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

Minutes of the 49th plenary meeting

Held on 23-25 09 2014, Parma

(Agreed on 21 10 2014)

Participants

- **Panel Members:**
  Claudia Bolognesi¹, Laurence Castle, Jean-Pierre Cravedi², Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Wim Mennes, Maria Rosaria Milana, André Penninks, Fátima Poças², Vittorio Silano, Andrew Smith, Christina Tlustos¹, Fidel Toldrá, Detlef Wölfle

- **Hearing Experts:**
  - Andy Hart (for item 6.1)³
  - Birgit Mertens⁴ (for item 8.3.2)

- **European Commission:**
  - Bastiaan Schupp (DG SANCO)²
  - Miguel Angel Granero Rosell (DG SANCO)⁴
  - Rafael Luis Perez Berbejal (DG SANCO)⁶

- **EFSA:**
  - FIP Unit: Margarita Aguilera-Gomez, Eric Barthélémy, Anna Federica Castoldi, Cristina, Croera, Maria Luisa Escudero Hernandez, Marina Goumenou, Claudia Heppner⁷, Georges Kass, Annamaria Rossi, Kim Rygaard Nielsen, Rositsa Serafimova, Anne Theobald

¹ Participated on 23 and 24 September 2014
² Participated on 24 and 25 September 2014
³ Participated on 25 September 2014 PM
⁴ Participated on 24 September 2014 PM
⁵ Participated on 24 September 2014 PM via teleconference
⁶ Participated on 23 and 25 September 2014 PM via teleconference
⁷ Participated on 23 September 2014
1. Welcome and apologies for absence
The Chair welcomed the members to the 49th CEF plenary meeting. Apologies for absence were received from following CEF Panel members: Holger Zorn for the full plenary meeting. The CEF Panel was informed that one member of the CEF WG BPA Tox, Andy Hart, was invited to participate as hearing experts to the discussion related to the draft BPA opinion. In addition, Birgit Mertens, attended the meeting as a hearing experts to present the outcome of the Art. 36 grant agreement on “Study on the implications on the requirements for submission of toxicological information, restrictions and administrative consequences of the draft revised guideline on Food Contact Materials “.

2. Adoption of agenda
The draft agenda was adopted without any changes.

3. Declarations of interest
In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes8 and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests9, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annexes I.

4. Agreement minutes 48th CEF plenary meeting (1-4 July 2014)
The minutes of the 48th plenary meeting were agreed on the 23 September 2014. The minutes will be available on the Authority’s webpage10.

5. Report on written procedures since 48th CEF plenary meeting
No scientific outputs were adopted by written procedure since the last plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

The Chair of the WG on BPA presented the main changes to BPA draft exposure assessment as a result of the comments submitted during the public consultation. These modifications were received positively by the Panel. A hearing expert was invited to present to the Panel (24 September from 2 pm to 3 pm) the structured approach developed to deal with the uncertainties related to toxicological endpoints.

The Panel was then presented and discussed the revised chapters on toxicokinetics and benchmark dose (BMD) calculations proposing changes that were incorporated.

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A teleconference was held between the CEF Panel and members of the SCENIHR’s WG on BPA and Secretariat in order to share information on the outcome of the public consultations of their respective draft opinions on BPA safety. As a result EFSA agreed to share with SCENIHR its draft opinion on BPA after each of the next Panel meetings.

6.2 N,N’-Bis(2,2,6,6-tetramethyl-4-piperidinyl)isophthalamide (EFSA-Q-2013-00887)
The rapporteurs introduced the draft opinion on the safety assessment of the substance, N,N’-Bis(2,2,6,6-tetramethyl-4-piperidinyl)isophthalamide, for use in food contact materials to the members of the CEF Panel and presented 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.
The full opinion is available on the Authority’s webpage.

6.3 Furan-2,5-dicarboxylic acid (EFSA-Q-2014-00013)
The rapporteurs introduced the draft opinion on the safety assessment of the substance, furan-2,5-dicarboxylic acid, for use in food contact materials to the members of the CEF Panel and presented 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.
The full opinion is available on the Authority’s webpage.

6.4 2,4,8,10-tetraoxaspiro[5.5]un-Decane-3,9-diethanol,β3,β3,β9,β9,-tetramethyl- (EFSA-Q-2012-00708)
The rapporteurs introduced the draft opinion on the safety assessment of the substance, 2,4,8,10-tetraoxaspiro[5.5]un-Decane-3,9-diethanol,β3,β3,β9,β9,-tetramethyl-, for use in food contact materials to the members of the CEF Panel and presented 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.
The full opinion is available on the Authority’s webpage.

6.5 FGE.73 Rev3 (EFSA-Q-2014-00347)
The rapporteurs introduced the draft opinion on the safety assessment of Flavouring Group Evaluation (FGE) 73 Rev3 to the members of the CEF Panel and presented 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.
The full opinion is available on the Authority’s webpage.
6.6  **alpha-amylase from a GM strain of B. licheniformis (NZYM-AC)**  
 **(EFSA-Q-2013-00586)**

The rapporteurs introduced the draft opinion on the safety assessment of alpha-amylase from a GM strain of B. licheniformis (NZYM-AC) and presented the main points for discussion. The CEF Panel members proposed to the WG Enzymes to revisit the exposure assessment and suggested to discuss the opinion again once this issue has been addressed.

6.7  **FGE.87 Rev2**  **(EFSA-Q-2014-00348 and -00349)**

The rapporteurs introduced the draft opinion on the safety assessment of Flavouring Group Evaluation (FGE) 87 Rev2 to the members of the CEF Panel and presented 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. The full opinion is available on the Authority’s webpage.

6.8  **FGE.09 Rev5**  **(EFSA-Q-2014-00342)**

The rapporteurs introduced the draft opinion on the safety assessment of Flavouring Group Evaluation (FGE) 09 Rev5 to the members of the CEF Panel and presented 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. The full opinion is available on the Authority’s webpage.

7. **New Mandates**

The deputy head of the FIP unit informed the members of the CEF Panel on new mandates which were received by EFSA falling within the remit of the CEF Panel since the previous meeting and provided an overview of the respective status (suitability check ongoing/accepted/rejected) of these mandates.

8. **Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission**

8.1 **Scientific Committee**

The chair of the Panel informed the panel members on the outcome of 68th and 69th Scientific Committee meetings which were held on 8-9 July 2014 and 16-17 September 2014. Details to the 68th SC meeting are provided in the minutes\(^1\). During the 69th SC meeting the following points were discussed: outcome of a procurement on risk-ranking, technical report on Horizon 2020 which will be shared with DG Research and other DGs and published on the Authorities webpage by Dec 2014, EFSA's review paper on scientific cooperation roadmap which outlines scientific capacity building and intelligent use of

resources, EFSA’s activities until 2019 in the area of bee health, update of the guidance documents on terrestrial ecotoxicology and respective deliverables between 2015 to 2018. In addition the panel was informed that in the EFSA journal an editorial is going to be published related to “Increasing robustness, transparency, and openness of scientific assessment”, that JRC-EFSA planning to have a Memorandum of understanding and that an Art 36 grant agreement related to the review of non-monotonic dose-response (NDMR) of substances for human risk assessment was awarded to ANSES, AGES, Karolinska Institute and RIVM. The project will run over a period of 3 month with three main objectives i) to provide an overview on the state of the science on NDMR hypothesis for substances, focusing on food safety area; ii) to provide a critical appraisal of toxicity studies on the basis of scientific criteria for the evaluation of robustness of NDMR studies and meta-analysis for comparable studies; and iii) provide an inventory of data extracted from selected toxicity studies.

8.2 Working Groups

8.2.1 CEF Standing WGs: state of play
The deputy head of the FIP unit informed the members of the CEF Panel of the near finalisation of the procedure of setting up the new Standing WGs.

8.2.2 WG BPA Tox
An update of the work of the WG was provided under 6.1.

8.2.3 WG FCM Recycling
The Chair of the WG informed the CEF Panel that the dates for all the meetings for 2014 and 2015 had been set.

8.2.4 WG FCM Substances
The Chair of the WG informed the CEF Panel that the dates for all the meetings for 2014 and 2015 had been set. He also informed the Panel that the FIP Network will hold a meeting dedicated to non-plastic FCM substances in Parma on 12-14 November.

8.2.5 WG Genotoxicity
The Chair of the WG informed the CEF Panel that a meeting with stakeholders will take place on 7 October 2014. He also informed the Panel that due to the resignation of a member of the WG, new members should be identified and invited to join the WG.

8.2.6 SC WGs of relevance to CEF
D. Woelfle and V. Silano reported as members of the WG Uncertainty in risk assessment and the WG Emerging Risks, respectively.

8.3 EFSA

8.3.1 General matters
The deputy Head of the FIP unit informed the members of the CEF Panel that the 53rd AF Meeting was taking place in Venice on 24-25 September. He reported on the new measures of efficiency and best practices that were adopted by the REPRO Department. In particular, a number of actions related to increase efficiency and
actions related to reducing the work load related to the Panel's scientific work were presented. The Panel was thanked for their contributions to the MATRIX project. It was agreed that the CEF Plenary scheduled from 1-3 September 2015 should be moved. The dates of 8-10 September were proposed for final approval by a poll to be sent out by the Unit. Finally, the Panel was informed of the following changes in the organisation of EFSA. The Head of the REPRO Department, P. Bergman, has resigned and that J. Kleiner will serve as the ad interim Head of REPRO. T. Robinson will be ad interim Head of SCISTRAT in addition to his assignment as Head of SCER. The Head of RESU, O. Ramsayer has also resigned to take up a post elsewhere, Finally, F. Lodi returned to the FIP Unit on 16 September to resume her post.

8.3.2 Outcome of procurement on food contact materials

The procurement on the impact of the draft food contact materials guidance on the requirements for submission of toxicological information, restrictions of use and administrative matters was presented by the grant holder. The report concludes that the proposed revision of the current guidance would only have an impact on a small number of already evaluated and authorised plastic substances. Following a general discussion, the Panel acknowledged the quality of the work done.

8.3.3 Discussion paper on Enzymes

The CEF Panel was presented with a discussion paper on exposure assessment for food enzymes. The CEF Guidance document proposed to use the budget method and the CEF Panel asked the WG to re-consider the key elements of the budget methods applied to food enzymes to address potential overestimation of exposure. The Panel was also informed that the applicant for one dossier where the budget method was applied and further clarification was sought will be invited to a technical hearing at the next WG meeting.

8.3.4 Horizon 2020

A presentation with an invitation to contribute suggestions to EFSA was made by J.L. Dorne of the SCER Unit.

8.4 European Commission

No information was provided.

9. Other scientific topics for information and/or discussions

No information was provided.

10. Any other business

No any other business was raised.
Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoi)\textsuperscript{12}

\textbf{a) CONFLICT OF INTEREST:} In his SDOI Dr. Detlef Wölfle declared the following interest: in a food contact material substance 2,4,8,10-tetraoxaspiro[5.5]unDecane-3,9-dietanol,\(\beta\)3,\(\beta\)3,\(\beta\)9,\(\beta\)9,-tetramethyl (EFSA-Q-2012-00708) where he has prepared working documents (SDS) for this substances under contract with EFSA. In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a conflict of interest.

This results in the impossibility for the expert to be present when this item (agenda item 6.4) is discussed, voted on or in anyway processed by that concerned scientific group.

\textbf{b) CONFLICT OF INTEREST:} In his SDOI Dr. Roland Franz declared the following interest: in a food contact material substance N,N'-Bis(2,2,6,6-tetramethyl-4-piperidinyl)isophthalamide (EFSA-Q-2013-00887) where his laboratory has done some analytical / experimental work for the petitioner which is used in this dossier. In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a conflict of interest.

This results in the impossibility for the expert to be present when this item (agenda item 6.2) is discussed, voted on or in anyway processed by that concerned scientific group.

\textsuperscript{12} The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.