laurence Castle, Riccardo Crebelli, Roland Franz, Koni Grob, Evgenia Lampi, Karla Pfaff, Gilles Rivière (Chair) and Detlef Wölfle<sup>2</sup>

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.

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<sup>&</sup>lt;sup>1</sup> Not present on 14 March

<sup>&</sup>lt;sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 3<sup>rd</sup> WG meeting, held on 24&29 January 2019

The minutes of the 3<sup>rd</sup> WG meeting held on 24 & 29 January 2019 were agreed by written procedure<sup>5</sup>.

#### 5. Scientific topic(s) for discussion

#### 5.1. Phosphorus acid, triphenyl ester, polymer with alpha-hydro-omegahydroxypoly[oxy(methyl1-1,2-ethanediyl)], C10-16 alkyl esters (EFSA-Q-2018-00411)<sup>6</sup>

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 aluminia (EFSA-Q-2014-00300)<sup>7</sup>

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)<sup>8</sup>

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.

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

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

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

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

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-O-2016-00510





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

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)<sup>10</sup>

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.

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

<sup>10</sup> http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=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 Independence<sup>11</sup> and the Decision of the Executive Director on Competing Interest Management<sup>12</sup>, 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

<sup>12</sup> 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 aluminia, under agenda item 5.2. In accordance with EFSA's Policy on Independence<sup>13</sup> and the Decision of the Executive Director on Competing Interest Management<sup>14</sup>, 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 Independence <sup>13</sup> and the Decision of the Executive Director on Competing Interest Management <sup>14</sup>, 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

<sup>14</sup> 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 3<sup>rd</sup> 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)<sup>1</sup>

#### **Participants**

#### Working Group Members:

Claudia Bolognesi<sup>2</sup>, Beat Johannes Brüschweiler, Riccardo Crebelli, Roland Franz, Koni Grob, Evgenia Lampi, Maria Rosaria Milana<sup>2</sup>, 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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,

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_1\_7.pdf

<sup>&</sup>lt;sup>1</sup> By written procedure

<sup>&</sup>lt;sup>2</sup> Present on 24 January only

<sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.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 2<sup>nd</sup> WG meeting (14-15 November 2018)

The minutes of the 2<sup>nd</sup> WG meeting held on 14-15 November 2018 were agreed by written procedure<sup>5</sup>.

#### 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.

<sup>5</sup> 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 Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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.

<sup>6</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

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 2<sup>nd</sup> meeting of the Working Group on Food Contact Materials 2018-2021

## Held on 14-15 November 2018, by teleconference (Agreed on 29 November 2018)<sup>1</sup>

#### **Participants**

#### • Working Group Members:

Claudia Bolognesi, Beat Johannes Brüschweiler, Laurence Castle, Riccardo Crebelli, Koni Grob, Evgenia Lampi, Maria Rosaria Milana, Karla Pfaff, Gilles Rivière (Chair) and Detlef Wölfle<sup>2</sup>

#### 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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

<sup>2</sup> For agenda item 5.1 only

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 1 7.pdf

<sup>&</sup>lt;sup>1</sup> By written procedure

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.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 1<sup>st</sup> WG meeting held on 9-10 October 2018 were agreed by written procedure<sup>5</sup>.

#### 5. Scientific topic(s) for discussion

#### 5.1 Phosphorus acid, triphenyl ester, polymer with alpha-hydro-omegahydroxypoly[oxy(methyl1-1,2-ethanediyl)], C10-16 alkyl esters (EFSA-Q-2018-00411)<sup>6</sup>

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)<sup>7</sup>

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)<sup>8</sup>

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.

#### Next meeting(s)

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

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

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2018-00411

<sup>&</sup>lt;sup>7</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2017-00412

<sup>&</sup>lt;sup>8</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2018-00549



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

# Minutes of the 1<sup>st</sup> 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)<sup>1</sup>

#### **Participants**

#### Working Group Members:

Claudia Bolognesi, Beat Johannes Brüschweiler, Laurence Castle, Koni Grob, Evgenia Lampi, Maria Rosaria Milana<sup>2</sup>, 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 1 7.pdf

<sup>&</sup>lt;sup>1</sup> By written procedure

<sup>&</sup>lt;sup>2</sup> Present on 9 October only

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.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)<sup>5</sup>

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)<sup>6</sup>

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)<sup>7</sup>

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)<sup>8</sup>

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.

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

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

<sup>&</sup>lt;sup>7</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2018-00064

<sup>&</sup>lt;sup>8</sup> 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 <a href="dedicated webpage">dedicated webpage</a>.

#### 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.