

**Scientific Panel on Food Contact Materials, Enzymes, Flavourings
and Processing Aids**

Minutes of the 51st Plenary meeting

Held on 25-27 November, 2014, Parma (Italy)

(Agreed on 10 December 2014)

Participants

a) Panel Members

Claudia Bolognesi¹, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel¹, Paul Fowler², Roland Franz, Konrad Grob, Trine Husøy¹, Wim Mennes (chair³), Maria Rosaria Milana⁴, André Penninks, Andrew Smith, Christina Tlustos, Fidel Toldrá, Holger Zorn

b) Hearing Experts⁵:

- Andy Hart⁶ and Ralph Pirow⁶ (for item 6.1)

c) European Commission and/or Member States representatives:

- Jonathan Briggs (DG SANCO, E6), Rafael Luis Perez Berbejal (DG SANCO, E3)⁶, Miguel Angel Granero Rosell (DG SANCO, E3)⁷ ;

d) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Eric Barthélémy, Anna Federica Castoldi, Maria Correia, Cristina Croera, Maria Luisa Escudero Hernandez, Claudia Heppner, Annamaria Rossi, Rositsa Serafimova
- Science Strategy & Coordination (SCISTRAT): Juliane Kleiner
- FEED: Claudia Roncancio Pena

¹ Participated on 25 and 26 November 2014

² Participated via teleconference

³ Acted as chair for this meeting due to absence of chair.

⁴ Participated on 25 November 2014

⁵ 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>

⁶ Participated on 26 November 2014 via teleconference

⁷ Participated on 27 November 2014 via teleconference

1. Welcome and apologies for absence

The Chair welcomed the participants and gave the floor to Juliane Kleiner and Claudia Roncancio Pena. Juliane informed the members of the Panel on the upcoming organisational changes within EFSA's senior and middle management which will come into effect as of 1 November 2014 and 1 January 2015, respectively (see also minutes of the 49th Plenary meeting).

Apologies were received from following members of the CEF Panel: Rainer Gürtler, Fátima Poças, Vittorio Silano and Detlef Wölfle.

Claudia Bolognesi, Karl Heinz Engel, Maria Rosaria, Trine Husøy did not participate in agenda points 6.2, 6.3, 6.4, and 7 to 10.

2. Adoption of agenda

The agenda was adopted without any changes, but some items of the agenda were anticipated in the timetable and not followed the chronological order.

3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on Declarations of Interest⁹, 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 ADol or the SDol, please refer to 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 50th Plenary meeting held on 21-23 October 2014, Brussels (Belgium)

The minutes of the 50th Plenary meeting held on 21-23 October 2014 were agreed¹⁰.

5. Report on the written procedures since 50th Plenary meeting

The opinion on Flavouring Group Evaluation 12, Revision 5 (FGE.12Rev5) ([EFSA-Q-2014-00343](#) to [-00346](#)) was adopted by written procedure on 18 November 2014.

The opinion on dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene (Pelestat) ([EFSA-Q-2014-00124](#)) was adopted by written procedure on 7 November 2014.

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁹ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

¹⁰ <http://www.efsa.europa.eu/en/events/event/141021.htm>

6. 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 CEF Working Groups (WG) BPA toxicology, flavourings and recycling plastics and to the EFSA staff members involved in each Working Group.

6.1 Bisphenol A ([EFSA-Q-2012-00423](#))

The Chair of the Panel reminded the members of the CEF Panel on the terms of reference (TOR) of the self-task related to bisphenol A (BPA). The TOR ask to carry out an exposure assessment taking into account all sources (non-dietary and dietary sources) but request that the risk to public health related to exposure to BPA from foodstuffs should be assessed. The members of the CEF Panel shared this view. The chair of the WG on BPA presented the following revised chapters taking into account the comments received during the public consultation process: biomonitoring, toxicokinetics and PBPK modelling, reproductive toxicity, immunotoxicity, non-monotonic dose response, cardiovascular, neurotoxicity, hazard characterisation and related uncertainties. The members of the CEF Panel discussed and endorsed these chapters and asked to revise a table related to non-monotonic dose response. The content of the risk characterisation and the related uncertainties were briefly discussed. The members of the Panel were invited to submit comments on the draft abstract and summary to the respective staff members of the FIP unit.

6.2 FGE.86 Rev2 ([EFSA-Q-2013-00865](#) and [EFSA-Q-2014-00071](#))

The rapporteurs introduced the draft opinion on the safety assessment of Flavouring Group Evaluation (FGE) 86 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 agreed with the opinion subject to incorporation of changes as suggested during the meeting. Due to a lack of quorum the chair of CEF Panel proposed to adopt this opinion by written procedure.

6.3 FGE.303 Rev1 ([EFSA-Q-2013-00438](#))

The rapporteurs introduced the draft opinion on the safety assessment of FGE 303 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 agreed with the opinion subject to incorporation of changes as suggested during the meeting. Due to a lack of quorum the chair of CEF Panel proposed to adopt this opinion by written procedure.

6.4 FGE.77 Rev2 ([EFSA-Q-2014-00195](#) to [-00197](#))

The rapporteurs introduced the draft opinion on the safety assessment of FGE 77 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 agreed with the opinion subject to incorporation of changes as suggested during the meeting. Due to a lack of quorum the chair of CEF Panel proposed to adopt this opinion by written procedure.

6.5 RECYC074 Sorepet GR + ([EFSA-Q-2010-01538](#))

The chair of the CEF WG recycling plastics introduced the draft opinion on the safety assessment of the recycling processes Sorepet GR 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 Head of the FIP unit informed the members of the CEF Panel that overall 18 new requests falling within the remit of the CEF Panel were received by EFSA since the last plenary meeting (21-23 October 2014). All requests are related to safety assessments of food enzymes ([EFSA-Q-2014-00800](#) to [00806](#); [EFSA-Q-2014-00730](#) to [00733](#); [EFSA-Q-2014-00735](#) and [EFSA-Q-2014-00794](#) to [00799](#)) and are under completeness check, this means the registration is not yet completed. In addition, for two applications related to new flavouring substances ([EFSA-Q-2014-00093](#) and [EFSA-Q-2014-00094](#)) received non-suitability letters.

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

8.1 Scientific Committee and Scientific Panel including their Working Groups

8.1.1 Scientific Committee including Working Groups

No feedback could be provided from the last (70th) Scientific Committee which was held on 11 November 2014 due to the absence of the chair of the CEF Panel. It was proposed to postpone this item to the next upcoming CEF plenary meeting.

8.1.2 CEF WG BPA Tox

The draft revised chapters of the BPA opinion which were prepared by the WG were discussed under item 6.1. No additional information was provided.

8.1.3 CEF WG Enzymes

A member of the CEF Panel reported back from the 2nd WG meeting of the CEF WG on food enzymes which took place from 10 to 11 November 2014 in Parma. Particular emphasis was given to update the members of the CEF Panel on the outcome of the discussion related to refined exposure assessment. The CEF Panel was presented with a proposal to apply the food additives intake model¹¹ (FAIM) which is based on actual food consumption data using the EFSA comprehensive food consumption database alone or in combination with the budget method. The CEF Panel noted the FAIM model however identified shortcomings which would not allow the application of the FAIM model for all food enzymes without further adjustments of the model. In addition, the CEF Panel noted that the current guidance document recommends the application of the budget method. The CEF Panel agreed that it should be further explored whether the FAIM model could be adjusted for exposure assessments of food enzymes. Once an update of the guidance document is undertaken the modified FAIM model could be included. For the time being the budget method will continue to be used. However the CEF Panel also stressed that in case the Margin of Exposure (MoE) is low the applicant will be asked to provide further information on the occurrence and level of the food enzyme or components thereof in the food and beverages as consumed. The CEF Panel noted that in

¹¹ <http://www.efsa.europa.eu/en/supporting/pub/566e.htm>

those cases, where the overall evaluation of the genotoxicity studies *in vitro* does not raise concern and where the 90-day studies are of adequate quality by current standards, the CEF Panel considered that, normally, an additional uncertainty factor of at least 3-fold in addition to the default uncertainty factor of 100, should be sufficient to cover the limited duration and statistical power of the subchronic 90-day feeding study. However, each safety assessment requires expert judgement and should consider the data package on a case-by case basis.

In addition, the WG chair informed the members of the CEF Panel on the progress made at the last WG meeting.

8.1.4 CEF WG Recycling Plastic

A member of the Panel and a member of the WG recycling plastics informed the CEF Panel that all opinions are on tack. It was outlined that at the next plenary meeting some steering from the CEF Panel related to polyolefins for currently operating commercial processes is needed.

8.1.5 CEF WG Food Contact Material

The chair of the WG informed the members of the CEF Panel that to the last WG meeting two applicants were invited to a technical hearing to present additional clarifications related to an ongoing request for additional data. The WG felt that this was a very useful and effective way of working. The CEF Panel was also informed that EFSA communicated the next steps and proposed timelines in relation with the draft FCM guidance document to DG Sanco. The first part comprises a draft opinion providing the scientific rationale to update the current guidance document which dates back to 2001. The aim is to endorse the draft opinion for public consultation during the CEF plenary meeting in January 2015. The second part, the actual guidance document for applicants which will outline the actual data requirements, can only be drafted after having received the level of protection from DG Sanco in 2015. It is aimed to finalise the guidance document including a public consultation by Dec 2016, however this deadline is depending on DG Sanco.

8.2 EFSA including its Working Groups /Task Forces

8.2.1 General matters

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

- The next meeting of the Advisory Forum (AF) will take place on 10 to 11 December 2014 in Parma and following items will be discussed: strategic discussions on EFSA's work with Member States, novel/traditional food, Art. 30 guidelines and AF towards the future.
- EFSA and Anses will meet for half a day on 3 December 2014 in Paris to outline and discuss the respective approaches of both organisations related to the risk assessment of BPA in order to identify potential sources of divergences and if divergences are identified to try to reconcile them, or alternatively explore how to effectively explain them. This visit is related to Art. 30 of the Regulation (EC) No 178/2002.
- The appointment of vice-chairs for Standing WGs was deferred to the next meeting.
- For 2015, as agreed earlier, the dates for plenary meetings of the CEF Panel are: 27-29 January, 17 to 19 March, 5-7 May, 23-25 June, 8-10 September, 13-15 October, and 1-3 December. Generally, the meetings will take place in Parma and will start on the first day around lunchtime and close the last day around lunchtime

A staff member of the FIP unit provided an overview of the feedback received from observers and Panel members in relation with the 50th CEF open panel meeting.

8.2.2 FIP Network on non-plastics FCMs

A staff member of the FIP unit provided an overview of the objectives, background and TOR of the Food Ingredient and Packaging (FIP) network which held its 1st meeting on food contact materials (FCM) from 12 to 14 November 2014. The focus of the 1st meeting was on non-harmonised non-plastic FCM such as printing inks, coatings, papers and boards where ongoing risk assessment activities and approaches used at national level were present, discussed and future areas of cooperation identified. During this meeting an update on the CEF Panel draft guidance document on plastic FCM was given. Within this context the CEF Panel agreed to share the endorsed draft opinion outlining the necessity to revise the current FCM guidance with the members of the network before the document undergoes public consultation. The minutes of the 1st network meeting will be published on the Authorities webpage.

8.3 European Commission

No information was provided.

9. Other scientific topics for information and/or discussion

No information was presented.

10. Any Other Business

No any other business was raised.

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 Franz declared the following interest: his laboratory has prepared dossiers or was involved in experimental work used in the dossiers related to recycled plastics but not directly in EFSA-Q-2010-01538 (Sorepet GR+). 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.

This results in exclusion of the expert from any discussion, voting or other processing of item 6.5 by the concerned scientific group.

¹² <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

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