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

Minutes of the 48th plenary meeting

Held on 1-4 July 2014, Parma

(Agreed on 23 September 2014)

Participants

- **Panel Members:**

  Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel[1], Paul Fowler, Roland Franz, Konrad Grob, Rainer Guertler, Trine Husøy, Wim Mennes[2], Maria Rosaria Milana, Fátima Poças, Vittorio Silano[3], Christina Tlustos, Fidel Toldrá, Detlef Woelfle, Holger Zorn

- **Hearing Experts :**
  - Lieve Herman (for item 25.1)
- **European Commission:**
  - Michael Walsh (DG SANCO, Unit 03)
- **EFSA:**
  - Executive Directorate: Bernahrd Url
  - COMMS Department: Alessia Vecchio
  - RASA Department: Marta Hugas
  - REPRO Department: Per Bergman
  - SCISTRAT Department: Juliane Kleiner
  - APDESK Unit: Carla Martino
  - AMU Unit: Elisa Aiassa
  - CHAN Unit: Arthur Healy
  - CORSER Unit: Carolina Di Bona, Giovanni Fuga
  - DATA Unit: Petra Gergelova

[1] Participated on 2 and 3 July 2014
[2] Participated on 1,2 and 3 July 2014
[3] Participated on 1,2 and 3 July 2014

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  - EXO Unit: Roy Kirby
  - Finance Unit: Christina Karkanti
  - FIP Unit: Margarita Aguilera-Gomez, Eric Barthélémy, Maria Carfí, Anna Federica Castoldi, Maria Correia, Cristina, Croera, Maria Luisa Escudero Hernandez, Eva Maria Ferrari, Marina Goumenou, Claudia Heppner, Georges Kass, Marco Lannutti , Maud Pâques, Annamaria Rossi, Kim Rygaard Nielsen, Rositsa Serafimova, Anne Theobald
  - LRA Unit: Dirk Detken, Citlali Pintado
- SCER Unit: Bernard Bottex,
- Others:
  - Consultant: Marco Castaldini

1. Welcome to the Panel members

The Executive Director of EFSA, Berharn Url, welcomed the members of the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and the members of the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) to the inauguration meeting and to the common induction training session of the two Scientific Panels.

2. Opening of the Induction Training

The Head of the Science Strategy and Coordination Department (SCISTRAT), Juliane Kleiner, introduced the induction training for Panel members, as well as the 2014-2016 training programme including e-learning proposals.

3. Introduction to EFSA

3.1 EFSA environment

The Head of the Scientific Evaluation of Regulated Products Department (REPRO), Per Bergman, presented an introduction to the EFSA's risk assessment activities including an overview to the REPRO and SCISTRAT Departments.

3.2.1 Independence

The Head of Legal & Regulatory Affairs, Dick Detken, introduced the 2011 EFSA's Policy on Independence and the principles leading to its next review (2015-2016)

3.2.2 DoI System

Marco Castaldini, Consultant for the Information and Technology Unit and Project Manager of the IT tool for the Declaration of Interest (DoI) provided an overview on the DoI tool funtions and its latest enhancements.

3.3 Openness & Transparency

The Head of of the Science Strategy and Coordination Department (SCISTRAT), Juliane Kleiner, introduced "Openness and Transparency" as EFSA core values providing a framework that promotes confidence in the work of EFSA among consumers and other stakeholders.

4. Administrative framework for supporting experts

4.1 Travel organisation, travel reimbursement, EFSA services

The Acting Head of the Corporate services Unit, Giovanni Fuga presented EFSA's centralised support for the organisation of meetings as well as an introduction to the "Expert's compensation guide"

4.2 Questions & Answers

5. Document Management in EFSA

The EFSA Quality Manager, Roy Kirby, informed the Panel members the state of play of the EFSA Document Management and communicated the future change from Sciencenet to Open Text

6. Opening

The Head of the Science Strategy and Coordination Department (SCISTRAT), Juliane Kleiner, opened the second day of the ANS and CEF panels Induction training (combined session**)**

7. Scientific Committee guidances (overview and purposes)

The Head of Scientific Committee and Emerging Risk Unit provided an overview of the role of the Scientific Committee in the area of developing Guidance on risk assessment methodologies.

8. EFSA's communication activities

The Acting Head of the Communication Department, Alessia Vecchio presented all the activities carried out by EFSA in communications and the upcoming work with regards to "New stories".

9. Publication of scientific outputs in the EFSA Journal

Arthur Healey, Lead Editor, introduced the EFSA Journal including its challenges and priorities for the upcoming years.

10. 10.1 Support of internal scientific services

The Head of the Risk Assessment and Scientific Assistance (RASA) Department, Marta Hugas, presented an overview of the RASA Department structure and core tasks together with Mary Gilsenan, Head of the Evidence Management (DATA) Unit, who introduced the DATA Unit and, in particular, the services provided to the ANS/ CEF panel members.

10.2 Selection and Appraisal of Evidence

Elisa Aissa, Scientific officer, presented the activities of the Assessment and methodological Support (AMU) Unit on Systematic Review, Evidence Appraisal and Evidence Retrieval, on behalf of Didier Verloo, Head of AMU Unit

11. Matrix project

The Head of the Scientific Evaluation of Regulated Products Department (REPRO), Per Bergman, introduced the MATRIX project to the Panel members who were kindly requested to review and confirm the completeness and correctness of the "draft Mapping Table of data requirements (Appendix A)" by the 5th September 2014.

Session of the CEF Panel only

12. Welcome and tour de table

The Head of the FIP Unit, Claudia Heppner, welcomed all participants to the CEF Panel session and chaired the meeting until item 17. She invited all the CEF Panel members and EFSA staff to introduce themselves.

13. Apologies for absence

Apologies were received from André Penninks and Andrew Gilbert Smith.

14. Adoption of agenda

The agenda was adopted without changes.

15. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[5], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process. For further details on the outcome of the Oral Declarations of Interests made at the beginning of the meeting, please refer to the Annex I.

16. Report on written procedures since 47th CEF plenary meeting

The minutes of 47th CEF Plenary meeting were agreed by written procedure. The CEF Panel was informed on the adoption of informed two scientific opinions on lipases (EFSA-Q-2013-1009 and EFSA-Q-2013-197) The summaries of the two opinions will be published within 15 working days. In accordance with article 11 of Regulation (EC) No 1331/2009 once the decision on confidentiality, in line with article 12(3) of the Regulation, will be received from the European Commission the full opinions will published on the Authority's website.

17. Election of chair and two vice-chairs

The election took place following the procedure established by EFSA[6] and under the supervision of Citlali Pintado (Legal & Regulatory Affairs). Vittorio Silano was elected as chair of the CEF Panel and Detlef Wölfe and Wim Mennes were elected as vice-chairs of the CEF Panel.

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[6] http://www.efsa.europa.eu/en/keydocs/docs/paneloperation.pdf

18. Panel specific regulatory framework and guidance - Overview and purposes

18.1 Regulatory framework applicable to CEF Panel

The representative from the European Commission introduced the relevant regulatory framework applicable to the CEF Panel and highlighted some critical aspects.
[7]

18.2 FCM Guidance (Substances, Active & Intelligent Packaging) – Q&A

A staff member of the FIP Unit gave a presentation on main elements of the guidance related to the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation which was endorsed by the EFSA Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) in 2008. The actual guidance document (chapter II) dates back to work of the Scientific Committee on food in 2001. The Panel was informed that currently a revision of this guidance document is ongoing.

18.3 Recycling processes – Q&A

A presentation on the respective regulatory framework and the main elements of guidance related to the submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food which was adopted by the AFC Panel in 2008 (and updated in 2009)[8] was given by a staff member of the FIP Unit. In addition, the different elements and data requirements for the risk assessment were presented and discussed.

18.4 Guidance on new Flavouring submissions – Q&A

A staff member of the FIP unit gave a presentation on the guidance related to data required for the risk assessment of flavourings to be used in or on foods which was adopted by the CEF Panel in 2010[9]. In addition, the different elements for the risk assessment were presented and discussed.

18.5 Guidance on Smoke Flavourings – Q&A

A staff member of the FIP unit gave a presentation of the guidance related to the submission of a dossier on a smoke flavouring primary product for evaluation which was adopted by the AFC Panel in 2005. In addition, the different elements and data requirements for the risk assessment were presented and discussed.

18.6 Guidance on Enzymes – Q&A

A staff member of the FIP unit presented the guidance related to the submission of a dossier on food enzymes for safety evaluation which was adopted by the CEF Panel in 2009[10]. In addition, the different elements and data requirements for the risk assessment were

[7] Available at: http://www.efsa.europa.eu/en/efsajournal/doc/21r.pdf
[8] Available at: http://www.efsa.europa.eu/en/efsajournal/pub/717.htm
[9] Available at: http://www.efsa.europa.eu/en/efsajournal/pub/1623.htm
[10] Available at: http://www.efsa.europa.eu/en/efsajournal/doc/1305.pdf

presented and discussed. Moreover the members of the CEF Panel were informed that also an explanatory note for the Guidance of the CEF Panel on the Submission of a Dossier on Food Enzymes is available[11]. The purpose of this document is to provide specific examples to applicants.

18.7 Applications Workflow

A staff member of the APDESK Unit outlined the role, function and tasks of EFSA´s Application helpdesk This includes reception, registration and verifying the administrative and basic scientific completeness of the information in the submitted applications in line with the relevant guidance documents and legislation. Once a suitability letter for an application is issued, the tasks of the APDESK unit is finalised and the risk assessment process with the involvement of the respective Unit and working group/Panel experts starts.

19. Workprogramme 2014-2017 and setting up of new working groups (WG)/confirmation of ongoing WGs

19.1 Draft workprogramme 2014-2017 & resources

A staff member of the FIP unit presented to the members of the Panel the tentative work programme for the next three years, highlighting that the majority of the work will be related food enzymes. In addition, a high level presentation of organisational aspects and resources available to accomplish these tasks were given.

19.2 WG Food Contact Materials

The secretariat gave a presentation on the objectives, the current status of the work and the composition of the WG on Food Contact Materials.

A staff member of the FIP unit responsible for the multi-mandate WG/Standing WG on food contact presented the remit of this WG, the current status of work and provided an overview of competencies needed in this WG. Details related to the mandate and the composition of the members of this WG will be published on the Authority webpage.

19.3 WG Recycling Plastic

A staff member of the FIP unit responsible for the multi-mandate WG/Standing on recycling plastics presented the remit of this WG, the current status of work and provided an overview of competencies needed in this WG. Details related to the mandate and the composition of the members of this WG will be published on the Authority webpage

19.4 WG Flavourings

A staff member of the FIP unit responsible for the multi-mandate WG/Standing WG on flavourings presented the remit of this WG, the current status of work and provided an overview of competencies needed in this WG. Details related to the mandate and the composition of the members of this WG will be published on the Authority webpage.

19.5 WG Genotoxicity

[11] Available at. http://www.efsa.europa.eu/en/supporting/doc/579e.pdf

A staff member of the FIP unit responsible for the multi-mandate WG/Standing WG on genotoxicity presented the remit of this WG, the current status of work and provided an overview of competencies needed in this WG. Details related to the mandate and the composition of the members of this WG will be published on the Authority webpage.

19.6 WG BPA

A staff member of the FIP unit responsible for the single mandate WG on Bisphenol A iwhich was set up under the previous CEF Panel presented the background to this risk assessment which is a self-mandate by the previous CEF Panel, the Terms of Reference and the status oft the work. Details related to the mandate are available on the Authority webpage. Trine Husoy agreed to continue as a chair of this WG. In addition, the composition of the members of this WG was confirmed.

19.7 WG Enzymes

A staff member of the FIP unit responsible for the multi-mandate WG/Standing WG on enzymes presented the remit of this WG, the current status of work and provided an overview of competencies needed in this WG. Details related to the mandate and the composition of the members of this WG will be published on the Authority webpage.

20. Agreement on WGs and appointment of Chairs for WGs

The Chair of the Panel proposed the following chairs for the multi-mandate WGs/Standing WGs of the CEF Panel during 2014-2017:

- Laurence Castle: Food Contact Materials
- Maria Rosaria Milana: Recycling Plastics
- Wim Mennes: Flavourings
- Rainer Gürtler Genotoxicity
- Fidel Toldrá: Food enzymes.

The WG chairs agreed with their nominations.

21. Resources: outsourcing activities

The deputy head of unit of the FIP unit provided an overview of existing and future grants and procurements to support of the work of WGs and the Panel.

22. Resources: EFSA staff

The deputy head of unit presented the tasks of the FIP unit and an overview of the role and tasks of the administrative and scientific staff of the FIP Unit.

23. Agreement on best practices for Panel meetings

Best practices for Panel meetings were proposed, discussed and agreed by the members of the Panel in order to improve efficiency

24. Administrative matters in relation to plenary meetings including meeting dates 2014/2015

The four staff members of the FIP unit which are responsible for the administrative work of the working groups, Panel and the unit introduced themselves and gave a presentation on administrative matters such as meeting organisation, and reimbursement.

25. Scientific Outputs Submitted for discussion and possible adoption.

The Chair of the CEF Panel expressed his appreciation for the work on the scientific outputs discussed at this meeting to the members of the previous Working Groups of the CEF Panel and respective staff members of the FIP unit.

25.1 Lipase from genetically modified *Aspergillus oryzae* (strain NZYM-AL) (EFSA-Q-2013-00198)

The rapporteurs introduced the draft opinion on lipase 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 summary of the opinion is available on the Authority's webpage. In accordance with article 11 of Regulation (EC) No 1331/2009 once the decision on confidentiality, in line with article 12(3) of the Regulation, will be received from the European Commission the full opinions will be published on the Authority's website.

25.2 FavorPac Variations (EFSA-Q-2013-00639, -725, -726)

The rapporteurs introduced the draft opinion on the safety assessment of the active substance, polyacrylic acid, sodium salt crosslinked, for use in active 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.

25.3 Petra Polimeri (EFSA-Q-2010-00104)

The rapporteurs introduced the draft opinion on the safety assessment of the process "Petra Polimeri" used to recycle polypropylene trays and insert trays for use as food contact material 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.

25.4 FGE.304 Rev1 (EFSA-Q-2013-00860)

The rapporteurs introduced the draft opinion on the safety assessment of Flavouring Group Evaluation (FGE) 304 Rev1 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.

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

The presentation and discussion of this agenda item was postponed to the next CEF Plenary meeting due to lack of time.

26. New Mandates

The 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.

27. Feedback from the Scientific Committee/the Scientific Panel, EFSA, the European Commission

27.1 Working Groups of the Scientific Committee

The Head of the Scientific Committee & Emerging Risks Unit informed the Panel hat a new draft template for scientific opinions will be presented to possible adoption by the SC at its next plenary meeting in July 2014. The Panel members were invited to provide comments. The final template is expected to come into force by mid 2015. No specific feedback from WG of scientific committee was given. However the CEF Panel proposed that Detlef Wölfe should represent the CEF panel in the ongoing SC WG on uncertainty

27.2 European Commission

No information in addition to item 18.1. was presented by the European Commission.

28. Other scientific topics for information and/or discussion

28.1 Approach to take on safety evaluation of the re-evaluation of flavourings

The Chair of the WG on flavourings gave a general overview of the approach used for the re-evaluation of flavourings. This was very much welcomed by the member of the CEF Panel. The chair of the CEF Panel proposed to have at the next plenary meeting a brief description of the process used for the evaluation of flavouring substances including information on the decision whether a compound is metabolised in a toxic or non-toxic metabolite.

28.2 Approach to take on safety evaluation of food enzymes

The member of the Panel and member of the previous WG on food enzymes gave a general overview and explained the various elements and the main challenges within the risk assessment of food enzymes. This was very much welcomed by the member of the CEF Panel and further discussions on certain aspects such as exposure assessment is needed.

28.3 Outlining the draft opinion on Bisphenol A (EFSA-Q-2012-00423)

The Chair of the CEF WG BPA gave a general overview of the draft opinion on BPA, highlighting the approach used for the risk assessment and its outcome prior to the two public consultations related to exposure assessment and human health risks. In addition, the chair of the CEF WG BPA presented the major changes to the draft risk assessment based on the comments received during the two public consultations.

28.4 Horizon 2020

The presentation and discussion of this agenda item was postponed to the next CEF Plenary meeting due to lack of time.

29. Any Other Business

No other business was raised.

Annex I

Interests and actions resulting from the Oral Declarations of Interests (ODoI) done at the beginning of the meeting

CONFLICT OF INTEREST: With regard to this meeting **Dr. Roland Franz** declared the following interests: in a food contact material active substance, polyacrylic acid, sodium salt crosslinked (EFSA-Q-2013-00639, -725, -726) where his lab was not involved with migration testing for these substances but his laboratory has carried out testing and preparation of dossiers for a competing product. 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 interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when this item (item 25.2) is discussed, voted on or in anyway processed by that concerned scientific group.