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

Minutes of the 72nd Plenary meeting

Held on 28-30 November 2017, Parma (Italy)

Meeting open to Observers

(Open session: 29 November 2017, 14:00-18:00h

30 November 2017, 09:00-15:30h)

(Agreed on 18 December 2017)

Participants

a) Panel Members

Claudia Bolognesi, Laurence Castle, Kevin Chipman, Jean-Pierre Cravedi, Karl-Heinz Engel, Roland Franz, Paul Fowler, Konrad Grob, Rainer Gürtler[1], Trine Husøy, Sirpa Orvokki Kärenlampi, Maria Rosaria Milana, Wim Mennes, Karla Pfaff, Gilles Rivière, Vittorio Silano, Jannavi Srinivasan[2], Maria De Fátima Tavares Poças[2], Christina Tlustos[3], Detlef Wölfle and Holger Zorn

b) Hearing Experts[4]:

- Ursula Gundert-Remy (for agenda item 10)

c) European Commission and/or Member States representatives:

- DG SANTE: Miguel-Angel Granero Rosell[5]

d) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Margarita Aguilera-Gomez, Maria Anastassiadou, Magdalena Andryszkiewicz, Eric Barthélémy, Julia Cara Carmona, Mary Carfi, Anna Federica Castoldi, Cristina Croera, Natalia Kovalkovicova, Alexandros Lioupis, Yi Liu, Joaquim Manuel Maia, Carla Martino, Claudia Roncancio Peña, Claudio Putzu, Annamaria Rossi, Ellen Van Haver, Katharina Volk
- DATA Unit: Davide Arcella
- Assessment and Methodological support Unit (AMU): Fulvio Barizzone

e) Observers[6]:

[1] Participated on 28 and 29 November 2017 pm
[2] Participated via teleconference
[3] Participated on 28-29 November 2017
[4] 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
[5] Participated via teleconference on 29 November 2017 pm

- Attending physically in Parma: Michel Cassart (PlasticsEurope), Ruggero Luca Lamacchia (STAR Industriale), Federica Manini (Soremartec Italia Srl), Silvia Toia (GB Foods)
- Attending via webstreaming: Stefanie Geiser (EAS Strategies), Anna Koltunowska (Keller and Heckman LLP), Elina Pahkala (Ministry of Agriculture and Forestry, Finland), Carlos Pires (TNA - Tecnologia e Nutrição Animal S.A.), Alessia Pia Scarlato (Intertek Italia SPA), Teodora Titi (Student, La Sapienza, Rome), Kate Trollope (EU Food Policy), Merja Virtanen (Finnish Food Safety Authority Evira)

CLOSED SESSION

28 November 2017, 13:30-18:00

29 November 2017, 9:00-13:00

Items under point 6 were closed to Observers due to confidential business information/proprietary data

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

Item 6.2 was removed from the agenda. The remainder of the agenda was adopted without further changes.

3. Declarations of Interest of Scientific Committee/Scientific Panel/ 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 Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel 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.

4. Agreement of the minutes of the 71st Plenary meeting held on 19-21 September 2017, Parma

The minutes of the 71st Plenary meeting held on 19-21 September were agreed on 9 October 2017 by written procedure[7].

5. Report on the written procedures since 71st Plenary meeting

No scientific outputs were adopted by written procedure since the last plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

[6] http://www.efsa.europa.eu/en/stakeholders/observers
[7] http://www.efsa.europa.eu/en/events/event/170503

6.1 Safety evaluation of the food enzyme aqualysin 1 protease from a genetically modified *Bacillus subtilis* strain LMGS 25520 (EFSA-Q-2014-00920)

The draft opinion on the safety evaluation of the food enzyme aqualysin 1 from a genetically modified *Bacillus subtilis* strain (LMGS 25520) was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel suggested some revisions of the opinion to be addressed by the WG on Food Enzymes.

6.2 Safety evaluation of the food enzyme alpha-amylase from a genetically modified *Bacillus licheniformis* strain NZYM-AN (EFSA-Q-2015-00084)

This agenda item was removed from the agenda due to the ongoing evaluation of the enzyme alpha-amylase by the Panel on Genetically Modified Foods (GMO). In order to ensure consistency and take into consideration the outcome of the GMO Panel's evaluation, the Working Group on Food Enzymes will finalise its assessment thereafter.

6.3 Evaluation of Morssinkhof Plastics recycling process (EFSA-Q-2016-00486)

The draft opinion on the safety evaluation of Morssinkhof Plastics recycling process was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.4 Evaluation of Envases Ureña (Starlinger Decon technology) recycling process (EFSA-Q-2017-00244)

The draft opinion on the safety evaluation of Envases Ureña (Starlinger Decon technology) recycling process was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.5 Evaluation of isobutane (EFSA-Q-2016-00509)

The draft opinion on the safety evaluation of isobutane, for use in food contact materials was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.6 Evaluation of Selenium nanoparticles (EFSA-Q-2017-00089)

The draft opinion on the safety evaluation of Selenium nanoparticles, for use in food contact materials was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.7 Evaluation of carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulphate (EFSA-Q-2017-00054)

The draft opinion on the safety evaluation of carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulphate, for use in active food contact materials was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

OPEN SESSION

29 November 2017, 14:00-18:00

30 November 2017, 9:00-15:30

7. Welcome and brief introduction of Panel members and Observers

The Chair welcomed the observers. The Chair invited all the participants to the meeting to briefly introduce themselves.

8. Presentation of the EFSA Guidelines for Observers[8]

The Head of FIP Unit presented the rules for observers to be followed during and after the open plenary meeting. Observers were given the possibility to send questions when submitting their registration and these questions would be answered in a dedicated session at the meeting. Observers were also informed that the Chair would grant opportunity for additional questions at the end of each discussion topic.

9. Scientific outputs submitted for discussion and/or possible adoption

9.1. FGE.406: [FL-no: 16.129] (S)-1-(3-(((4-amino-2,2-dioxido-1H-benzo[c][1,2,6]thiadiazin-5-yl)oxy)methyl)piperidin-1-yl)-3-methylbutan-1-one (EFSA-Q-2015-00082)

The draft opinion on the safety evaluation of the flavouring substance (S)-1-(3-(((4-amino-2,2-dioxido-1H-benzo[c][1,2,6]thiadiazin-5-yl)oxy)methyl)piperidin-1-yl)-3-methylbutan-1-one was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

9.2. Safety evaluation of the food enzyme peroxidase obtained from soybean (Glycine max) hulls (EFSA-Q-2013-00897)

The draft opinion on the safety evaluation of the food enzyme peroxidase obtained from soybean (Glycine max) hulls was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

10. Other scientific topics for information and/or discussion

10.1. Bisphenol A (BPA) hazard assessment protocol (EFSA-Q-2016-00635 and EFSA-Q-2016-00673)

[8] https://www.efsa.europa.eu/sites/default/files/observersguidelines.pdf

The Chair of the working group on BPA hazard assessment protocol, Ursula Gundert-Remy, presented the substantial revisions to the BPA protocol proposed by the working group taking into consideration the comments received during the web-based public consultation and a Workshop held in Brussels on 14 September 2017 with specialists, interested members of the public and other stakeholders. Important amendments to the document as compared with the version endorsed for public consultation by the CEF Panel at their 13-15 June 2017 Plenary meeting relate to the study inclusion and exclusion criteria, appraisal of the evidence, confidence in the results as well as grading and integrating the human and animal evidence.
The CEF Panel raised some questions for clarifications, and agreed with the modifications that were brought into the document.
Once the report of the US CLARITY-BPA two-year core study on rodents and publications by academic researchers on various health endpoints (e.g. cardiovascular disease, obesity, immune function, learning and behaviour, etc.) using animals and tissues from the CLARITY study become available in 2018, the protocol[9] will enable a methodologically rigorous re-assessment of the safety of BPA for consumers, for which EFSA set in 2015 a TDI on a temporary basis.

10.2. Report on the public consultation on the draft EFSA BPA hazard assessment protocol (EFSA-Q-2017-00491)

This report summarises the outcome of the web-based public consultation that was held on the draft BPA hazard assessment protocol, and lists the 151 comments that were received from 16 different parties, including national agencies and governmental bodies, industry and industry associations, non-governmental organisations, academia and private citizens. The consultation took place from 30 June till 3 September 2017.

This report also includes in an Appendix the summary report of the Workshop on BPA hazard assessment protocol which took place on 14 September 2017 and which was attended by several contributors to the consultation as well as other relevant parties.

The CEF Panel took note of this EFSA technical report[10].

11.New Mandates

11.1 New questions since the previous meeting

The following new mandates have been received since the last Plenary meeting: two for food contact materials and one for flavourings.

Food Sector	EFSA-Q-Number	Subject	Reception date
FCM	EFSA-Q-2017-00645	Request for the evaluation of a substance: tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	19/09/2017
FLAV	EFSA-Q-2017-00701	Smoke flavouring SF-001 application for modification of authorisation	13/10/2017
FCM	EFSA-Q-2017-00740	Request for the evaluation of a substance: cellulose pulp, bleached	10/11/2017

11.2 Valid questions since the previous meeting

The following questions have been considered valid for the start of the assessment since the last Plenary meeting: four for the safety assessment of food contact materials.

[9] http://www.efsa.europa.eu/sites/default/files/1354e.pdf
[10] http://www.efsa.europa.eu/sites/default/files/1355e.pdf

Food Sector	EFSA-Q-Number	Subject	Valid on
FCM	EFSA-Q-2017-00660	Request for safety evaluation of Concept Plastic Packaging recycling process (Starlinger viscotec deCON technology)	23/10/2017
FCM	EFSA-Q-2017-00616	Request for safety evaluation of EstPak Plastik recycling process (Starlinger viscotec deCON technology)	22/09/2017
FCM	EFSA-Q-2017-00494	Request for safety re-evaluation of Ground sunflower seed hulls, FCM No 1060 for use as additive in plastics	29/09/2017
FCM	EFSA-Q-2017-00444	Request for the evaluation of a substance: Di(m-2,2',2''-nitrilotris(ethanol)-diperchlorato)dinatrium, synonym: TEAP; Catena-nitrilotris(ethanol)-diperchlorato)dinatrium, CAS 156157-97-0	22/09/2017

These questions were assigned to the respective working groups.

11.3 Withdrawn questions since the previous meeting

No applications have been withdrawn since the last CEF Plenary meeting.

12. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

12.1 Scientific Committee and Scientific Panel including their Working Groups

12.1.1 Scientific Committee and its Working Groups

The Scientific Committee Plenary was held on 15 November 2017. The Chair provided feedback on the main issues discussed.

12.1.2 CEF Standing Working Group on Food Enzymes

The chair of the WG informed the Panel members and the observers about the launching of the 2nd call-for-data for the exposure assessment of food enzymes on the 30th of November 2017 on the EFSA website[11]. The Panel agreed with a proposal for a new self-tasking activity to develop a publically available food enzyme intake model that the working group intends to undertake.

The minutes of the last working group meeting are published on the EFSA website.

12.1.3 CEF Standing Working Group on Genotoxicity

No specific issue was brought to the attention of the Panel and the observers in addition to what has already been recorded in the minutes of the WG.

12.1.4 CEF Standing Working Group on Recycling Plastics

The chair of the WG informed the Panel members and the observers about the number of recycling processes currently under evaluation by the WG.

The minutes of the last working group meeting are published on the EFSA website.

[11] http://www.efsa.europa.eu/en/data/call/171130

12.1.5 CEF Standing Working Group on Food Contact Materials

The chair of the WG informed the Panel members and the observers about the number of FCM substances currently under evaluation by the WG, and about possible revisions of the EC legislative framework in the area of FCM that might impact the work of the working group in the future.

The minutes of the last working group meeting are published on the EFSA website.

12.1.6 CEF Standing Working Group on Flavourings

The chair of the WG informed that Panel members and the observers about two new members that recently joined the working group.

The minutes of the last working group meeting are published on the EFSA website.

12.1.7 CEF Ad hoc Working Group on phthalates

The EFSA secretariat informed the Panel members and observers about the nomination of Laurence Castle (CEF Panel member) to chair the new *ad hoc* working group on phthalates. The remit of the working group is to update EFSA's opinions, published in 2005, on the safety assessment of di-butylphthalate (DBP, FCM No 157), butyl-benzyl-phthalate (BBP, FCM No 159) and bis(2-ethylhexyl)phthalate (DEHP, FCM No 283), which have been authorised for use as plasticisers and technical support agents in plastic Food Contact Materials (FCM). This mandate (EFSA-Q-2017-00588/-589/-590), received from the European Commission, follows the publication of an opinion on DBP, BBP and DEHP, along with DIBP (di-ios-butylphthalate), by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) in March 2017, which is expected to lead to a proposal for an amendment of Annex XVII to REACH. The re-evaluation should determine whether, based on the data package used by ECHA for the before-mentioned evaluation, the opinion and the authorisation under Regulation (EU) No 10/2011 are still in accordance with the FCM regulation.

12.1.8 CEF Standing Working Group on decontamination substances

The Panel members and observers were informed about the nomination of Paul Fowler (CEF Panel member) as Chair and Panagiotis Skandamis (BIOHAZ Panel member) as vice chair of the newly established standing working group on the evaluation of substances used to reduce microbial contamination from products of animal origin. The remit of the working group is to perform the risk assessment of two new mandates received from the Commission on the use of organic acids (lactic and acetic acids) to reduce microbial surface contamination from pork carcasses and cuts (EFSA-Q-2017-00666) and on the use of lactic acid to reduce microbiological surface contamination on carcasses from wild game and small stock (EFSA-Q-2017-00667).

12.2 EFSA including its Working Groups/Task Forces

In accordance with EFSA's standard operating procedures, EFSA Panels need to screen their guidance documents and assess whether they need to be updated before the end of each Panel's mandate. The CEF Panel will perform this activity at a coming plenary meeting in early 2018.

12.3 European Commission

No updates were provided.

13. Answers to questions from Observers (in application of the *EFSA Guidelines for Observers*)

Michel Cassart (PlasticsEurope) praised EFSA for discussing transparently its strategy for the next BPA hazard assessment in several open contexts. He also acknowledged that comments from the public consultation have been considered thoroughly by EFSA, even though some of those submitted by PlasticsEurope have not been implemented in the revised version of the protocol on BPA hazard assessment.

14. Any Other Business

There was no other business.

The Chair closed the open session by thanking the participants and the observers for their attention and contribution.

Annex

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

CONFLICT OF INTEREST: In his SDoI, Dr Roland Franz declared the following interest for agenda item 6.3 (Evaluation Morssinkhof Plastics recycling process) and agenda item 6.4 (Evaluation of Envases Ureña (Starlinger Decon technology) recycling process).
In general, in the area of recycling for food contact his lab has prepared numerous dossiers for industry for submission to and evaluation by EFSA. Therefore a general conflict for recycling processes is declared, either because of direct involvement of his lab in the dossier or indirectly because of a possible market competition between the process under evaluation and the processes for which his lab has contributed.
With respect to agenda item 6.4: the petitioner has included a challenge test conducted by his lab as a technical annex to the dossier. Overall the interest declared on agenda item 6.4. was deemed to represent a conflict of interest and results in exclusion of the expert from any discussion, voting or other processing of item 6.4.
Concerning agenda item 6.3, his lab was not involved in the dossier. But due to the fact that it is also a recycling process, the possible market competition with recycling processes that were supported with data from the expert's lab leads to a conflict of interest. This results in exclusion of the expert from any discussion, voting or other processing of item 6.3.