

**SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS
AND PROCESSING AIDS (CEF)**
**Minutes of the 31st plenary meeting of the Scientific Panel
on Food Contact Materials, Enzymes, Flavourings and Processing Aids
Held on 29-31 01 2013, Parma**

Agreed on 18 02 2013

Participants

- **Panel Members:**

Ulla Beckman Sundh, Mona Lisa Binderup¹, Claudia Bolognesi, Leon Brimer, Laurence Castle, Alessandro di Domenico, Karl-Heinz Engel, Roland Franz, Klaus-Dieter Jany, Kettil Svensson, Martine Kolf- Clauw², Catherine Leclercq (Vice-chair), Wim Mennes (Vice-chair), Maria Rosaria Milana, Fátima Poças, Iona Pratt (Chair), Fidel Toldrá and Detlef Wölfle.

- **Hearing Experts:**

Riccardo Crebelli (chair of the working group FCM, present for item 8.1 to 8.2).

- **European Commission:**

Bastiaan Schupp³

- **EFSA:**

- **Food Ingredients and Packaging (FIP) Unit:**

Eric Barthelémy, Anna F. Castoldi, Maria Luisa Escudero Hernandez, Claudia Heppner, George Kass, Alina Lupu, Kim Rygaard Nielsen, Hanne Pedersen, Rositsa Serafimova, Alexandra Tard, Elisavet Thessalonikeos and Anne Theobald.

- **Dietary & chemical monitoring (DCM) Unit**

Davide Arcella, Francesco Pomilio and Francesco Vernazza.

- **SCISTRAT - Planning and Monitoring Team**

Raquel Garcia Matas

- **Legal and Regulatory Affairs (LRA) Unit**

Dirk Detken

¹ Present on 29 and 31 January 2013

² Present on 30 to 31 January 2013

³ Present on 29 to 30 January 2013

- **Editorial and Media Relations (EDIT) Unit**

Antony Smith

- **Observers:**

Jan Demyttenaere (European Flavour Association EFA), Emanuela Di Martino (Azienda USL Bologna), Melanie Moethrath (Bayer Material Science representing Plastic Europe), Miguel Angel Prieto Arranz (European Chemical Industry Council CEFIC), Stela Sava-Albaladejo (Université de Versailles Saint Quentin en Yvelines) and Rob Veraart (Keller&Heckman LLP).

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the members to the 31st CEF plenary meeting. The Chair invited the new Panel members Claudia Bolognesi and Alessandro di Domenico to introduce themselves. On the second day of the plenary meeting the chair welcomed the new Panel member Martine Kolf-Clauw and invited her to introduce herself. In addition, the chair welcomed the observers.

Apologies for absence were received for the full plenary meeting from the following members of the CEF Panel: Rainer Gürtler and Trine Husøy. Partial apologies are stated in footnotes 1 to 3. Consequently Martine Kolf-Clauw did not participate in agenda items 1 to 6.6 and Mona Lisa Binderup did not participate in agenda item 8.1, 8.2, 8.3 and 8.7. In addition, the chair of the CEF Panel was only partially present on 29 January 2012 due to her participation in ANS WG Food Additives B. During her absence the meeting was chaired by vice-chair Catherine Leclercq. Claudia Heppner from the FIP unit sent her apologies for the 29 January 2013.

2. Adoption of agenda

The draft agenda was adopted without changes. It was noted that Karl Heinz Engel would also contribute to the Facet presentation (see item 10.1).

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, EFSA screened the Annual Declarations of interest (ADoI) and the Specific Declarations of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, as well as the Oral Declaration of Interest (ODOI) at the beginning of the meeting, please refer to Annex I and Annex II.

4. Information open plenary meeting

The deputy head of FIP Unit informed the Panel that an open plenary meeting would start on 30 January 2013 and that a staff member of the SCISTRAT - Planning and Monitoring Team was invited to present the EFSA guidelines on attendance of observers in open plenary meetings.

5. Agreement of the minutes of the 30th plenary meeting held on 20-22 11 2012, Parma

The draft minutes were discussed and some editorial changes were suggested. With these modifications the draft minutes were agreed by the members of the CEF Panel. The minutes are available on the Authority's webpage⁴.

6. Scientific outputs submitted for discussion and possible adoption

6.1. Draft opinion on safety evaluation of the process "PKR (OHL)" used to recycle post-consumer PET into food contact materials ([EFSA-Q-2009-00734](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The Vice-Chair of the CEF Panel, chairing this part of the meeting, expressed her appreciation for the work done by the CEF WG Recycling.

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

6.2 Draft opinion on safety evaluation of the process "Diamat_New_Re-Ev" used to recycle post-consumer PET into food contact materials ([EFSA-Q-2011-00936](#))

The draft opinion was discussed and some revision of the text is needed to address the variability of the decontamination efficiency calculated from the two submitted challenge tests. Therefore the opinion was not adopted and will be discussed at the next plenary meeting on 20 February 2013.

6.3 Draft opinion on safety evaluation of the process "MOPET_Pellets" used to recycle post-consumer PET into food contact materials ([EFSA-Q-2009-00757](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The Vice-Chair of the CEF Panel, chairing this part of the meeting, expressed her appreciation for the work done by the CEF WG Recycling.

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

6.4 Draft opinion on FCM polyacrylic acid, sodium salt, crosslinked ([EFSA-Q-2011-00136](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The Vice-Chair of the CEF Panel, chairing this part of the meeting, expressed her appreciation for the work done by the CEF WG FCM.

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

6.5 Draft opinion on FCM cellulose (E460), citric acid (E330), sodium hydrogen carbonate (E500ii), polyacrylic acid polymer sodium salt crosslinked ([EFSA-Q-2011-00219](#))

Due to lack of time the draft opinion was not discussed but was deferred to the plenary meeting in March 2013.

⁴ <http://www.efsa.europa.eu/en/events/event/121120a-m.pdf>

⁵ <http://www.efsa.europa.eu/en/efsajournal/doc/3095.pdf>

⁶ <http://www.efsa.europa.eu/en/efsajournal/doc/3094.pdf>

⁷ <http://www.efsa.europa.eu/en/efsajournal/doc/3096.pdf>

6.6 Draft opinion on FCM sodium carbonate peroxyhydrate, bentonite, sodium chloride, sodium carbonate ([EFSA-Q-2011-00236](#))

Due to lack of time the draft opinion was not discussed but was deferred to the plenary meeting in March 2013.

7. Introduction to the open plenary meeting

A staff member of the SCISTRAT - Planning and Monitoring Team presented the EFSA guidelines on attendance of observers.

8. Scientific outputs submitted for discussion and possible adoption in the public session

8.1 Guidelines: application for safety assessment of a substance to be used in food contact materials ([EFSA-Q-2011-00107](#)) – approach discussions

The Chair of the CEF Food Contact Material (FCM) working group (WG) presented the approach under discussion in the FCM WG for the toxicological data to be requested for the safety evaluation of food contact substances. The Panel members discussed the presented approach and provided further steering to the FCM WG.

8.2 Draft opinion on flavourings FGE.06Rev4 ([EFSA-Q-2012-00683](#), [EFSA-Q-2012-00684](#), [EFSA-Q-2012-00685](#), [EFSA-Q-2012-00686](#), [EFSA-Q-2012-00687](#), [EFSA-Q-2012-01013](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The Chair of the CEF Panel expressed her appreciation for the work done by the CEF WG Flavourings.

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

8.3 Draft opinion on flavourings FGE.23Rev4 ([EFSA-Q-2012-00688](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The Chair of the CEF Panel expressed her appreciation for the work to the CEF WG Flavourings.

The full opinion is available on the Authority's webpage⁹.

8.4 Draft opinion on flavourings FGE.208 ([EFSA-Q-2012-00828 to -00837](#))

Due to lack of time the draft opinion was not discussed but was deferred to the plenary meeting in March 2013.

8.5 Draft opinion on flavourings FGE.224 ([EFSA-Q-2012-00678](#))

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The Chair of the CEF Panel expressed her appreciation for the work done by the CEF WG Genotoxicity.

The full opinion is available on the Authority's webpage¹⁰.

⁸ <http://www.efsa.europa.eu/en/efsajournal/doc/3091.pdf>

⁹ <http://www.efsa.europa.eu/en/efsajournal/doc/3092.pdf>

¹⁰ <http://www.efsa.europa.eu/en/efsajournal/doc/3093.pdf>

8.6 Draft opinion on flavourings FGE.305 ([EFSA-Q-2010-01503](#))

Due to lack of time the draft opinion was not discussed but was deferred to the plenary meeting in March 2013.

8.7 Draft opinion on re-evaluation of the TDI value for phenol ([EFSA-Q-2010-00177](#))

The draft opinion was discussed and the Panel proposed that a rough estimation of the relative contribution of non dietary sources of phenol to the overall phenol exposure for the general population should be made. In addition, information on phenol oxidation products was requested. Therefore the opinion was not adopted and it was proposed to be discussed at the plenary meeting in March 2013.

8.8 New Mandates

The Panel members were informed that six new applications related to food contact materials (EFSA-Q-2013-00023, EFSA-Q-2013-00029, EFSA-Q-2013-00030, EFSA-Q-2013-00031, EFSA-Q-2012-001011, EFSA-Q-2012-01008) were received by EFSA since the last plenary. The completeness check is still ongoing. In addition two applications on food enzymes were received (EFSA-Q-2012-01009, EFSA-Q-2012-01010) and it was concluded the data provided are suitable for risk assessment. The CEF WG on enzymes will now start with the assessment which needs to be completed within 18 months. Further information can be found on the Authority's webpage.

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

9.1 Scientific Committee

The Chair and a member of the Panel informed the members on the progress of the SC WG on endocrine disruptors.

9.2 Update from Working Group "Bisphenol A toxicology"

A staff member of the FIP unit informed the Panel members on the progress in the hazard characterisation. The members of the Panel learnt that the weight of evidence approach is being currently applied, using one toxicological endpoint as an example. The outcome of this work will be presented and discussed at the next plenary meeting on 20 February 2013.

9.3 Update from Working Group "Bisphenol A exposure"

The Chair of the Working group "Bisphenol A exposure" presented the exposure part of the draft opinion on BPA, followed by a presentation on the dietary exposure approach, given by a staff member of the Dietary and Chemical Monitoring, DCM unit. The presentations were followed by a short discussion. The Panel members were invited to provide feedback on the approach taken to the Chair of the CEF WG on BPA exposure. In addition, at the next plenary meeting the discussion on the exposure assessment will continue.

9.4 Update from Working Group Flavourings

The Chair of the WG informed the Panel members that WG meetings took place in October and November where progress on some FGEs was made. A meeting in January had to be cancelled due to other commitments. The next meeting is scheduled for March. Additional data were received for a number of flavouring substances.

9.5 Update from Working Group Genotoxicity

Due to lack of time this item was not discussed and was deferred to the plenary meeting in March 2013.

9.6 Update from Working Group Food Contact Materials

Due to lack of time this item was not discussed and was deferred to the plenary meeting in March 2013.

9.7 Update from Working Group Recycling

The Chair of the WG informed the Panel that three meetings took place since the last Panel meeting. Three draft opinions were finalised which were presented to the Panel. Most dossiers are on PET but two on polyolefins are under evaluation, one on crates (closed-loop) and one on mechanical recycling. The possibility to develop guidelines to identify the critical steps for polyolefins is under discussion.

9.8 Update from Working Group Enzymes

The Secretariat gave an update on an EFSA info session on applications - food enzymes – technical meeting with applicants which was held on 18 January 2013 in Parma. More details can be found on EFSA webpage¹¹. The Chair of the WG provided an update on the WG and outlined that the Note for Guidance will be updated. The WG is currently working on two dossiers and the next WG meeting is scheduled for 27 February 2013.

9.9 Update from Working Group of SC on topics of interest to CEF Panel

A member of the Panel informed on the progress of the SC WG on emerging risks. A first meeting took place in September and two sub-WGs will be set up to discuss chemical and biological issues.

9.10 EFSA

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

- The Management Board (MB) of EFSA issued at its meeting held on 13 December 2012 recommendations in relation to the external evaluation¹². In addition the MB adopted the Authority's workprogramme and budget for 2013 as well as nominated Alessandro Di Domenico, Martine Kolf-Clauw and Claudia Bolognesi as new members to the CEF Panel and Agneta Oskarsson and Martin Rose as new members to the ANS Panel.
- The upcoming Advisory Forum meeting will be held on 6 to 7 March in Dublin and EFSA will present its workprogramme 2013 as well as Member States involvement, particularly linked to the multiannual plan (2014 to 2016).
- EFSA aims to publish a new call for expressions of interest for ANS and CEF Panel members in April 2013. The mandate of the current ANS and CEF panels will end in June 2014.
- Within the SCISTRAT Directorate Juliane Kleiner was appointed as HoU of the Scientific Committee as of 15. February 2013. Valerio Curtui was nominated as acting HoU of Nutri unit
- The FIP unit is aiming to launch two new Framework contracts in February 2013, one related to enzymes and one related to flavourings. These contracts should support the work of the WG and Panels. In addition, Eric Barthelemy will lead the food contact material team. Carlotta Ferrari, in-service trainee, will leave the FIP unit by mid February 2013.

¹¹ <http://www.efsa.europa.eu/en/events/event/130117.htm>

¹² <http://www.efsa.europa.eu/en/keydocs/docs/mbrecommendations2012.pdf>

9.11 European Commission

No feedback was provided by the Commission.

10. Other scientific topics for information and/or discussion

10.1 FACET exposure tools

A member of the Panel gave a general introduction into the objectives and output of the FACET project which was funded by DG Research.¹³ Another member of the Panel presented the status of the FACET software used to assess dietary exposure to flavourings. The main tasks performed were the development of a database on reported use levels of flavouring substances, the selection of 41 target flavourings, the analytical determination of target flavouring substances in food products and the development of exposure models to flavouring substances. A third member of the Panel presented the status of the FACET Exposure tool applicable to Food Contact Materials. The FACET tool will allow to perform exposure assessment through a probabilistic approach. The Facet tool is not yet publicly available since it is still being tested. The European Commission's Joint Research Centre (JRC) will host the FACET exposure tool on its webpage¹⁴.

11. Any other business

No other business was raised.

12. Questions from the Observers

The Chair granted the observers the opportunity to ask questions in a dedicated session after they had observed the meeting. These questions, which had been circulated more than one week in advance of the meeting, were answered by the chair of the CEF Panel.

Questions from Jan Demyttenaere (EFFA – Belgium):

1. EFSA request for additional data FL No 02.146 (FGE18rev.2) clarification needed on grouping /read across with linalool.

Answer:

In the statement of the CEF Panel on E-3,7-dimethylocta-1,5,7-trien-3-ol (FGE.18Rev2) which was adopted on 22 Nov 2012, the additional data requirement means a 90-day study on 3,7-dimethylocta-1,5,7-trien-3-ol [FL-no: 02.146] or on a sufficiently structurally related substance has to be provided in order to establish an appropriate NOAEL. Citation from the adopted statement: "The Panel concluded that linalool [FL-no: 02.013] (subgroup 2 of FGE.18) is not sufficiently structurally related to 3,7-dimethylocta-1,5,7-trien-3-ol [FL-no: 02.146] (subgroup 3) for a re-evaluation of [FL-no: 02.146]. Accordingly, a 90-day study on 3,7-dimethylocta-1,5,7-trien-3-ol [FL-no: 02.146] or on a sufficiently structurally related substance has to be provided in order to establish an appropriate NOAEL. This is fully in compliance with other cases, for instance note of FGE.24Rev1, where it is stated that for each subgroup in a FGE, a representative substance for testing is required".

2. Most adequate way for the submission of additional data & timing & general?

Answer:

The deadlines for submission of additional data are set in Commission Regulation EC 871/2012. Further clarifications on data submission should be addressed to European Commission.

¹³ <http://www.ucd.ie/facet/projectoverview/projectstructure>

¹⁴ http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food/FACET/the-facet-exposure-tool

3. Most appropriate follow up testing for FGE19 subgroups in particular damascenones (subgroup 2.4&2.7) 5-membered rings of subgroup 2.6.&subgroup 1.2.1FGE 204 Type of additional data & type of assay (test) to perform.

Answer:

The statement of the CEF Panel “Genotoxicity Test Strategy for Substances belonging to Subgroups of FGE.19” describes which data are requested for the genotoxicity evaluation of these substances.

“The Panel recommends as minimum data set for representative substances from subgroups of FGE.19 the following in vitro tests:

- bacterial gene mutation test (OECD guideline 471)
- an in vitro mammalian cell genotoxicity test (e.g. the mouse lymphoma assay with colony sizing (OECD guideline 476))

In case of positive results, the CEF Panel recommends to perform an in vivo Comet assay in addition to a mouse micronucleus assay.”

The above mentioned statement was published in 2008. In addition, to this statement two more recently published documents from the Scientific Committee¹⁵ should be considered.

Follow up testing of FGE19 subgroup: the CEF panel could not address this specific question raised as this is a case by case assessment which will be carried out by the CEF WGs.

Question from Miguel Angel Prieto Arranz (CEFIC –Belgium):

1. Request information on the progress of the work carried out by the CEF panel and priorities for 2013.

Answer:

In 2012 the CEF panel adopted overall 50 opinions. 25 opinions covered substances used to manufacture materials in contact with foodstuffs of which 9 opinions were related to recycling processes. 21 opinions covered the evaluation of new flavouring substances as well as additional data provided for the re-evaluation of substances of the Flavourings Evaluation Programme. In addition, the CEF Panel as adopted 3 opinions related to smoke flavourings. The CEF Panel jointly adopted an opinion with the BIOHAZ Panel on a processing aid to decontaminate raw poultry products, and assisted the CONTAM Panel in its adoption of a scientific opinion on Mineral hydrocarbons in food.

A detailed report on the achievements of the CEF Panel will be presented in the EFSA annual activity report 2012 which will be published on EFSA webpage in 2013.

For 2013 the WG of the CEF Panel will undertake evaluations related to the first applications for food enzymes, continue its work in the area of plastic food contact materials; recycled materials; active and intelligent packaging. In relation to flavourings substances the re-evaluation of FGE (Flavouring Group Evaluation) 19 and footnote 10 substances will continue. The CEF Panel will also deliver a full risk assessment on bisphenol A. In addition, the Panel will develop a new guidance document on food contact materials. The work programme and estimated outputs of the CEF Panel for 2013 is available in the Management Plan 2013 which was adopted by EFSA Management Board in Dec 2012 and it is published on the webpage.

¹⁵ EFSA Scientific Committee, Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011;9(9):2379. [68 pp.] doi:10.2903/j.efsa.2011.2379. Available online: www.efsa.europa.eu/efsajournal; Minimum Criteria for the acceptance of in vivo alkaline Comet Assay Reports.

Question from Stela Sava-Albaladejo (Université de Versailles- France) :

1. Other than the known criteria, are there any methods of evaluation of the external scientific experts so they can be selected?

Answer:

The selection of experts for the Scientific Panels (SP) and Scientific Committee (SC) as well as for working groups set up by the SP and SC is laid down in the Decisions of the Executive Director concerning the selection of members of the SC/SP and external expert to assist EFSA with its scientific work. Experts for the SP/SC need to fulfil the selection criteria such as Experience in carrying out scientific risk assessment and/or providing scientific advice in fields with the EFSA's remit in general and in particular in the areas of competence and expertise of the Scientific Committee or the respective Scientific Panel or working group.

- Proven scientific excellence in one, or preferably several fields linked to the area covered by the Scientific Committee or the respective Scientific Panel or working group.
- Experience in peer-reviewing scientific work and publications, preferably in fields related to the area covered by the Scientific Committee or the respective Scientific Panel or working group.
- Ability to analyse complex information and dossiers, often from a wide range of scientific disciplines and sources and to prepare draft scientific opinions and reports.

The selection of experts for working groups (WG) is laid down in a Management Board Decision concerning the establishment and operations of the SC/SP and their WG.

Both decisions are published on the Authorities webpage.

2. The CEF panel has 11 units assisting it, each unit adopts a scientific opinion, so when there are different scientific opinion how do the CEF Panel works so that only one scientific opinion is adopted to a specific question?

Answer:

The CEF Panel has 21 members. These members adopt jointly an opinion. If necessary minority opinions can be also expressed. The CEF Panel can set up working groups which are chaired by a CEF Panel member with additional external experts in a particular area to prepare draft opinions such as WG flavourings. Information on each WG of the Panel is published on the Authority's webpage. The WG has the task to prepare the draft opinions. The WG submits final draft opinions to the Panel for possible adoption. The Panel can also return the opinion back to the WG if revision is needed. The Panels is responsible for the opinion.

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOI

a) CONFLICT OF INTEREST:

In his SDOI Dr Franz declared the following: his employer has prepared dossiers for the following applications: RECYC009-recycling process PKR (agenda item 6.1), RECYC076 - Recycling process Holfeld (DIAMAT) (agenda item 6.2), 'RECYC001-Recycling process MOPET (pellets) (agenda item 6.3) and his employer has carried out experimental migration testing for the petitioner of the dossier on polyacrylic acid, sodium salt, crosslinked (agenda item 6.4) and cellulose (E460), citric acid (E330) , sodium hydrogen carbonate (E500ii), polyacrylic acid polymer sodium salt crosslinked (agenda item 6.5) . In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Dols) and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interests above was deemed to represent a conflict of Interest. This results in the impossibility for the expert to be present when these items are discussed, voted on or in anyway processed by that concerned specific group.

Annex II

INTERESTS AND ACTIONS RESULTING FROM DECLARATIONS DONE

AT BEGINNING OF THE MEETING

NO CONFLICT LEVEL A: With regard to this meeting Dr. Iona Pratt declared the following interest: her employer has submitted the dossier RECYC076 - Recycling process Holfeld (DIAMAT) (agenda item 6.2) for assessment to the European Commission. Her employer is the competent authority for submission of dossiers to the European Commission and is not involved in the preparation of dossiers. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of Interest for the expert concerned.