

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

Minutes of the 29th meeting of the Working Group on Food Contact Materials 2017-2018

Held on 15-17 May 2018, Parma (Italy) (Agreed on 8 June 2018)¹

Participants

Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi², Maria de Fátima Tavares Poças, Roland Franz, Martine Kolf-Clauw, Karla Pfaff³, Maria Rosaria Milana², Gilles Rivière, Kettil Svensson and Detlef Wölfle

European Commission and/or Member States representatives:

DG SANTE: Bastiaan Schupp⁴

EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Cristina Croera, Alexandros Lioupis,

Ellen Van Haver, Katharina Volk Apdesk Unit: Remigio Marano

SCER Unit: Georges Kass (for agenda item 6)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Koni Grob.

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 and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the working group members invited for the present meeting. No Conflicts of

¹ By written procedure

² Not present on 17 May

Attended by teleconference on 15 and 17 May

⁴ Present on 15 May only

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
 http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the of the minutes of the 28th WG meeting (6-7 February 2018)

The minutes of the 28th WG meeting held on 6-7 February 2018 were agreed by written procedure⁷.

5. Scientific topic(s) for discussion

5.1 FAVOR® PAC 600 Series (EFSA-Q-2018-00003)8

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 CEF or future CEP Panel.

5.2 Montmorillonite organic clay (EFSA-Q-2013-00641)9

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 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2017-00495)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 CEF Panel.

5.4 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2017-00412 – all foods)¹¹

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.

5.5 Di(m-2,2',2''-nitrilotris(ethanol)-diperchlorato)dinatrium (EFSA-Q-2017-00444)¹²

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.

⁷ https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/fcmwg2014-2018.pdf

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2018-00003

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

¹⁰ http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-O-2017-00495

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

http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00444



5.6 Ln 1,4-Benzene Dicarboxylic acid (with Ln=La,Eu,Gd,Tb) (EFSA-2016-00128)¹³

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 CEF or future CEP Panel.

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

The European Commission representative, B. Schupp, informed the WG about the status of the ongoing Roadmap initiative to evaluate the FCM legislation, and about ongoing work at the European Commission in the area of ceramics and recycling processes. The WG was also informed about new mandates the European Commission intends to send to EFSA with regard to the re-evaluation of some listed substances.

G. Kass (EFSA SCER Unit) presented to the WG the <u>Guidance</u> on the risk assessment of substances present in food intended for infants below 16 weeks of age. This was followed by a presentation given by E. Barthélémy (EFSA FIP Unit) and a preliminary discussion with the WG on the possible implications of this cross-cutting guidance for the evaluation of FCM.

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 and about an application that has been withdrawn since the last WG meeting.

Next meeting(s)

The next meeting date will be fixed once the new CEP Panel is established in July 2018.

 $^{^{13} \ \}text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00128}$



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

Minutes of the 28th meeting of the Working Group on Food Contact Materials 2017-2018

Held on 6-7 February 2018, Parma (Italy) (Agreed on 22 February 2018)¹

Participants

• Working Group Members:

Laurence Castle (Chair), Jean-Pierre Cravedi², Maria de Fátima Tavares Poças, Roland Franz, Koni Grob, Karla Pfaff, Maria Rosaria Milana, Gilles Rivière, Kettil Svensson and Detlef Wölfle

Hearing Experts³:

Rhodri Evans (for agenda item 6.3) and Ian Cooper (for agenda item 6.3)

• European Commission and/or Member States representatives:

DG SANTE: Takis Daskaleros

• EFSA:

FIP Unit: Eric Barthélémy, Anna F. Castoldi, Cristina Croera, Alexandros Lioupis, Claudia Roncancio Penã (for agenda point 9), Ellen Van Haver, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants. 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 and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the working group members invited for the present meeting. No Conflicts of

² Attended by teleconference on 6 February

¹ By written procedure

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



Interest related to the issues discussed in this meeting have been identified during the screening process.

For further details on the outcome of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

4. Agreement of the of the minutes of the 27th WG meeting (6-7 December 2017)

The minutes of the 27th WG meeting held on 6-7 December 2017 were agreed by written procedure⁶.

5. Hearing experts

Rhodri Evans and Ian Cooper were invited for agenda item 6.3 to provide clarification on the additional data they submitted in October 2017 for application Amines, bis (hydrogenated rape-oil alkyl) methyl, N-oxides (EFSA-Q-2015-00443). They attended the meeting on 7 February from 9:00 till 10.15.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA invited Rhodri Evans and Ian Cooper to submit an ADoI. Their participation was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group, in accordance with the applicable legal framework⁷.

6. Scientific topic(s) for discussion

6.1 Re-evaluation of (perfluorobutyl)ethylene (PFBE) (EFSA-Q-2016-00393)⁸

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.

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

6.3 Amines, bis (hydrogenated rape-oil alkyl) methyl, N-oxides (EFSA-Q-2015-00443)¹⁰

Upon request from EFSA, the interested parties were given the opportunity to clarify the additional data that the applicant provided following the request of the WG, as the data were not considered satisfactory to conclude on the risk assessment of the substance. Following the discussion during the hearing, EFSA will follow up by providing the

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/assets/fcmwg2014-2017.pdf

⁷ Decision of the Executive Director on Declarations of Interest:

⁸ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00393

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2017-00645

http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00443



interested parties with a written summary of the points discussed. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

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

The European Commission representative, T. Daskaleros, informed the WG about the process and timelines of the ongoing Roadmap initiative to evaluate the FCM legislation. A <u>public consultation</u> on the roadmap was held from 28 November till 26 December 2017. Consultations with relevant stakeholders, including EFSA, are planned to be carried out in the course of the evaluation.

8. Other scientific topics for discussion

No other topics were discussed.

9. Any Other Business

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

10.Next meeting(s)

The next meeting is scheduled for 20-21 March 2018.



Annex

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

With regard to this meeting, Dr. K. Pfaff and Dr. D. Wölfle declared the following interest: in relation to agenda item 6.2 Tris (2-ethylhexyl) benzene-1,2,4-tricarboxylate (EFSA-Q-2017-00645) the experts indicated that they were involved in the risk assessment of this substance as printing ink in the context of their employment with the national risk assessment body, BfR. The advice was given to a public body, more than 5 years ago and in addition the final report from BfR will not be reviewed in the course of the evaluation by the WG. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹¹ and the Decision of the Executive Director on Declarations of Interest¹², 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 experts concerned.

 $^{^{11}\ \}underline{\text{http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf}}$

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 27th meeting of the Working Group on Food Contact Materials 2017-2018

Held by teleconference, 6-7 December 2017

(Agreed on 19 December 2017)¹

Participants

• Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi², Roland Franz, Koni Grob, Eugenia Lampi², Kettil Svensson³ and Detlef Wölfle

• European Commission and/or Member States representatives:

• EFSA:

FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Ellen Van Haver, Katharina Volk

1. Welcome and apologies for absence

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

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 and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest (ADoI) and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

² Participated to agenda item 5.3 only

¹ By written procedure

Participated to agenda items 5.1 and 5.3

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Agreement of the of the minutes of the 26th WG meeting (10-12 October 2017)

The minutes of the 26th WG meeting held on 10-12 October 2017 were agreed by written procedure⁶.

5. Scientific topic(s) for discussion

5.1 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2017-00412)⁷

Further to the receipt of the additional information requested from the applicant, the draft opinion 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 Amines, bis (hydrogenated rape-oil alkyl) methyl, N-oxides (EFSA-Q-2015-00443)⁸

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

5.3 Titanium dioxide treated with fluoride modified alumina (EFSA-Q-2014-00300)⁹

Further to the receipt of the additional information requested from the applicant, the draft opinion 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. Any Other Business

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

7. Next meeting(s)

The next meeting is scheduled for 6-7 February 2018.

⁶ http://www.efsa.europa.eu/sites/default/files/assets/fcmwq2014-2017.pdf

¹ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-O-2017-00412

⁸ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00443

⁹ http://regi<u>sterofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2014-00300</u>



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

Minutes of the 26th meeting of the Working Group on Food Contact Materials 2017-2018

Held on 10-12 October 2017, Athens (Greece) (Agreed on 26 October 2017)¹

Participants

Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Maria de Fátima Tavares Poças², Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi², Karla Pfaff, Maria Rosaria Milana³, Gilles Rivière, Kettil Svensson and Detlef Wölfle

European Commission and/or Member States representatives:

DG SANTE: Bastiaan Schupp

EFSA:

FIP Unit: Eric Barthélémy, Cristina Croera, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants and thanked the State General Chemical Laboratory for hosting the meeting at their premises.

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 and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to the Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

² Not present on 12 October

By written procedure

Not present on 11-12 October

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
 http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Agreement of the of the minutes of the 25th WG meeting (27-28 June 2017)

The minutes of the 25th WG meeting held on 27-28 June 2017 were agreed by written procedure⁶.

5. Scientific topic(s) for discussion

5.1 Isobutane (EFSA-Q-2016-00509)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 CEF Panel.

5.2 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2017-00495)⁸

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 Selenium nanoparticles (EFSA-Q-2017-00089)9

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

5.4 Active mixture Spongel (EFSA-Q-2017-00054)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 CEF Panel.

5.5 Reaction product of stearyl-diethanol-amine with C18 saturated fatty acids (additive) (EFSA-Q-2016-00510)¹¹

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.

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

⁶ http://www.efsa.europa.eu/sites/default/files/assets/fcmwg2014-2017.pdf

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00509

⁸ http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-O-2017-00495

http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-Q-2017-00089

¹⁰ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-0-2017-00054

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

http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00444



5.7 Ground sunflower seed hulls (EFSA-Q-2017-00494)¹³

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.

5.8 Ln 1,4-Benzene Dicarboxylic acid (with Ln=La,Eu,Gd,Tb) (EFSA-Q-2016-00128)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, CEF Panel and the European Commission

The WG was informed about the 5th meeting of the FCM Network meeting that was held 10-11 July 2017. The minutes and presentations of that meeting are available on the EFSA website.

The European Commission representative, B. Schupp, informed the WG about ongoing activities at the EC in the area of FCM, including biocides that are in the <u>provisional list of additives used in plastics</u> and more generally on biocides used in food contact materials and the related cooperation with ECHA.

As a follow-up to the last Plenary meeting of the CEF Panel (19-21 September 2017), the WG learnt about the need to implement cross-cutting guidance documents of the Scientific Committee consistently across EFSA Panels. The WG briefly discussed this matter and will bring forward an indicative implementation plan for having these risk assessment methodologies applied at the level of the WG where applicable.

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 and about applications that have been withdrawn since last WG meeting.

The WG was informed that Jean Claude Lhuguenot, sadly passed away recently. Jean Claude was member of the WG on FCM from 2003 till 2014 and was Chairperson for much of that time. He was highly appreciated for his scientific ability and human qualities. He had a passion for science, music, family and friends. He will be remembered as a colleague and a friend.

Next meeting(s)

The next meeting will take place on 5-7 December 2017.

http://registerofguestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00494

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00128



Annex

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

In his SDoI filled for the present meeting Dr. R. Franz declared the following interest: his laboratory has done some experimental work in support of this dossier, under agenda item 5.7. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁵ and the Decision of the Executive Director on Declarations of Interest¹⁶, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 5.7 by the concerned scientific group.

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
 http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 25th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 27-28 June 2017, Parma (Agreed on 13 July 2017)1

Participants

Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Maria de Fátima Tavares Poças², Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi², Maria Rosaria Milana³, Kettil Svensson and Detlef Wölfle

European Commission and/or Member States representatives:

EFSA:

FIP Unit: Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

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 and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to the Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

By written procedure

Not present on 28 June PM

Not present on 28 June

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Agreement of the of the minutes of the 24th WG meeting (16-18 May 2017)

The minutes of the 24th WG meeting held on 16-18 May 2017 were agreed by written procedure⁶.

5. Scientific topic(s) for discussion

5.1 [3-(2,3-Epoxypropoxy)propyl]trimethoxysilane (EFSA-Q-2016-00001)⁷

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

5.2 Re-evaluation of (perfluorobutyl)ethylene (PFBE) (EFSA-Q-2016-00393)⁸

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 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2017-004129 and EFSA-Q-2017-0049510)

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.

In relation to mandate EFSA-Q-2017-00495, the European Commission requests EFSA to supplement its opinion on poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate), which was adopted in May 2016^{11} , to assess any potential risk resulting from contact between a FCM manufactured with this substance and dry foods. The former opinion focused on the intended use of the substance in contact with food groups 04.01 and 04.04 (unpeeled fruits and vegetables). For accommodating the request of the EC, additional data will be requested from the applicant.

5.4 Selenium nanoparticles (EFSA-Q-2017-00089)¹²

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 http://www.efsa.europa.eu/sites/default/files/assets/fcmwg2014-2017.pdf

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00001

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-O-2016-00393

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2017-00412

¹⁰ http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-O-2017-00495

https://www.efsa.europa.eu/en/efsajournal/pub/4464

http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00089



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

No updates were provided.

7. Other scientific topics for discussion

The WG members were informed about the outcome of the workshop on Uncertainty organised by the EFSA Scientific Committee WG which was held on 22-23 June 2017, where the outcome of the trial phase for implementing the principles of the uncertainty guidance in various areas of EFSA, including the FCM, was discussed.

8. Any Other Business

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

9. Next meeting(s)

The next meeting will take place on 10-12 October 2017.



Annex

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

In his SDoI filled for the present meeting Dr. R. Franz declared the following interest: His institute has done some experimental work for [3-(2,3-Epoxypropoxy)propyl]trimethoxysilane, under agenda item 5.1 and the results are included in the technical annex of the dossier. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹³ and the Decision of the Executive Director on Declarations of Interest¹⁴, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 5.1 by the concerned scientific group.

 $^{^{13} \ \}underline{\text{http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf}}$

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 24th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 16 - 18 May 2017, Parma (Agreed on 31 May 2017)¹

Participants

• Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi², Maria de Fátima Tavares Poças², Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana², Kettil Svensson and Detlef Wölfle

European Commission and/or Member States representatives:

DG SANTE: Bastiaan Schupp³

EFSA:

FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros

Lioupis, Ellen Van Haver, Katharina Volk

SCER Unit: Tilemachos Goumperis⁴

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 and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

¹ By written procedure

 $^{^{2}}$ Not present on 18 May 2017

³ Only present on 17 May 2017

⁴ Only present for agenda item 8

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



For further details on the outcome of the screening of the ADoI or the SDoI, please refer to the Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 21st (7 – 9 March), 22nd (28 April) and 23rd (8 May) WG meetings

The minutes of the 21^{st} WG meeting held on 7 – 9 March 2017 were agreed by written procedure. The minutes of the 22^{nd} WG meeting held on 28 April and of 23^{rd} WG meeting held on 8 May 2017 were agreed⁷.

5. Scientific topic(s) for discussion

5.1 [3-(2,3-Epoxypropoxy)propyl]trimethoxysilane (EFSA-Q-2016-00001)⁸

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

5.2 Isobutane (EFSA-Q-2016-00509)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 Dimethyl carbonate for use as monomer (EFSA-Q-2015-00832)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 CEF Panel.

5.4 Active mixture Spongel (EFSA-Q-2017-00054) 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 Selenium nanoparticles (EFSA-Q-2017-00089)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.

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

The WG was informed about the progress made by the EFSA RASFF WG that was set up following a request¹³ from the European Commission "for scientific technical assistance to

⁷ http://www.efsa.europa.eu/sites/default/files/assets/fcmwg2014-2017.pdf

⁸ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00001

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00509

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00832

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00054

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00089

¹³ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00709



the Rapid Alert System for Food and Feed (RASFF) on chemical contaminants". The RASFF WG would welcome receiving comments from the FCM WG on the proposed methodology for assessing exceedance of legal limits and substances with potential concern.

The European Commission representative, B. Schupp, presented to the WG the state of play of printed food contact materials and the possible ways to get them regulated in the near future.

7. Other scientific topics for discussion

As part of the trial phase for the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM, the FCM WG finalised the work material on their experiences on the uncertainty trial. These documents will be presented at the workshop on Uncertainty of the EFSA Scientific Committee which is scheduled for 22-23 June 2017.

8. Any Other Business

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

9. Next meeting(s)

The next meeting will take place on 27-28 June 2017.



Annex

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

In his SDoI filled for the present meeting Dr. R. Franz declared the following interest: His institute has done some experimental work for [3-(2,3-Epoxypropoxy)propyl]trimethoxysilane (Glymo - Glass Fibres), under agenda item 5.1 and the results are included in the technical annex of the dossier. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁴ and the Decision of the Executive Director on Declarations of Interest¹⁵, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 5.1 by the concerned scientific group.

¹⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 23th meeting of the Working Group on Food Contact Materials 2014-2017 – Subgroup on Uncertainty guidance

Held by TELE-conference, 08 May 2017

(Agreed on 16 May 2017)

Participants

Working Group Members:

Laurence Castle (Chair) and Detlef Wölfle

Hearing Experts

Peter Craig, Andy Hart and Josef Schlatter

• EFSA:

FIP Unit: Cristina Croera, Anna Federica Castoldi and Ellen Van Haver

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declaration of Interest² and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Scientific topic(s) for discussion

4.1 Uncertainty guidance from EFSA Scientific Committee

The WG members discussed the pending issues on the approach taken by the CEF Panel for implementing the SC Uncertainty guidance into the FCM case study selected for the trial phase. Some revisions of the wording was agreed to be introduced to make the exercise more transparent. The revised version will be presented to the next WG meeting.

5. Next meeting(s)

The next meeting will take place on 16-18 May 2017.



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

Minutes of the 22nd meeting of the Working Group on Food Contact Materials 2014-2017

Held by TELE-conference on 28 April 2017 (Agreed on 16 May 2017)

Participants

- Working Group Members:
 - Laurence Castle, Jean-Pierre Cravedi, Martine Kolf-Clauw, Eugenia Lampi, Eugenio Vilanova, Detlef Wölfle (Chair)
- European Commission and/or Member States representatives:
 Not applicable
- EFSA:
 - FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Fabiola Pizzo and Ellen Van Haver

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest (ADoI) and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Scientific topic(s) for discussion

4.1 Doverphos LGP-11 (phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters) (EFSA-Q-2013-00903)³

The draft opinion 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. Any Other Business

No other business was raised.

6. Next meeting(s)

The next meetings will take place on 8 May 2017 (subgroup on Uncertainty guidance) and 16-18 May 2017.

 $^{^{3} \ \}underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00903}$



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

Minutes of the 21st meeting of the Working Group on Food Contact Materials 2014-2017

Held on 7 – 9 March 2017, Parma (Agreed on 23 March 2017)¹

Participants

• Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Maria de Fátima Tavares Poças, Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Kettil Svensson and Detlef Wölfle

European Commission and/or Member States representatives:

DG SANTE: Takis Daskaleros

EFSA:

FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros

Lioupis, Carla Martino², Ellen Van Haver, Katharina Volk

APDESK Unit: Sara De Berardis² SCER Unit: Tilemachos Goumperis³

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 and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group (WG) members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

 $^{\rm 2}$ Only present for agenda item 7

¹ By written procedure

³ Only present for agenda item 8



4. Agreement of the minutes of the 20th WG meetings held on 18-19 January 2017

The minutes of the 20th WG meetings held on 18-19 January 2017 were agreed by written procedure⁴.

5. Scientific topic(s) for discussion

5.1 Isobutane (EFSA-Q-2016-00509)⁵

The dossier received from the applicant was discussed. The WG identified issues for clarification to be further discussed at a next WG meeting.

5.2 Reaction product of stearyl-diethanol-amine with C18 saturated fatty acids (EFSA-Q-2016-00510)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.

5.3 Dimethyl-1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylate (EFSA-Q-2015-00242)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 CEF Panel.

5.4 Re-evaluation of Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters (EFSA-Q-2016-00006)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 CEF Panel.

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

The WG was informed about the 4^{th} FIP FCM Network meeting dedicated to the safety assessment of coatings that was held 16^{th} of February 2017. The minutes and presentations of that meeting are available on the <u>EFSA website</u>.

The European Commission representative, T. Daskaleros, informed the FCM WG that from now on he will follow within DG SANTE the file on plastic food contact materials.

7. Other scientific topics for discussion

As part of the trial phase for the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM, the FCM

⁴ http://www.efsa.europa.eu/sites/default/files/assets/fcmwg2014-2017.pdf

⁵ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00509

⁶ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00510

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00242

⁸ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00006



WG continued the discussions held at the 20th FCM WG meeting and at the 66th CEF Plenary meeting. The FCM WG discussed in particular the uncertainties linked to the non-toxicity data of an FCM application that was selected for this exercise. The FCM WG will present their experiences on the uncertainty trial as feedback to the dedicated WG of the EFSA Scientific Committee.

Following the discussions at the 66th CEF Plenary meeting on the revisions EFSA intends to bring into the Note for Guidance for FCM substances, and to be able to address the comments that were received afterwards from the European Commission, the scope for revising this guidance document was clarified to the FCM WG, and some further amendments were discussed. The outcome of this discussion will be presented to the CEF Panel at their next plenary meeting.

8. Any Other Business

The WG was informed about a request⁹ from the European Commission "for scientific technical assistance to the Rapid Alert System for Food and Feed (RASFF) on chemical contaminants", and this include substances migrating from food contact materials. EFSA is requested to evaluate and propose a methodology that would allow for a risk-based classification of RASFF notifications on chemical contaminants. An EFSA Working Group has been set up by the Scientific Committee and Emerging Risks Unit and the members of the FCM WG will be informed about the work progress and the proposals made by that EFSA RASFF WG.

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

Next meeting(s)

The next meeting will take place on 16-18 May 2017.

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http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00709



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

Minutes of the 20th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 18 – 19 January 2017, Parma (Agreed on 3 February 2017)¹

Participants

• Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Kettil Svensson and Detlef Wölfle

Maria de Fátima Tavares Poças participated via teleconference

• European Commission and/or Member States representatives:

Bastiaan Schupp

• EFSA:

FIP Unit: Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Carla Martino², Claudia Putzu, Ellen Van Haver, Katharina Volk

APDESK Unit: Sara De Berardis²

1. Welcome and apologies for absence

The Chair welcomed the participants. The Chair also welcomed Claudio Putzu as a trainee in the FIP Unit.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group (WG) members invited for the present meeting. No Conflicts of

¹ By written procedure

² Only present for agenda item 8



Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 18th and 19th WG meetings held on 8-10 November and 21 December 2016

The minutes of the 18th and 19th WG meetings held on 8-10 November (Parma) and 21 December 2016 (by teleconference) were agreed by written procedure³.

5. Scientific topic(s) for discussion

5.1 Genox EP (EFSA-Q-2015-00443)⁴

The draft opinion 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, CEF Panel and the European Commission

The WG was informed about the "OpenFoodTox" Chemical Hazards Database that is accessible from the EFSA website⁵.

B. Schupp asked the WG for clarifications on the safety assessment of a FCM substance for which EFSA has recently published a favourable opinion. These clarifications will enable the European Commission to take the appropriate risk management measures for authorising the substance.

7. Other scientific topics for discussion

As part of the trial phase for the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM, the FCM WG continued the discussions on the elicitation training exercise following the discussions held at the 18th and 19th FCM WG meetings. The FCM WG discussed in particular the uncertainties linked to the toxicity data of an opinion on food contact materials that was selected for this exercise. The exercise will be continued in the next FCM WG.

8. Any Other Business

The WG was informed about the changes the EFSA Application Desk intends to bring into the EFSA administrative guidance document on plastic food contact materials and into the Note for Guidance for FCM substances. EFSA aims at publishing the revised versions of these documents before the end of February 2017.

9. Next meeting(s)

The next meeting will take place on 7-9 March 2017.

³ http://www.efsa.europa.eu/sites/default/files/assets/fcmwq2014-2017.pdf

⁴ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00443

⁵ http://www.efsa.europa.eu/en/data/chemical-hazards-data



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

Minutes of the 19th meeting of the Working Group on Food Contact Materials 2014-2017 – Subgroup on Uncertainty guidance

Held by TELE-conference, 21 December 2016

(Agreed on 9 January 2017)¹

Participants

- Working Group Members:
 - Laurence Castle (Chair), Koni Grob, Wim Mennes, Maria de Fátima Tavares Poças and Detlef Wölfle
- EFSA:
 - FIP Unit: Cristina Croera, Claudio Putzu, Ana Maria Rincon and Ellen Van Haver

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 and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1 Uncertainty guidance from EFSA Scientific Committee

The WG members discussed the drafts proposed for the implementation of the Uncertainty guidance in an opinion selected for the trial phase. Further discussion will be

¹ By written procedure



needed for the finalisation of the exercise. Tasks were allocated to the WG members for the next WG meeting.

5. Next meeting(s)

The next meeting will take place on 18-19 January 2017.



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

Minutes of the 18th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 8 – 10 November 2016, Parma (Agreed on 24 November 2016)¹

Participants

Working Group Members:

 Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Maria de Fátima Tavares Poças², Kettil Svensson, Eugenio Vilanova³, Detlef Wölfle

• Hearing Experts⁴:

Andrew Hart (for agenda point 7 only)

• European Commission and/or Member States representatives:

Bastiaan Schupp⁵

• EFSA:

- FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Ellen Van Haver, Katharina Volk, Lei Zhu
- PPR Unit: Andrea Terron

1. Welcome and apologies for absence

The Chair welcomed the participants, including Lei Zhu from China National Centre for Food Safety Risk Assessment who has been temporarily joining the FIP Unit as guest scientist.

2. Adoption of agenda

The agenda was adopted without changes.

¹ By written procedure

² Not present on 9 November and attendance by teleconference on 10 November

³ Not present on 9 November pm and 10 November

⁴ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.

Not present on 9-10 November



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 17th Working Group meeting held on 27-29 September 2016, Parma

The minutes of the 17th Working Group meeting held on 27-29 September 2016 were agreed⁶.

5. Hearing Expert

Andrew Hart was invited to present his views on the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM during the trial phase (see agenda item 7).

6. Scientific topic(s) for discussion

6.1 Tungsten Oxide (EFSA-Q-2014-00726)⁷

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

6.2 Re-evaluation of Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl triesters (Weston 705) (EFSA-Q-2016-00006)⁸

The draft opinion 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.

6.3 Re-evaluation of (perfluorobutyl)ethylene (EFSA-Q-2016-00393)9

The draft opinion 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 Isooctadecanamide (EFSA-Q-2014-00651)¹⁰

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

⁶ http://www.efsa.europa.eu/sites/default/files/assets/fcmwg2014-2017.pdf

⁷ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2014-00726

⁸ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00006

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00393

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2014-00651



7. Other scientific topics for discussion

As part of the trial phase for the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM, Andy Hart (WG Uncertainty in Risk Assessment) continued the elicitation training exercise which was initiated at the last FCM WG to identify the uncertainties and the way how to address them in an FCM Opinion. The exercise will be continued in the next FCM WG.

8. Any Other Business

Andrea Terron (PPR Unit) informed the FCM WG about the OECD-EFSA workshop on "Developmental neurotoxicity: the use of non-animal test methods for regulatory purposes", which was held on 18-19 Oct 2016.

9. Next meeting(s)

The next meetings will take place on 21 December 2016 (teleconference) and 18-19 January 2017.



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

Minutes of the 17th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 27 - 29 September 2016, Parma (Agreed on 8 November 2016)

Participants

Working Group Members:

Claudia Bolognesi¹, Laurence Castle (Chair), Jean-Pierre Cravedi, Roland Franz², Koni Grob, Martine Kolf-Clauw³, Eugenia Lampi, Wim Mennes (for agenda point 8 only), Maria Rosaria Milana, Maria de Fátima Tavares Poças, Kettil Svensson, Detlef Wölfle

Hearing Experts³:

Andrew Hart (for agenda point 8 only)

• European Commission and/or Member States representatives:

Bastiaan Schupp (by teleconference, for certain items under agenda point 6)

• EFSA:

- FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Carla Martino, Ellen Van Haver, Katharina Volk
- APDESK Unit: Sara De Berardis

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 and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA

Not present on 27 September AM

² Not present on 29 September

³ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.



screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 15th Working Group meeting held on 5-7 July 2016, Parma, and of the 16th Working Group teleconference meeting held on 22 July 2016

The minutes of the 15th Working Group meeting held on 5-7 July 2016 and the minutes of the 16th Working Group teleconference meeting held on 22 July 2016 were agreed⁴.

5. Hearing Expert

Andrew Hart was invited to present his views on the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM during the trial phase (see agenda item 8).

6. Scientific topic(s) for discussion

6.1 Re-evaluation of Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl triesters (EFSA-Q-2016-00006)⁵

The draft opinion was discussed and will be further discussed at the next Working Group meeting.

6.2 Dimethyl-1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylate (EFSA-Q-2015-00242)⁶

The draft opinion 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.

6.3 Dimethyl carbonate for use as monomer (EFSA-Q-2015-00832)⁷

The draft opinion 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 Isooctadecanamide (EFSA-Q-2014-00651)⁸

The draft opinion 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.

6.5 (Butadiene-styrene-methyl methacrylate-butyl acrylate) copolymer (EFSA-Q-2015-00061)⁹

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

⁴ http://www.efsa.europa.eu/en/fipwqs/documents/foodcontactmaterialswq.pdf

⁵ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00006

⁶ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00242

⁷ http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-O-2015-00832

⁸ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00651

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00061



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

The WG was informed about the statement on the developmental immunotoxicity of bisphenol A (BPA)¹⁰ adopted by the CEF Panel at their last plenary meeting, following a question from the Dutch Ministry of Health, Welfare and Sport (RIVM).

8. Other scientific topics for discussion

As part of the trial phase for the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM, Andy Hart (WG Uncertainty in Risk Assessment) provided the WG with an expert elicitation training to identify the uncertainties and the way how to address them in an FCM Opinion. The exercise will be continued in the next FCM WG.

9. Any Other Business

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

10.Next meeting(s)

The next meeting will take place on 8-10 November 2016.

¹⁰ http://www.efsa.europa.eu/en/efsajournal/pub/4580



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

Minutes of the 16th meeting of the Working Group on Food Contact Materials 2014-2017

Held by TELE-conference on 22 July 2016 (Agreed on 27 September 2016)

Participants

- Working Group Members:
 - Jean-Pierre Cravedi, Martine Kolf-Clauw, Eugenia Lampi, Eugenio Vilanova, Detlef Wölfle (Chair)
- European Commission and/or Member States representatives:
 Not applicable
- EFSA:
 - FIP Unit: Anna Federica Castoldi and Ellen Van Haver

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest (ADoI) and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Agreement of the minutes of the 15th Working Group meetings held on 5-7 July 2016, Parma

The minutes of the 15th Working Group meeting held on 5-7 July 2016 were agreed on 27 September 2016³.

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-2013-00903)⁴

The draft opinion 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. Any Other Business

No other business was raised.

7. Next meeting(s)

The next meeting will take place on 27-29 September 2016.

³ http://www.efsa.europa.eu/sites/default/files/assets/fcmwg2014-2017.pdf

http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00903



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

Minutes of the 15th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 5 - 7 July 2016, Parma (Agreed on 27 September 2016)

Participants

• Working Group Members:

 Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Roland Franz, Koni Grob, Eugenia Lampi, Maria de Fátima Tavares Poças (by teleconference, on 7 July only), Kettil Svensson, Detlef Wölfle (on 5-6 July)

• Hearing Experts¹:

Andrew Hart (for agenda point 8 only)

• European Commission and/or Member States representatives:

Not applicable

• EFSA:

- FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Ellen Van Haver, Katharina Volk
- APDESK Unit: Sara De Berardis

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Martine Kolf-Clauw and Maria Rosaria Milana.

Roland Franz did not participate in agenda points 6.4 and 6.5 due to a Conflict of Interest being identified for these agenda items.

2. Adoption of agenda

The agenda was adopted without changes.

As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest (ADoI) and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declarations of Interest were requested at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 13th Working Group meetings held on 11-13 May 2016, Parma, and of the 14th Working Group teleconference meeting held on 31 May 2016

The minutes of the 13th Working Group meeting held on 11-13 May 2016 were agreed by written procedure on 30 May 2016⁴. The minutes of the 14th Working Group teleconference meeting held on 31 May 2016 were agreed on 6 July 2016⁵.

5. Hearing Expert

Andrew Hart was invited to present his views on the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM during the trial phase (see agenda item 8).

6. Scientific topic(s) for discussion

6.1 2,3,3,4,4,5,5-heptafluoro-1-pentene (EFSA-Q-2015-00050)⁶

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

6.2 Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omegahydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters (EFSA-Q-2013-00903)⁷

The draft opinion was discussed. A Working Group teleconference meeting will be organised to continue the scientific evaluation of the toxicological data of the substance.

6.3 Amines, bis (hydrogenated rape-oil alkyl) methyl, N-oxides (EFSA-Q-2015-00443)⁸

The draft opinion 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.

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁴ http://www.efsa.europa.eu/en/fipwgs/documents/foodcontactmaterialswg.pdf

⁵ The 14th Working Group meeting concerned a subgroup to deal with the implementation of the Uncertainty guidance from the EFSA Scientific Committee

⁶ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00050

⁷ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00903

⁸ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00443



6.4 [3-(2,3-Epoxypropoxy)propyl]trimethoxysilane (EFSA-Q-2016-00001)⁹

The draft opinion 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.

6.5 Monomer Cyclooctene (EFSA-Q-2016-00016)¹⁰

The draft opinion 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. Feedback from EFSA, CEF Panel and the European Commission

The WG was informed about the kick-off meetings on Chemical mixtures and on Nanotechnologies, organised by the EFSA Scientific Committee.

8. Other scientific topics for discussion

The FCM WG discussed the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) in the field of FCM during the trial phase. Andy Hart (WG Uncertainty in Risk Assessment) will support the WG during this trial phase, and participated in the WG meeting as a hearing expert, to get an overview of the subjects covered and providing advice to identify uncertainties and how to address them in the Opinion to be selected for the trial exercise.

9. Any Other Business

No other business was raised.

10.Next meeting(s)

The next meetings will take place on 22 July 2016 (by teleconference) and 27-29 September 2016.

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00001

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00016



Annex I

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

a) In the SDoI filled for the present meeting Dr. Roland Franz declared the following institute has done experimental work Epoxypropoxy)propyl]trimethoxysilane (Glymo - Glass Fibres), under agenda item 6.4, and for Monomer Cyclooctene, under agenda item 6.5 and the results are included in the technical annexes of both dossiers. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹¹ and the Decision of the Executive Director on Declarations of Interest¹² and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a Conflict of Interest (CoI). This results in the exclusion of the expert from any discussion, voting or other processing of items 6.4 and 6.5 by the concerned scientific group.

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
 http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 14th meeting of the Working Group on Food Contact Materials 2014-2017-Subgroup on Uncertainty guidance

Held by TELE-conference on 31 May 2016

(Agreed on 06 July 2016)

Participants

• Working Group Members:

Koni Grob, Maria de Fátima Tavares Poças and Detlef Wölfle (Chair)

EFSA:

FIP Unit: Cristina Croera and Ellen Van Haver

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

Not applicable, because no question number is associated with the item discussed.

4. Scientific topic(s) for discussion

4.1 Uncertainty guidance from EFSA Scientific Committee

The measures to implement into a FCM opinion the revised draft "Guidance on Uncertainty in EFSA Scientific Assessments" from the EFSA Scientific Committee (SC)¹, was discussed. A proposal of the work plan for the trial period was done by the WG members.

5. Next meeting(s)

The next meeting will take place on 5-7 July 2016.

 $^{^{1}\} https://www.efsa.europa.eu/sites/default/files/160321DraftGDUncertaintyInScientificAssessment.pdf$



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

Minutes of the 13th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 11 - 13 May 2016, Madrid (Agreed on 30 May 2016)¹

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Roland Franz, Koni Grob, Martine Kolf-Clauw (on 11-12 May), Eugenia Lampi (on 11-12 AM May), Maria Rosaria Milana, Maria de Fátima Tavares Poças, Kettil Svensson, Detlef Wölfle
- European Commission and/or Member States representatives:
 - Bastiaan Schupp (DG SANTE) (on 11 May)
- EFSA:
 - FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants and thanked the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) for hosting the meeting at their premises.

Roland Franz did not participate in agenda points 5.5 and 5.8 due to a Conflict of Interest being identified for these agenda items.

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 and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest (ADoI) and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

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

¹ By written procedure

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declarations of Interest were requested at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 12th Working Group meeting held on 1-3 March 2016, Parma.

The minutes of the 12th Working Group meeting held on 1-3 March 2016 were agreed by written procedure on 15 March 2016⁴.

5. Scientific topic(s) for discussion

5.1 Diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate (Irgamod) (EFSA-Q-2012-00908)⁵

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.2 Doverphos LGP-11 (phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters) (EFSA-Q-2013-00903)⁶

The draft opinion was discussed and changes were noted. Subject to these changes, a new draft opinion will be scheduled for the July WG meeting.

5.3 Dimethyl carbonate for use as monomer (EFSA-Q-2015-00832)⁷

The draft opinion 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 Methanone,(2,4-diflurophenyl)(4-fluorophenyl)- (EFSA-Q-2015-00121)⁸

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.5 Superabsorbent Polymer FAVOR® P500 (EFSA-Q-2015-00612)9

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

⁴ http://www.efsa.europa.eu/en/fipwqs/documents/foodcontactmaterialswq.pdf

⁵ http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-0-2012-00908

⁶ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2013-00903

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00832 http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00121

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00612



5.6 CO2 emitter for poultry meat (EFSA-Q-2015-00848)10

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.7 Freshness indicator for poultry meat (EFSA-Q-2016-00007)11

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.8 Ground sunflower seed shells (lignocellulose) (EFSA-Q-2015-00427)12

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

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

The WG was informed about the Uncertainty guidance from the EFSA Scientific Committee (http://www.efsa.europa.eu/en/topics/topic/uncertainty) and the training course organised by EFSA for implementing the principles of uncertainty on a case study during the trial phase.

7. Any Other Business

No other business was raised.

8. Next meeting(s)

The next meeting will take place on 5-7 July 2016.

 $^{^{10} \} http://registerof questions.efs a. europa.eu/roq Frontend/question Loader? question = EFSA-Q-2015-00848$

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00007

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00427



Annex I

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

a) In the SDoI filled for the present meeting Dr. Roland Franz declared the following interests: His institute has previously done some testing for an active and intelligent packaging (FAVOR®PAC) which is similar to agenda items 5.5 (Superabsorbent Polymer FAVOR® P500) and could compete on the market with the active and intelligent packaging under evaluation; his institute has done experimental work (screening analysis and migration tests) for Ground sunflower seed shells (lignocellulose), under agenda item 5.8. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹³ and the Decision of the Executive Director on Declarations of Interest¹⁴ and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a Conflict of Interest (CoI). This results in the exclusion of the expert from any discussion, voting or other processing of items 5.5 and 5.8 by the concerned scientific group.

¹³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 12th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 1 – 3 March 2016, Parma (Agreed on 15 March 2016)¹

Participants

Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi (on 2-3 March), Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana (on 1-2 March), Maria de Fátima Tavares Poças, Kettil Svensson (on 1-2 March), Detlef Wölfle

• European Commission and/or Member States representatives:

- Bastiaan Schupp (DG SANTE)

• EFSA:

 FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

- LRA Unit: Simone Gabbi (for agenda point 6.2)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Detlef Wölfle did not participate in agenda point 5.4, and Roland Franz in agenda point 5.5 due to a Conflict of Interest being identified for these agenda items.

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 and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest (ADoI) and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

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

¹ By written procedure

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declarations of Interest were requested at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 10th Working Group meeting held on 19-21 January 2016, Parma.

The minutes of the 10th Working Group meeting held on 19-21 January 2016 were agreed⁴. The minutes of the 11th⁵ Working Group meeting were agreed by written procedure on 27 February 2016.

5. Scientific topic(s) for discussion

5.1 2,3,3,4,4,5,5-Heptafluoro-1-pentene (EFSA-Q-2015-00050)⁶

The draft opinion 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 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2015-00414)⁷

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.3 Dimethyl carbonate for use as monomer (EFSA-Q-2015-00832)8

The draft opinion 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 Re-evaluation of Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl triesters (Weston 705) (EFSA-Q-2016-00006)⁹

The draft opinion 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 Sodium polyacrylate, cross linked (EFSA-Q-2014-00449)¹⁰

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.6 VINNAPAS LL 8324 (EFSA-Q-2015-00411)11

The draft opinion was discussed. The WG requires additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

⁴ http://www.efsa.europa.eu/en/fipwqs/documents/foodcontactmaterialswq.pdf

⁵ The 11th Working Group meeting concerned a subgroup to deal with a mandate for supplying additional information following the publication of an inconclusive opinion on HDPE recycling processes

⁶ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00050

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00414

http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-O-2015-00832

⁹ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00006

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00449

¹¹ http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-0-2015-00411



6. Any Other Business

6.1 New Mandates

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

6.2 Confidentiality and data sharing

The WG was informed about the rules regarding confidentiality of information in applications vs. in opinions, as well as about the restrictions on the sharing of existing data with respect to the safety assessment of food contact materials.

6.3 Analytical methods for control purposes

The WG had a discussion on how to assess the appropriateness of analytical methods suitable for use by control authorities, as required by article 10.4(c) of Regulation (EC) 1935/2004.

7. Next meeting(s)

The next meeting will take place on 11-13 May 2016.



Annex I

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

- a) In the SDoI filled for the present meeting Dr. Detlef Wölfle declared that he provided in the context of a contract between EFSA and BfR preparatory work documents for the substance 4-(2-methylbutan-2-yl)phenyl]x [2,4-bis(2-methylbutan-2-yl)phenyl]3-x phosphite (x = 0, 1, 2, 3) which is equivalent to the substance of agenda point 5.4. on Phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl triesters (Weston 705). An opinion on the substance itself was adopted on 06.07.11 and the substance is under discussion at this WG meeting for extension of the SML. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹² and the Decision of the Executive Director on Declarations of Interest¹³ 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). This results in the exclusion of the expert from any discussion, voting or other processing of item 5.4 by the concerned scientific group.
- b) In the SDoI filled for the present meeting Dr. Roland Franz declared the following interest: His institute has done some migration tests on products of the petitioner. The test reports were used in a technical annex of the petitioner's dossier related to agenda item 5.5: Sodium polyacrylate, cross linked. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁴ and the Decision of the Executive Director on Declarations of Interest¹⁵ 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). This results in the exclusion of the expert from any discussion, voting or other processing of item 5.5 by the concerned scientific group.

¹² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014

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

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 11th meeting of the Working Group on Food Contact Materials 2014-2017 -Subgroup on Mandate for supplying additional information following the publication of an inconclusive opinion on HDPE recycling processes

Held on 21-22 January 2016, Parma

(Agreed on 27 February 2016)

Participants

Working Group Members:

Claudia Bolognesi, Laurence Castle (Chair) and Maria Rosaria Milana Trine Husøy participated via teleconference Vittorio Silano participated via teleconference, on day 2 only

Hearing Experts:

Josef Schlatter

European Commission and/or Member States representatives: Not applicable

• EFSA:

FIP Unit: Anna Federica Castoldi, Cristina Croera and Alexandros Lioupis

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Wim Mennes.



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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 10th Working Group meeting held on 19-21 January 2016, Parma.

The agreement of the minutes of the previous meeting held on 19-21 January was deferred due to the invitation in the current meeting of only a subgroup of experts.

5. Hearing Expert

Dr. Josef Schlatter was invited to present his views for the scientific topic of the present meeting.

6. Scientific topic for discussion

6.1 . Identification of the substances from the Carcinogenic Potency Database (CPDB) which are of particular concern even if ingested at doses below 0.0025 $\mu g/kg$ body weight per day (EFSA-Q-2015-00238)³

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

³ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00238



7. Any Other Business

Not applicable

8. Next meeting

The next meeting will take place in Parma on 1-3 March 2016.



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

Minutes of the 10th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 19 - 21 January 2016, Parma (Agreed on 1 March 2016)

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Fátima Poças, Kettil Svensson, Detlef Wölfle
- European Commission and/or Member States representatives:
 - Bastiaan Schupp (DG SANTE) on 20 21 January 2016
- EFSA:
 - FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jean-Pierre Cravedi.

Roland Franz did not participate in agenda point 5.5 due to a Conflict of Interest being identified for this agenda item.

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declarations of Interest were requested at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 8th Working Group meeting held on 10-12 November 2015, Parma.

The minutes of the 8th³ Working Group meeting held on 10-12 November 2015 were agreed by written procedure⁴ on the 2nd of December 2015.

5. Scientific topic(s) for discussion

5.1 Zinc Oxide, nanoparticles (EFSA-Q-2014-00529)⁵

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

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

The draft opinion 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 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2015-00414)⁷

The draft opinion was discussed and changes were noted. Subject to these changes, a new draft opinion will be scheduled for the March WG meeting.

5.4 Butadiene – styrene – methyl methacrylate – butyl acrylate copolymer cross-linked with divinylbenzene or 1,3-butanediol (EFSA-Q-2015-00061)⁸

The draft opinion 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 A&I Sodium polyacrylate, crosslinked (EFSA-Q-2014-00449)9

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.6 Antioxidant Phosphorous acid, triphenyl ester, polymer with alphahydro-omega-hydroxypoly[oxy(methyl-1,2-ethediyl)],C10-16 alkyl esters (Doverphos LGP-11) (EFSA-Q-2013-00903)¹⁰

The draft opinion 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.

³ The 9th Working Group meeting dealt with the revision of the draft 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-Q-2011-00107)", following its public consultation

⁴ http://www.efsa.europa.eu/en/fipwgs/documents/foodcontactmaterialswg.pdf

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2014-00529

⁶ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00300

http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00414

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00061 http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00449

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2013-00903



5.7 A&I additive Oxyfresh W1 (EFSA-Q-2012-00940)11

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. The scientific evaluation is currently suspended.

6. Any Other Business

The Working Group was informed about the new mandates on food contact materials that were received by EFSA.

7. Next meeting(s)

The next meeting will take place in Parma on 1-3 March 2016.

 $^{11}\ \underline{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00940}$



Annex I

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

a) In the SDoI filled for the present meeting Dr. Roland Franz declared the following interest: His institute has done some migration tests on products of the petitioner. The test reports were used in a technical annex of the petitioner's dossier related to agenda item 5.5: A&I SAP DSorb 228X5. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹² and the Decision of the Executive Director on Declarations of Interest¹³ 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). This results in the exclusion of the expert from any discussion, voting or other processing of item 5.5 by the concerned scientific group.

¹² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

¹³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 9th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 12- 13 November 2015, Parma (Agreed on 6 January 2016)

Participants

- Working Group Members:
 - Laurence Castle (Chair), Roland Franz¹, Koni Grob, Detlef Wölfle and Maria de Fátima Tavares Pocas
- EFSA:
 - FIP Unit: Eric Barthélémy, Katharina Volk, Alexandros Lioupis, Cristina Croera² and Ellen van Haver³
 - DATA Unit: Davide Arcella⁴

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 and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

¹ Participated via teleconference

² Participated only on 12 November

³ Participated only on 12 November

⁴ Participated in discussion on exposure

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Adoption of the Minutes from the 7th FCM WG meeting on 26-27 October

The minutes of the 7th FCM WG meeting held on 26-27 October 2015 were agreed on 12th November⁷.

5. Scientific outputs submitted for discussion

5.1Public consultation on draft 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-Q-2011-00107)" - EFSA-Q-2015-00293

The public consultation on the draft 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-Q-2011-00107) ended on 7 October (http://www.efsa.europa.eu/en/consultations/call/150707). Following the comments received, the WG met on 15th October (preparatory teleconference) and 26-27 October (7th FCM WG meeting) to discuss the further elaboration of the draft opinion sent out for public consultation and the answers to comments received.

In this 9th FCM WG meeting, the WG further elaborated the draft opinion, notably the exposure and food consumption considerations, with the support of the EFSA DATA Unit. The WG also discussed the corresponding EFSA technical report aiming to compile the comments received and to provide a response. A revised draft opinion incorporating changes as suggested during the meeting and a technical report on the Public Consultation will be prepared.

The draft revised opinion will be scheduled at the next 59^{th} CEF Panel meeting on 1-3 December for discussion and possible adoption. The EFSA technical report will be presented too.

6. Any Other Business

No other business was raised.

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⁷ The Minutes of the 8th Working Group meeting were agreed by written procedure on 2nd December 2015.



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

Minutes of the 8th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 10 - 12 November 2015, Parma (Agreed on 2 December 2015)

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Fátima Poças, Kettil Svensson, Detlef Wölfle
 - Roland Franz participated via teleconference, in agenda points 5.2, 5.6 and 5.9
- European Commission and/or Member States representatives:
 - Bastiaan Schupp (DG SANTE) participated via teleconference

EFSA:

 FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Alexandros Lioupis, Ellen Van Haver, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants.

Roland Franz did not participate in agenda point 5.5 due to a Conflict of Interest being identified for this agenda item.

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declarations of Interest were requested at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 6th Working Group meeting held on 23-24 September 2015, Parma.

The minutes of the 6th³ Working Group meeting held on 23-24 September 2015 were agreed by written procedure⁴ on the 16th of October 2015.

5. Scientific topic(s) for discussion

5.1 Isooctadecanamide (EFSA-Q-2014-00651)⁵

The draft opinion 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 α-Tocopherol acetate (EFSA-Q-2015-00434)⁶

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.3 VINNAPAS® LL 8324 (EFSA-Q-2015-00411)⁷

The draft opinion 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 Genox EP (EFSA-Q-2015-00443)8

The draft opinion 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 Ground sunflower seed shells (lignocellulose) (EFSA-Q-2015-00427)9

The draft opinion 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.

³ The 7th Working Group meeting dealt with the revision of the draft 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-Q-2011-00107)", following its public consultation

⁴ http://www.efsa.europa.eu/en/fipwgs/documents/foodcontactmaterialswg.pdf

⁵ http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-0-2014-00651

⁶ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00434

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00411 http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00443

⁹ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00427



5.6 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate (EFSA-Q-2015-00414)¹⁰

The draft opinion was discussed and changes were noted. Subject to these changes, a new draft opinion will be scheduled for the January WG meeting.

5.7 Diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate (EFSA-Q-2012-00908)¹¹

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.8 Biocork®sulphites-active caps (EFSA-Q-2015-00104)12

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled for discussion and possible adoption at the next Panel plenary meeting.

5.9 Public consultation on draft 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-Q-2011-00107)" (EFSA-Q-2015-00293)¹³

The Chair of the Working Group on food contact materials and the EFSA staff coordinator of the self-task reported on i) the comments received through the public consultation that was launched on 7 July and ended on 7 October 2015 and ii) the outcome of the first discussion held at the 58th CEF Panel meeting on 27-28 October.

6. Any Other Business

The Working Group was informed about the new mandates on food contact materials that were received by EFSA.

7. Next meeting(s)

The next meetings will take place in Parma on 19-21 January and 1-3 March 2016.

 $[\]frac{10}{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00414}}$

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00908

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00104

http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00293



Annex I

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

a) In the SDoI filled for the present meeting Dr. Roland Franz declared the following interest: His lab has done experimental work (screening analysis and migration tests) for application Ground sunflower seed shells (lignocellulose). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁴ and the Decision of the Executive Director on Declarations of Interest¹⁵ 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). This results in the exclusion of the expert from any discussion, voting or other processing of item 5.5 by the concerned scientific group.

¹⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

¹⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



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

Minutes of the 7th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 26- 27 October 2015, Parma (Agreed on 12 November 2015)

Participants

- Working Group Members:
 - Laurence Castle (Chair), Roland Franz¹, Koni Grob and Detlef Wölfle
- EFSA:
 - FIP Unit: Eric Barthélémy, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants.

Fátima Poças was apologised.

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 and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 6th Working Group meeting held on 23-24 September 2015, Parma.

The minutes of the 6th Working Group meeting held on 23-24 September 2015 were agreed by written procedure on the 16th of October 2015.

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

¹ Participated via teleconference

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



5. Scientific outputs submitted for discussion

5.1Public consultation on draft 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-Q-2011-00107)" - EFSA-Q-2015-00293

The public consultation on the draft 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-Q-2011-00107) ended on 7 October (http://www.efsa.europa.eu/en/consultations/call/150707). Following to the comments received and the preparatory meeting held by teleconference on 15th October, the WG discussed on the further elaboration of the draft opinion sent out for public consultation.

A revised draft opinion incorporating changes as suggested during the meeting and a technical report on the Public Consultation will be prepared.

The CEF Panel will be informed at its 58th plenary meeting, on the administrative outcome of the public consultation, the scientific issues raised through the comments received and the workplan for revising the draft opinion and preparing the technical report. The WG will also propose to discuss major issues.

6. Any Other Business

No other business was raised.



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

Secretary's notes of the 6th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 23 - 24 September 2015, Parma (Agreed on 16 10 2015)

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Roland Franz, Koni Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Kettil Svensson, Detlef Wölfle
- European Commission and/or Member States representatives:
 - Bastiaan Schupp (DG SANTE)
- EFSA:
 - FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera, Rositsa Serafimova, Ellen Van Haver, Katharina Volk

1. Welcome and apologies for absence

The Chair welcomed the participants.

The Chair thanked Rositsa Serafimova, transferring from the FIP unit from November 2015 to another post in EFSA, for her invaluable contribution to the work of the WG.

Fátima Poças participated in the whole meeting via 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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declarations of Interest were requested at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 5th Working Group meeting held on 8-9 July 2015, Parma.

The minutes of the 5th Working Group meeting held on 8-9 July 2015 were agreed.³

5. Scientific topic(s) for discussion

5.1 N,N-Bis(2hydroxyethyl)alkyl(C8-C18) amine (EFSA-Q-2014-00859)⁴

The draft opinion was discussed and changes were noted. Subject to these changes and clarifications on the mandate, a new draft opinion will be scheduled for the next WG meeting.

5.24-Acrylamido-4-methyl-2-pentanone (EFSA-Q-2013-00031)⁵

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.3 Methanone, (2,4-diflurophenyl) (4-fluorophenyl) - (EFSA-Q-2015-00121)⁶

The draft opinion 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 Biocork®sulphites-active caps (EFSA-Q-2015-00104)⁷

The draft opinion was discussed and changes were noted. Subject to these changes, a new draft opinion will be scheduled for a next WG meeting

5.5 Dimethyl-1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylate (EFSA-Q-2015-00242)⁸

The draft opinion 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.

³ http://www.efsa.europa.eu/en/fipwqs/documents/foodcontactmaterialswq.pdf

⁴ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2014-00859

⁵ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00031

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00121

⁷ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00104

⁸ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00242



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

- 6.1 Feedback from Panel on data sharing data protection issues.
- 6.2 Feedback from EFSA on the public consultation procedure and further planning on draft 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"
- 6.3 New mandates

7. Next meeting(s)

The next meetings will take place in Parma 26-27 October and 10-12 November 2015.



Annex I

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

a) In the SDoI filled for the present meeting Dr. Detlef Woelfle declared the following interest: His institute (BfR) had prepared the Summary Data Sheet for "4-acrylamido-4-methyl-2-pentanone" as part of a contract with EFSA. This contract is no longer active. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest 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. Therefore the concerned expert shall be allowed to take part in the discussions and in the drafting phase of the scientific output for "4-acrylamido-4-methyl-2-pentanone".

⁹ The previous version of the minutes referred to "a waiver was granted", however, this sentence has been amended in line with the rules of the Decision of the Executive Director on Declarations of Interest (31/07/2014).



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

Minutes of the 5th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 8 - 9 July 2015, Parma (Agreed on 23 09 2015)

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Koni Grob, Eugenia Lampi, Maria Rosaria Milana, Fátima Poças, Kettil Svensson, Detlef Wölfle
- European Commission and/or Member States representatives:
- EFSA:
 - FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Joaquim Maia, Rositsa Serafimova

1. Welcome and apologies for absence

The Chair welcomed the participants.

Martine Kolf-Clauw participated via teleconference on 8 July and did not participate on 9 July.

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Agreement of the minutes of the 4th Working Group meeting held on 27-29 May 2015, Parma.

The minutes of the 4th Working Group meeting were agreed by written procedure on 18 June 2015.3

5. Scientific topic(s) for discussion

5.1 Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omegahydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters (EFSA-Q-2013-00903)

The draft opinion 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 Titanium dioxide treated with fluoride modified aluminia (EFSA-O-2014- $00300)^{5}$

The draft opinion 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.

5.32,4-di-t-Amylphenol (EFSA-Q-2015-00091)⁶

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.4 Isooctadecanamide (EFSA-Q-2014-00651)⁷

The draft opinion 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.

Next meeting(s)

The next meeting will take place in Parma from 23-24 September 2015.

³ http://www.efsa.europa.eu/en/fipwgs/documents/foodcontactmaterialswg.pdf

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00903

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

⁶ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00091

http://registerofguestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00651



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

Minutes of the 4th meeting of the Working Group on Food Contact Materials 2014-2017

Held on 27 - 29 May 2015, Parma (Agreed on 18 06 2015)

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Martine Kolf-Clauw, Koni Grob, Eugenia Lampi, Maria Rosaria Milana, Fátima Poças, Kettil Svensson, Detlef Wölfle
- European Commission and/or Member States representatives:
 - Bastiaan SCHUPP (DG SANTE)
- EFSA:
 - FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Joaquim Maia, Rositsa Serafimova

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jean-Pierre Cravedi for the whole meeting

Maria Rosaria Milana did not participate on Friday 29 May

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 3rd Working Group meeting held on 21-23 April 2015, Porto.

The minutes of the 3rd Working Group meeting were agreed by written procedure on 14 May 2015.³

5. Scientific topic(s) for discussion

5.1 Montmorillonite clay modified with dimethyldialkyl(C14-C18)ammonium chloride (EFSA-Q-2013-00437)⁴

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.2 Montmorillonite clay modified with hexadecyltrymethylammonium bromide (EFSA-Q-2013-00641)⁵

The draft opinion 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 Perfluoromethyl perfluorovinylether (EFSA-Q-2014-00314)⁶

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.4 A&I SAP DSorb 228X5 (EFSA-Q-2014-00449)⁷

The draft opinion 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 Isooctadecanamide (EFSA-Q-2014-00651)⁸

The draft opinion was discussed. The WG requested to consult the CEF Panel. The draft opinion will be scheduled for the next Panel meeting for discussion.

5.6 Biocork® sulphites-active caps (EFSA-Q-2015-00104)9

The draft opinion 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.

³ http://www.efsa.europa.eu/en/fipwqs/documents/foodcontactmaterialswq.pdf

⁴ http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00437

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

⁶ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2014-00314

⁷ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00449

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00651
 http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00104



5.7 Zinc Oxide, nanoparticles (EFSA-Q-2014-00529)¹⁰

The draft opinion was not discussed. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.8 Glass fibre sizing agents (EFSA-Q-2013-00838)¹¹

The draft opinion was not discussed.

Next meeting(s)

The next meeting will take place in Parma from 8-9 July 2015 (to be confirmed).

 $[\]frac{\text{10}}{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00529}}{\text{http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00838}}$



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

Minutes of the 3rd meeting of the Working Group on Food Contact Materials 2014-2017

Held on 21 - 23 April 2015, Porto (Agreed on 14 May 2015)

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Martine Kolf-Clauw, Koni Grob, Eugenia Lampi, Maria Rosaria Milana, Fátima Poças, Kettil Svensson, Detlef Wölfle
- European Commission and/or Member States representatives:
 - Bastiaan SCHUPP (DG SANTE)
- EFSA:
 - FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Joaquim Maia

1. Welcome and apologies for absence

The Chair welcomed the participants and thanked ESB/CBQ for kindly hosting the meeting.

2. Adoption of agenda

The agenda was adopted with changes. The item 5.8. "Nano-Montmorillonite Organoclay (EFSA-Q-2013-00641)" was deleted from the agenda.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. Agreement of the minutes of the 2nd Working Group meeting held on 10-12 February 2015, Parma.

The minutes of the 2nd Working Group meeting were agreed by written procedure on 04 March 2015.³

5. Scientific topic(s) for discussion

5.1 Zinc Oxide, nanoparticles (EFSA-Q-2014-00529)⁴

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.2 Oxyfresh W1 (EFSA-Q-2012-00904)⁵

The draft opinion 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.

5.32,3,3,4,4,5,5-heptafluoro-1-pentene (EFSA-Q-2015-00050)⁶

The draft opinion was discussed and changes were noted. The WG require additional information to complete the safety assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.4 Dimethyl ether as an extraction solvent (EFSA-Q-2014-00860)⁷

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.5 Glass fibre sizing agents (EFSA-Q-2013-00838)8

The draft opinion was discussed. The revised draft opinion will be scheduled in the Panel for discussion.

5.6 (Butadiene - styrene - methyl methacrylate - butyl acrylate) copolymer crosslinked with divinylbenzene or 1,3-butanediol dimethacrylate (EFSA-Q-2015-00061)⁹

The draft opinion was discussed and changes were noted. The WG require additional information to complete the safety assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

³ http://www.efsa.europa.eu/en/fipwqs/documents/foodcontactmaterialswq.pdf

http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00529

⁵ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00940

⁶ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2015-00050

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2014-00860 http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2013-00838

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00061



5.7 Montmorillonite clay modified by dimethyldialkyl(C14-C18)ammonium chloride (EFSA-Q-2013-00437)¹⁰

The draft opinion was discussed and changes were noted. The WG require additional information to complete the safety assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.8 Nano-Montmorillonite Organoclay (EFSA-Q-2013-00641)¹¹

The item was deleted from the agenda

 $5.9\,\text{FCM}$ Guidance / 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-Q-2011-00107) 12

Following its presentation at the 54th CEF Panel in March 2015, the draft opinion was revised. The main revisions were presented to the WG. The revised draft opinion will be scheduled for the Panel for discussion and possible endorsement. Once endorsed, it will be presented to the FIP FCM Network before being published for public consultation.

6. Next meeting(s)

The next meeting will take place in Parma from 27-29 May 2015.

¹⁰ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2013-00437

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

¹² http://reqisterofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00107



Title Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Minutes of the 2nd meeting of the Working Group on Food Contact Materials 2014-2017

Held on 10 - 12 February 2015, Parma (Agreed on 4 March 2015)

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Philippe Saillard, Kettil Svensson, Detlef Wölfle
- European Commission and/or Member States representatives:
 - Bastiaan SCHUPP (DG SANTE)
- EFSA:
 - FIP Unit: Eric Barthélémy, Anna Federica Castoldi, Cristina Croera,
 Georges Kass, Joaquim Maia, Rositsa Serafimova

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Koni Grob and Maria de Fatima Pocas for the whole meeting

Maria Rosaria Milana did not participate on Thursday 12 February

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declarations of Interest were requested at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 1st Working Group meeting held on 18-20 November 2014, Parma.

The minutes of the 1st Working Group meeting were agreed by written procedure on 11 December 2014.³

5. Scientific topic(s) for discussion

5.1 FCM Guidance (EFSA-Q-2011-00107)⁴

The draft opinion was not discussed.

5.2 Tetraethyl orthosilicate (TEOS)(EFSA-Q-2012-01011)⁵ and Hexamethyldisilazane (HMDS)(EFSA-Q-2013-00029)⁶

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.3 Benzenepropanamide 3,5-bis(1,1 -dimethylethyl) - 4hydroxy-, N-C16-18-alkyl derivs. (EFSA-Q-2013-00425)⁷

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.4 Zinc Oxide, nanoparticles (EFSA-Q-2014-00308)8

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

5.5 Tungsten Dioxide (EFSA-Q-2014-00726)9

The draft opinion was discussed. The WG require additional information to complete the risk assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

5.6 Glass fibre sizing agents (EFSA-Q-2013-00838)¹⁰
The terms of reference and the general approach to be taken were discussed.

³ http://www.efsa.europa.eu/en/fipwqs/documents/foodcontactmaterialswq.pdf

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00107

⁵ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2012-01011

⁶ http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2013-00029

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00425

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00308
 http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00726

¹⁰ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00838



6. Any Other Business

6.1 Discussion on the benchmark dose approach – applicability in the risk assessment on FCM

Next meeting(s)

The next meeting will take place in Porto from 21-23 April 2015.



Annex I

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

a) In the SDoI filled for the present meeting Dr. Detlef Woelfle declared the following interest: His institute (BfR) had prepared the Summary Data Sheet for "TEOS" and "HMDS" as part of a contract with EFSA. This contract is no longer active. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest 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 11. Therefore the concerned expert shall be allowed to take part in the discussions and in the drafting phase of the scientific output for "TEOS" and "HMDS".

 $^{^{11}}$ The previous version of the minutes referred to "a waiver was granted", however, this sentence has been amended in line with the rules of the Decision of the Executive Director on Declarations of Interest (31/07/2014).



Food Ingredients and Packaging Unit (FIP UNIT)

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

Minutes of the 1st meeting of the Working Group on Food Contact Materials 2014-2017

Held on 18 - 20 November 2014, Parma
(Agreed on 11 December 2014)

Participants

- Working Group Members:
 - Claudia Bolognesi, Laurence Castle (Chair), Jean-Pierre Cravedi, Riccardo Crebelli, Roland Franz, Konrad Grob, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Philippe Saillard, Kettil Svensson, Maria de Fatima Pocas, Detlef Wölfle
- European Commission and/or Member States representatives:
 - Bastiaan SCHUPP (DG SANCO)
- EFSA:
 - FIP Unit: Eric Barthélémy, Marisa Escudero Hernandez, Georges Kass, Joaquim Maia, Rositsa Serafimova.
- Others:
 - ApDesk Unit: Sara De Berardis and Karine Lheureux

1. Welcome and apologies for absence

The Chair welcomed the participants.

Jean-Pierre Cravedi did not participate on Tuesday 18 November

Maria de Fatima Pocas, Maria Rosaria Milana and Riccardo Crebelli did not participate on Thursday 20 November

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 and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest ², EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADol or the SDol, please refer to Annex I. Oral Declarations of Interest were requested at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 62nd Working Group meeting held on 9-11 September 2014, Parma.

The minutes of the 62nd Working Group meeting were agreed by written procedure on 26 September 2014.³

5. Hearing Expert (s)

Mr. Ulrich Wietschorke (WTConsulting GmbH), Dr. Andreas Tschech (WTConsulting GmbH) and Mr. Kazuhiko Hayashi (ADEKA Corporation) were invited to present their view for item 7.5 of the present meeting.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA had invited Mr. Ulrich Wietschorke, Dr. Andreas Tschech and Mr. Kazuhiko Hayashi to submit an ADol. Their participation was limited to providing testimony, without the possibility to take on any role undertaken by members of the WG, in accordance with the applicable legal framework².

6. Scientific topic(s) for discussion

6.1 1,7 Octadiene (EFSA-Q-2013-00614)⁴

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

6.2 Doverphos LGP-11(EFSA-Q-2013-00903)⁵

The draft opinion was discussed. More data are needed to finalise the evaluation in the WG. The Secretariat will request the applicant to provide the additional data. Subject to the data provided, a new draft opinion will be scheduled for a next WG meeting.

6.3 ADH (EFSA-Q-2013-00030)⁶ and DAAM (EFSA-Q-2013-00031)⁷

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

http://www.efsa.europa.eu/en/fipwgs/documents/ceffcmwg.pdf

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2013-00614

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00903

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00030

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00031



6.4 Diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate (EFSA-Q-2012-00908)⁸

The draft opinion was discussed. More data are needed to finalise the evaluation in the WG. The Secretariat will request the applicant to provide the additional data. Subject to the data provided, a new draft opinion will be scheduled for a next WG meeting.

6.5 Nano-copolymer (EFSA-Q-2013-00100)9

The draft opinion was finalised in the WG and it will be scheduled in the Panel for discussion and possible adoption.

6.6 Ethylene Glycol Dipalmitate (EFSA-Q-2014-00434)¹⁰

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

6.7 Dipentaerythritol stearate (EFSA-Q-2014-00494)¹¹

The draft opinion was discussed and changes were noted. The revised draft opinion will be scheduled in the Panel for discussion and possible adoption.

7. Any Other Business

- 7.1 Introduction to FCM WG
- 7.2 Presentation of the new template scientific opinion
- 7.3 Update on ToR and way forward for Glass fiber sizing agents (EFSA-Q-2013-00838)
- 7.4 Presentation of new SDS templates
- 7.5 Benzenepropanamide 3,5-bis(1,1 -dimethylethyl) 4hydroxy-, N-C16-18-alkyl derivs. (EFSA-Q-2013-00425)

Upon request to EFSA, the applicant and their consultants were given the opportunity to present on above topic an oral explanation to the WG. The applicant and their consultants attended the WG meeting by teleconference, as hearing expert on 20 November 2014 from approximately 9:15 to 10:00.

7.6 Update on way forward for the new FCM Guidance (EFSA-Q-2011-00107)

Following discussion with the Commission, EFSA has agreed to follow a two-step approach. First, the scientific necessity to revise the existing guidelines will be rationalized in the form of an opinion which will undergo public consultation (1st quarter 2015). Commission should then inform EFSA on the level of protection to be afforded to the Consumers. This will enable the CEF Panel to prepare, in a second step, the draft updated guidance on data

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00494

⁸ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00908

⁹ http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00100

http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00434



requirement for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation. This document will also undergo public consultation.

7.7 Feedback from the FIP Network meeting held on 12-14 November 2014

Terms of reference and objectives of the FIP Network especially for the subgroup on Food Contact Materials, as well as feedback from the "Food Contact Materials Network" meeting held on 12-14 November were presented.

The FIP network provides a platform for discussion and consultation on risk assessment activities and approaches of mutual interest to EFSA and Member States. The Network enhances cooperation between scientists involved in risk assessment of food contact materials to support and harmonise risk assessment practices in this area.

The Food Contact Materials Network was set in summer 2014. It is composed of 26 countries, of observers such as the European Commission (EC: DG SANCO and JRC) and the Council of Europe (CoE), and of chairs of the FCM and "Plastic recycling" WGs who also represent the CEF Panel.

At the meeting in November, Member States (MS) presented on-going activities and approaches used at national level for risk assessment of "non-plastic" (non-EU harmonised) food contact materials, especially printing inks, varnishes and coatings, papers and boards as well as metallic elements used in ceramics and metals and alloys. The network discussed future challenges expected by Member States in this area and identification of common interests, possible subjects for scientific cooperation and priorities for further work. The meeting was the opportunity for EU (EC, EFSA) and international bodies (CoE) to inform on their activities of interest for this meeting. The Network was also informed on existing cooperations between MS.

The terms of reference, the objectives, the list of members and the agenda of the meeting can be consulted on the EFSA website at the link: http://www.efsa.europa.eu/en/fip/fipnetworks.htm. Minutes will be published once adopted by the participants.

8. Next meeting(s)

The next meeting will take place in Parma from 10-12 February 2014.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADol) or Specific Declarations of Interest (SDol)

- a) In the SDol filled for the present meeting Dr Roland Franz declared the following interest: His Institute was involved in experimental work used in the dossier for "Glass fiber sizing agents". In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², and taking into account the fact that the item was not discussed and only general information was presented by the EU Commission, a waiver was granted. Therefore the concerned expert was allowed to listen to the presentation by the EU Commission.
- b) In the SDol filled for the present meeting Dr. Detlef Woelfle declared the following interest: His institute (BfR) had prepared the Summary Data Sheet for "ADH" and "DAAM" as part of a contract with EFSA. This contract is no longer active. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest² 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 concerned¹². Therefore the concerned expert shall be allowed to take part in the discussions and in the drafting phase of the scientific output for "ADH" and "DAAM".

¹² The previous version of the minutes referred to "a waiver was granted", however, this sentence has been amended in line with the rules of the Decision of the Executive Director on Declarations of Interest (31/07/2014).