

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings
and Processing Aids (CEF)
Minutes of the 35th plenary meeting
Held on 14-16 05 2013, Parma, Italy
(Agreed by written procedure)**

Participants

- **Panel Members:**

Ulla Beckman Sundh, Claudia Bolognesi, Leon Brimer, Laurence Castle, Alessandro Di Domenico, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Rainer Gürtler, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq (Vice-Chair), Iona Pratt (Chair), Kettil Svensson and Fidel Toldrá¹.

- **Hearing Experts:**

Riccardo Crebelli (chair of CEF WG Food Contact Materials).

- **European Commission:**

Annette Schäfer

- **EFSA:**

Food Ingredients and Packaging (FIP) Unit: Eric Barthélémy, Anna F. Castoldi, Cristina Croera, Maria Luisa Escudero Hernandez, Claudia Heppner, Kim Rygaard Nielsen, Alina Lupu, Hanne Pedersen, Rositsa Serafimova, Annamaria Rossi, Anne Theobald and Elisavet Thessalonikeos.

- **Observers:**

None

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the members to the 35th CEF plenary meeting. Apologies for absence were received for the full plenary meeting from: Mona-Lise Binderup, Martine Kolf-Clauw, Wim Mennes, Maria Rosaria Milana, Fátima Poças and Detlef Wölfle.

¹ Present only on 14-15 May 2013.

2. Adoption of agenda

The draft agenda was adopted with a change, agenda item 6.6 (Iron mixtures EFSA-Q-2012-00739) was removed from the agenda as the draft opinion was not available in time for possible discussion.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests³, 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 Annex I.

4. Agreement of the minutes of the 34th plenary meeting held on 19 to 21 April 2013

The minutes of the 34th plenary meeting were agreed by the members of the CEF Panel during the 35th plenary meeting on 14 May 2013. They are available on the Authority's webpage⁴.

5. Report on written procedure since 34th 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 CEF Panel expressed her appreciation for the work on the scientific outputs to be discussed at this meeting, to the Working Group (WG) Food on Contact Materials, the WG on Recycling, the WG on Flavourings, the WG Genotoxicity the WGs on BPA Exposure and BPA Toxicology and the EFSA staff members involved in each WG.

6.1 Draft opinion on Bisphenol A (BPA) ([EFSA-Q-2012-00423](#))

The members of the CEF Panel discussed the chapters of the draft opinion dealing with BPA exposure assessment, particularly the chapters on biomonitoring and migration. Some questions in relation with the migration data of BPA from polyamide plastic were raised and the Working Group BPA exposure will be asked to address these questions. In addition, the chapters on reproductive and development effects, neurobehavioural effects, metabolic effects and carcinogenicity were discussed. The Panel also noted the very tight timetable to finalise the BPA opinion for public consultation.

6.2 Draft opinion on Flavouring FL-no 15.024 from FGE.19 subgroup 5.2. ([EFSA-Q-2013-00323](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the Authority's webpage⁵.

6.3 Draft opinion on Flavouring FGE.207 ([EFSA-Q-2013-00024](#), [EFSA-Q-2013-00025](#), [EFSA-Q-2013-00026](#), [EFSA-Q-2013-00027](#), [EFSA-Q-2013-00028](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting.

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

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

⁴ <http://www.efsa.europa.eu/en/events/event/130409b-m.pdf>

⁵ <http://www.efsa.europa.eu/en/efsajournal/pub/3227.htm>

The full opinion is available on the Authority's webpage⁶.

6.4 Draft opinion on 1,4:3,6-dianhydrosorbitol ([EFSA-Q-2011-00769](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. .

The full opinion is available on the Authority's webpage⁷.

6.5 Draft opinion on the active substance, iron, polyethyleneglycol disodium pyrophosphate, monosodium phosphate and sodium chloride ([EFSA-Q-2011-00191](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the Authority's webpage⁸.

7. New Mandates

The Head of Unit informed the Panel members that since the last plenary meeting three applications related to substances used in food contact materials ([EFSA-Q-2013-00363](#), [EFSA-Q-2013-00364](#), [EFSA-Q-2013-00562](#)) are under consideration by EFSA. One application related to a safety evaluation of recycling processes ([EFSA-Q-2013-00324](#)) was accepted by EFSA and the CEF WG Recycling will start working on this dossier. Moreover, three mandates ([EFSA-Q-2013-00355](#) to [00357](#); [EFSA-Q-2013-00393](#) to [00398](#); [EFSA-Q-2013-00373](#) to [00392](#)) related to the re-evaluation programme of flavourings (additional data request) were received and are also under consideration by EFSA. A mandate related to the re-evaluation of flavourings ([EFSA-Q-2013-00323](#)) was accepted by EFSA and the WG will start working on this question. In addition, a request to evaluate a new additive on Monoisopropanolamine intended for use in paper and paperboard applications was not accepted as the application does not fall within the scope of Regulation EC No 1935/2004. Further information can be found on the Authority's webpage.

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

8.1. Scientific Committee (SC)

The chair informed the members of the CEF Panel that the chair of the Management Board of EFSA attended the first day of the SC meeting where she presented the recommendations of the Management Board following the external evaluation of EFSA in 2012 and invited the members of the SC to express their views. EFSA presented the draft multiannual work plan (2014-2016), multi-annual activities in relation to grants and procurement, harmonised timelines for submitting information to EFSA within the stop the clock mechanism, virtual library project and consideration of new data available after the adoption of opinions. In addition, the chair of the CEF Panel gave a presentation on the weight of evidence approach which will be used in the BPA opinion. The approach was found very useful by the members of the SC. Moreover a joint presentation on formaldehyde currently under evaluation by the FEEDAP Panel and the ANS Panel (as a metabolite of methanol) was presented and the members of the SC recommended to elaborate on the kinetics of formaldehyde and model the internal exposure to formaldehyde for both uses.

⁶ <http://www.efsa.europa.eu/en/efsajournal/pub/3228.htm>

⁷ <http://www.efsa.europa.eu/en/efsajournal/pub/3244.htm>

⁸ <http://www.efsa.europa.eu/en/efsajournal/pub/3245.htm>

8.2. Working Groups

8.2.1. WG BPA Exp

The outcome of the WG discussions was discussed under 6.1.

8.2.2. WG BPA Tox

The outcome of the WG discussions was discussed under 6.1.

8.2.3. WG Enzymes

The chair of the WG informed the members of the CEF Panel that the WG is currently working on 6 draft opinions and it was proposed that during one of the upcoming plenary meetings the approach of the safety evaluation should be presented and discussed with the CEF Panel. This proposal was welcomed by the CEF Panel. It is expected that an additional 60 dossiers for 2013 and 200 dossiers for 2014 will be submitted to EFSA.

In addition, during the last WG meeting it was noted that some additional expertise in the area of general toxicology, genotoxicity, biotechnology and dietary exposure is needed. The chair of the WG encouraged panel members having such competencies and who can make time available to join this WG, to inform the Secretariat. In addition, EFSA will seek additional experts with these competencies in line with its respective procedures. The Panel was also informed that the guidance document on the "Submission of a Dossier on Food Enzymes for Safety Evaluation"⁹ has been updated to accommodate some minor editorial changes.

8.2.4. WG Flavourings

The vice-chair of the WG flavourings shared the outcome of the last WG meeting, which focussed on finalisation of the draft output on FL-no 15.024 to be presented at the 35th CEF panel meeting. In addition, progress was made on ongoing draft safety evaluations of flavourings and some draft opinions are ready to be presented for possible adoption at the July plenary meeting.

8.2.5. WG Genotoxicity

The chair of the WG Genotoxicity, gave an update on the work done. In the March meeting four opinions were discussed from which three were finalised and one needed to be re-discussed due to new data received just before the meeting. In the meeting in April the WG discussed the evaluation of BPA for genotoxicity.

8.2.6. WG Food Contact Materials (FCMs)

A member of the WG Food Contact Materials provided an overview of the ongoing work highlighting that this WG has many ongoing opinions on FCMs with a very short legal deadline of 6 month which is challenging to handle. Within this context appreciation for the contribution of staff members of the FIP unit was given. It was also highlighted that the exchange of information with the applicant can be quite time consuming. The CEF Panel was also informed that the WG made progress with the draft guidelines on FCMs.

⁹ Available at <http://www.efsa.europa.eu/en/efsajournal/pub/1305.htm>

8.2.7. SC WGs of interest to CEF

The chair informed the Panel members of the latest outcome of the SC WGs (emerging risks, environmental hazards, QPS for botanicals).

8.3. EFSA

The Head of the FIP Unit informed the members of the CEF Panel on the following matters:

The EFSA Consultation Stakeholder Platform meeting will take place on 12 June 2013 in Brussels where; the work of EFSA Application desk will be presented, also the harmonisation of the timelines for submission of applications to EFSA, CEFIC will give a presentation on Food Contact Materials and a member of the CEF Panel will present the work of the Panel¹⁰.

The next Advisory Forum meeting will take place from 19 to 20 June 2013 in London where the chairs of the ANS Panel and CEF Panels are invited to present their work. In addition, the proposal to set up a network on food ingredients and packaging will be presented. The proposal will be to ask for nominations from Member States on specific areas such as food contact materials, flavourings, food enzymes and food additives. The members of the CEF Panel supported this initiative.

The next Management Board meeting will take place on 26 to 27 June 2013.

Within EFSA as of 16 May 2013 the Director of SCISTRAT Hubert Deluyker will become the scientific adviser to Executive Director. Juliane Kleiner was appointed as Director of SCISTRAT. The units of the Scientific Committee and the EMRISK unit will be merged and headed by Tobin Robinson. Within the FIP unit three vacant scientist posts could be filled. Anna Christodoulidou chemist, toxicologist and long standing expertise in risk assessment on genetically modified organisms during her work in GMO unit of EFSA will join the FIP unit as of 1.6.2013. She will work in the area of food enzymes and food additives. The names of the other two staff members will be disclosed when the administrative procedures are finalised.

8.4. European Commission

Commission informed the Panel that Sirkku Heinimaa, currently working on legislative matters in the area of flavourings, will as of 1 June 2013 work on novel foods. A. In addition, a roadmap for the non-harmonised FCM was developed by the Commission¹¹. The road map will be the basis for the impact assessment on this matter. A discussion paper on biocides in food contact materials is currently under consultation with Member States and stakeholders. The Panel was also informed that a new mandate will be submitted to EFSA where an approach to evaluate the safety of coatings of glass fibres for reinforcement of plastics will be asked.

9. Other scientific topics for information and/or discussion

9.1 Guidelines: application for safety assessment of a substance to be used in FCM (EFSA-Q-2011-00107)

¹⁰

<http://www.efsa.europa.eu/en/news/events.htm?text=%22EFSA+Stakeholder+Consultative+Platform%22&panel=stakeholders>

¹¹

http://ec.europa.eu/governance/impact/planned_ia/docs/2014_sanco_005_fcm_specific_provisions_for_materials_other_than_plastics_en.pdf

A staff member informed the Panel on the progress made on the guidelines. The panel was also informed that the Commission expressed concerns in relation to the impact on the legislation. Thus the proposal is to carry out an impact assessment of the draft guidelines. The panel supported this and felt that it is best to do such an impact assessment at the same time when the opinion will go for public consultation. This will have the implication that the deadline of the finalisation of the new guidelines has possibly to be postponed.

10. Any other business

Due to the time needed for the BPA evaluation and allowing also sufficient time to discuss and possibly adopt opinions on food contact materials, recycling processes and flavourings it was agreed by the members to extend the plenary meetings in July, September and October by one day. Therefore the dates for the next Panel meetings will be 2-5 July 2013, 24-27 September 2013 and 22-25 October 2013.

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)¹²

- a) **CONFLICT OF INTEREST:** In his SDoI filled for the present meeting, Roland Franz declared the following interests: his laboratory has carried out some experimental migration testing as contract work for the petitioner of the dossier (Iron as a scavenger substance, agenda item 6.5). The test reports have been used as appendices to these dossiers and his lab has prepared the dossier on behalf of the petitioning company. 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. These results in the impossibility for the expert to be present when the item (Iron as a scavenger substance, agenda item 6.5) was discussed, voted on or in anyway processed by that concerned scientific group.

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.