29 01 2013
EFSA, FIP/2

SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Minutes of the 30th plenary meeting of the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids Held on 20-22 11 2012, Parma

Agreed on 29 01 2013

Participants

- **Panel Members**:

  Ulla Beckman Sundh, Mona Lisa Binderup[1], Leon Brimer, Laurence Castle, Karl-Heinz Engel, Roland Franz, Rainer Gürtler, Klaus-Dieter Jany, Svensson Kettil, Catherine Leclercq (Vice-Chair), Jean-Claude Lhuguenot, Maria Rosaria Milana, Fátima Pocas, Iona Pratt (Chair), Fidel Toldrá, Detlef Wölfle.

- **Hearing Experts**:

  Pia Lund (for item 6.1. to 6.5.).

- **European Commission:**

  Bastiaan Schupp.

- **EFSA:**

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

    Eric Barthelémy, Anna F. Castoldi, Maria Carfi, Cristina Croera, Alexandre Feigenbaum, Claudia Heppner, Alina Lupu, Kim Rygaard Nielsen, Hanne Pedersen, Rositsa Serafimova, Dimitrios Spyropoulos, Elisavet Thessalonikeos, Anne Theobald.

  - **Application Desk Unit (APDESK):**

    Karine Lheureux, Carla Martino

- **Observers:**

  None.

- **Others:**

  None.

[1] Present on 20 and 21 November 2012

1. Welcome and apologies for absence

The Chair of the CEF Panel welcomed the members to the 30th CEF plenary meeting.

Apologies for absence were received from following members of the CEF Panel Nathalie Gontard, Trine Husøy and Wim C. Mennes.

The Chair of the CEF Panel informed the members that Jean-Claude Lhuguenot will resign from the CEF Panel after the 30th plenary meeting. In addition, the 30th plenary meeting will be the last one for following staff members of the FIP unit Alexandre Feigenbaum and Dimitrios Spyropoulos due to retirement and taking up another assignment within EFSA, respectively. The chair thanked Jean-Claude Lhuguenot for his long-standing participation and excellent contribution to the work of the EFSA Panel on Food additives, flavourings, processing aids and materials in contact with food (AFC) and CEF Panel and the working group on food contact materials. Furthermore, the Chair thanked Alexandre Feigenbaum and Dimitrios Spyropoulos for their valuable scientific support to the CEF Panel and wished all of them the best for their private and professional future.

2. Adoption of agenda

The draft agenda was adopted without changes.

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, please refer to Annex I. At the begin of this meeting no Oral Declarations of interests (ODoI) were made by the experts related to the issues discussed in this meeting.

4. Agreement of the minutes of the 29th Plenary meeting held on 25-7/09/2012, 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 webpage[2].

5. Report on written procedures since 29th Plenary meeting

The draft opinion on the safety evaluation of the recycling process, "INTERSEROH Step 1" to produce recycled polypropylene intended to be used for manufacture of materials and articles in contact with food (EFSA-Q-2010-00892) was adopted by written procedure on 11 October 2012.

The Panel concluded that any contamination can be ruled out when the process is run under the conditions described by the applicant. Therefore the recycling process "INTERSEROH Step 1" is able to produce recycled polypropylene (PP) suitable for manufacturing PP crates intended to be used in contact with whole fruits and vegetables as requested by the applicant.

The full opinion is available on the Authority's webpage[3].

[2] http://www.efsa.europa.eu/en/events/event/120925b-m.pdf
[3] http://www.efsa.europa.eu/en/efsajournal/pub/2912.htm

6. Scientific outputs submitted

6.1. Draft opinion on flavourings FGE.204 (EFSA-Q-2012-00458 to 00475)

The Flavour Industry provided, as requested, additional genotoxicity studies for two representative substances, 4-methylpent-3-en-2-one [FL-no: 07.101] and 7-methyl-3-octenone-2 [FL-no: 07.177], of FGE.19 subgroup 1.2.1 (FGE.204). Based on these new data, the Panel concluded that the flavouring substance [FL-no: 07.101] does not present a safety concern with respect to genotoxicity and accordingly it can be evaluated using a stepwise approach (the Procedure as laid down in Commission Regulation (EC) No 1565/2000[4]). The Panel could not conclude on the *in vivo* genotoxicity of [FL-no: 07.177] and more appropriate *in vivo* genotoxicity tests, considering also first site of contact, should be performed. In addition, the substance 4-methyl-3-hepten-5-one [FL-no: 07.261] was now identified as a substance for which no representative substances could be identified in the present FGE, resulting in a need for additional data on the genotoxic potential of this flavouring substance. However, the Panel noted that the 2-methyl substituted α,β-unsaturated aldehydes in FGE.201Rev1 can be considered as structurally related to [FL-no: 07.261]. Thus, the final conclusion on [FL-no: 07.261] will be drawn based on the outcome of the evaluation of FGE.201Rev1.

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 webpage[5].

6.2. Draft opinion on flavourings FGE.305 (EFSA-Q-2010-01503)

The Panel was requested to evaluate one flavouring substance, the dipeptide L-methionylglycine [FL-no: 17.037] in the Flavouring Group Evaluation 305 (FGE.305). The substance was considered not to have genotoxic potential. The draft opinion was discussed and but some revision of text is needed by the rapporteur and therefore the opinion was not adopted and will be discussed at next plenary meeting.

6.3. Draft opinion on flavourings FGE.12Rev3 (EFSA-Q-2012-00682)

This revision 3 of FGE.12 is made due to inclusion of one additional flavouring substance, 2,6,6-trimethylcyclohex-2-ene-1-carboxaldehyde [FL-no: 05.182]. None of the total 10 substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure as laid down in Commission Regulation (EC) No 1565/2000[2]) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that all 10 substances [FL-no: 02.134, 02.186, 05.157, 05.182, 05.183, 05.198, 08.135, 09.342, 09.670 and 09.829] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach.

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 webpage[6].

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[4] Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council (Text with EEA relevance). OJ L 180,19.7.2000, p. 8-16.

[5] http://www.efsa.europa.eu/en/efsajournal/pub/2992.htm

[6] http://www.efsa.europa.eu/en/efsajournal/pub/2993.htm

6.4. Draft opinion on flavourings FGE.20Rev4 (EFSA-Q-2012-00621, EFSA-Q-2012, 00620, EFSA-Q-2012-00619, EFSA-Q-2012-00618)

This revision 4 of FGE.20 is made due to inclusion of four additional substances, *o*-, *m*- and *p*-tolualdehyde [FL no: 05.026, 05.028 and 05.029] and phenylmethyl 2-methyl-2-butenoate [FL no: 09.858]. None of the total 45 substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure as laid down in Commission Regulation (EC) No 1565/2000[2]) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that all the substances do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach.

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 webpage[7].

6.5. E-3,7-dimethylocta-1,5,7-trien-3-ol (FGE.18Rev2) (EFSA-Q-2012-00718)

In 2010 the CEF Panel concluded in its Opinion FGE.18Rev2 that for the substance 3,7-dimethylocta-1,5,7-trien-3-ol [FL-no: 02.146], no appropriate NOAEL was available in order to establish a margin of safety, and additional data were requested (90 days study or ADME). 3,7-Dimethylocta-1,5,7-trien-3-ol [FL-no: 02.146] is allocated to subgroup 3 of FGE.18. In 2012, EFSA received new data on linalool [FL-no: 02.013], a supporting substance in FGE.18Rev2 (subgroup 2). However, the CEF Panel concluded that linalool [FL-no: 02.013] is not sufficiently structurally related to 3,7-dimethylocta-1,5,7-trien-3-ol [FL-no: 02.146] for the 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.

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

The full statement is available on the Authority's webpage[8].

6.6. Draft opinion on the substance 2H-Perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] (TFEE5) (EFSA-Q-2011-00966)

The scientific opinion related to the safety evaluation of 2H-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether], CAS No 37486-69-4 and the Food Contact Material (FCM) substance No 903, for use as polymer production aid (PPA) for manufacturing sintered and non-sintered (processed) fluoropolymers.

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The chair of the CEF Panel expressed his appreciation for the work to the CEF WG Food Contact Materials.

The Panel concluded that the use of the substance does not cause safety concern for the consumers when used as a polymer production aid in the polymerisation of fluoropolymers and when the restriction set on the production processes are followed.

The full opinion is available on the Authority's webpage[9].

[7] http://www.efsa.europa.eu/en/efsajournal/pub/2994.htm
[8] http://www.efsa.europa.eu/en/efsajournal/pub/2995.htm
[9] http://www.efsa.europa.eu/en/efsajournal/pub/2978.htm

In this context there was a more general discussion on the recent increase in use of perfluorinated substances for single use articles in contrast to repeated use articles. Such a change might lead to higher production volumes of these substances resulting in higher release to the environment both in the production place and from waste disposals. Therefore the Panel suggests the Commission to take this issue into consideration including all sources of exposure for an integrated risk assessment.

6.7. Draft opinion on FCM on Sodium carbonate peroxyhydrate, bentonite, sodium chloride, sodium carbonate (Oxyfresh) (EFSA-Q- 2011-00236)

The draft opinion was discussed and revisions in the area of genotoxicity were proposed to the CEF WG Food Contact Materials. The opinion was not adopted and will be scheduled for possible adoption at the next Plenary.

6.8. Draft opinion on FCM on Polyacrylic acid, sodium salt, crosslinked (Luquasorb® FP800) (EFSA-Q-2011-00136)

The draft opinion was discussed and editorial revisions were proposed to the CEF WG Food Contact Materials. The opinion was not adopted and will be scheduled for possible adoption at the next Plenary.

6.9. Draft opinion on FCM on safety evaluation of the following processes based on Starlinger IV+® technology used to recycle post-consumer PET into food contact materials "BTB, PRT, Valplastic, Fellinger B and BariQ. (EFSA-Q-2009-00897, EFSA-Q-2009-00946, EFSA-Q-2010-00047, EFSA-Q-2010-01271, EFSA-Q-2012-00766)

This scientific opinion of the Panel deals with the safety evaluation of the recycling processes BTB, PRT, Valplastic, Fellinger B and BariQ (EC register numbers RECYC010, RECYC011, RECYC043, RECYC060 and RECYC084 respectively) which are all based on the same STARLINGER IV+ ® technology. The decontamination efficiency of all these processes was demonstrated using the same challenge test.

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The chair of the CEF Panel expressed his appreciation for the work to the CEF WG recycling plastics.

The Panel concluded that the recycled PET obtained from these processes intended for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

The full opinion is available on the Authority's webpage[10].

6.10. Draft opinion on FCM on safety evaluation of the process "RPET Nosinyec", used to recycle post-consumer PET into food contact material (EFSA-Q-2012-00409)

This scientific opinion of the Panel deals with the safety evaluation of the recycling process RPET Nosinyec, EC register number RECYC082.

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The chair of the CEF Panel expressed his appreciation for the work to the CEF WG recycling plastics.

The Panel concluded that the recycled PET obtained from this process intended for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

The full opinion is available on the Authority's webpage[11].

[10] http://www.efsa.europa.eu/en/efsajournal/pub/2979.htm

6.11. Draft opinion on FCM on safety evaluation of the following processes based on Buhler C technology used to recycle post-consumer PET into food contact materials "Buhler C'' and "FENC'' (EFSA-Q-2010-00087, EFSA-Q-2012-00222)

This scientific opinion of the Panel deals with the safety evaluation of the recycling processes ''Buhler C'' and "FENC'' (EC register numbers RECYC037 and RECYC083 respectively) which are based on the same BUHLER C technology. The decontamination efficiency of these processes was demonstrated using the same challenge tests.

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The chair of the CEF Panel expressed his appreciation for the work to the CEF WG recycling plastics.

The Panel concluded that the recycled PET obtained from these processes intended for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

The full opinion is available on the Authority's webpage[12].

6.12. Draft opinion on FCM safety the safety evaluation of the process 'PRT' based on the recoSTAR PET-FG technology used to recycle post-consumer PET into food contact materials (EFSA-Q-2010-00105)

This scientific opinion of the Panel deals with the safety evaluation of the recycling process PRT (recoSTAR PET-FG) (EC register number RECYC050).

The CEF Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The chair of the CEF Panel expressed his appreciation for the work to the CEF WG recycling plastics.

The Panel concluded that the recycled PET obtained from the process intended for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

The full opinion is available on the Authority's webpage[13].

7. New Mandates

The Panel members were informed about new mandates related to food contact materials and recycling processes which were received by EFSA since the last Plenary. The registration is not yet completed and further information can be found also on the Authority's webpage.

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

8.1. Scientific Committee

The chair informed the members on the progress of the SC WG on endocrine disrupting substances, the formation of the SC WG on environmental risk assessment and the outcome of EFSAs high level conference on "ready for the challenges of tomorrow" held on 14 November 2012 in Parma. Further information can be found on the Authority's webpage [14].

[11] http://www.efsa.europa.eu/en/efsajournal/pub/2980.htm
[12] http://www.efsa.europa.eu/en/efsajournal/pub/2981.htm
[13] http://www.efsa.europa.eu/en/efsajournal/pub/2982.htm
[14] http://www.efsa.europa.eu/en/events/event/121113.htm

8.2. Working Groups (WG)

8.2.1. WG on Flavourings

In absence of the WG chair no report back from this WG to the members of the CEF panel was given.

8.2.2. WG on Genotoxicity

The chair of the WG informed the members of the CEF Panel that several physical meetings and conference calls were held since the last plenary meeting. Good progress was made in respect to the EFSA scientific report on comet assay.

8.2.3. WG on FCM

The chair of the WG informed the members of the CEF Panel on the progress of the evaluations of substances for plastic FCM and active and intelligent packaging.

Following the resignation of the chair of the WG, J-C. Lhuguenot (see item 1), the Panel nominated Riccardo Crebelli, member of the Panel on Food Additives and Nutrient Sources added to Food (ANS) and a long standing member of the CEF WG on FCM as new chair of the WG subject to approval of the annual declaration of interests. The panel members were also informed on the progress of the draft opinion on phenol, a request from a Member State (Germany). The WG is aiming to conclude on the draft phenol opinion and bring the opinion for possible adoption to the plenary meeting which takes place in January 2013**.**

8.2.4. WG on Recycling

The chair of the WG informed the members of the CEF Panel on the progress of the evaluations of recycling processes. Good progress is made when PET recycling processes are used however missing data were identified for evaluating polyolefins recycling processes.

8.2.5. WG on BPA Toxicology

The Chair of the WG on BPA Toxicology informed the Panel members of the outcome of the last WG meetings as well as the upcoming WG meeting where ECHA and SCENIR will participate as observers. The need to hold an ad hoc extra-Plenary meeting in 2013 was flagged.

8.2.6. WG on BPA Exposure

The Chair of the WG on BPA Exposure informed the Panel members of the outcome of the last WG meetings. At the next plenary meeting in 2013 a first feedback on the exposure estimates could be provided.

8.2.7. WG on Enzymes

The Chair of the WG informed the Panel that a stakeholder meeting will take place in Parma on January 17, 2013 and feedback on this event will be given at the next Plenary meeting.

8.3. EFSA

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

- Feedback on the outcome of the 10th anniversary scientific conference “Challenging boundaries in risk assessment ” which took place from 7 to 8

November 2012 in Parma. Further information on the outcome can be found on the Authority's webpage[15].

- On 29 to 30 October 2012 EFSA held a meeting with european and national experts on bisphenol A (BPA) to share information about each other's previous or ongoing work related to the safety assessment of BPA. Participants agreed that the meeting helped them with their respective work on BPA. A short communication note is published on the Authority's webpage[16] and a meeting report with the presentations will be published in 2013.
- On 14 November 2012 the APDESK unit in close collaboration with the FIP unit organised a stakeholder meeting on flavourings where e.g. guidelines for submission of flavouring substances (administrative and scientific issues, particularly genotoxicity data) were presented and discussed including views from stakeholders.
- On 19 November 2012 a meeting between FIP and DG Sanco E3 and E 6 took place to discuss ongoing matters within the area of the CEF Panel. Here the EC flagged following matters as high priority i) finalisation of the risk assessment on BPA, ii) clarifications on the implications of the new guidance document for food contact materials and its finalisation 2013 and iii) additional genotoxicity data for the evaluation of flavouring substances.
- On 21 November 2012 EFSA´s stakeholder platform met in its new composition for the first time.
- The CEF Panel has a high workload and still vacancies to have the maximum number of 21 experts in the Panel. Therefore additional experts which have expertise in toxicology, genotoxicity, and chemistry and who are on the reserve list will be proposed for possible nomination to the Management Board at its next meeting on 13 December 2012.
- Specialised risk assessment training courses in the area of exposure assessment, uncertainties and variability, and evidence base for risk assessment will be organised on behalf of EFSA by the Karolinska institute for Scientific Panel and Scientific Committee members. Members of the CEF panel were invited to register for these courses which will be held over the next three years.

8.4. European Commission

No feedback was provided by the Commission .

9. Other scientific topics for information and/or discussion

9.1. Presentation of the on line e-FLAVIS data base for experts and Panel members

Due to the absence of a representative of FLAVIS (Danish Technical University) the agenda item was postpone to another plenary meeting.

9.2. Revision of FCM Guidelines, examples of application of the new approach presented

The members of the CEF panel discussed briefly the current state of art of the guidelines on FCM. Within this context, members of the FIP unit presented the main changes proposed in exposure assessment and toxicological assessment compared to the current FCM guideline.

[15] http://www.efsa.europa.eu/en/events/event/121107.htm
[16] http://www.efsa.europa.eu/en/events/event/121029.htm

The members appreciated the effort made so far, but proposed to have a more detailed discussion on this matter during the next plenary meeting.

9.3. Scientific Report on minimum criteria for the acceptance of in vivo alkaline Comet Assay reports

A member of the FIP unit presented the final document on the minimum criteria for the acceptance of *in vivo* comet assay reports, a scientific report of EFSA. The amendments suggested by other EFSA Panels were taken up and the CEF panel endorsed the scientific report of EFSA.

10. Any Other Business

The head of Application Desk unit introduced the tasks and responsibilities of the unit. She explained that the unit has two main tasks which are supporting the EFSA units dealing with applications and informing and assisting stakeholders and applicants during the application process. Furthermore she reported back from the stakeholder meeting on flavourings which took place 14 November 2012 in Parma. During the meeting applicants had the chance to exchange views and bring up suggestions to EFSA and Panel members.

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: recycling processes based on Starlinger IV+® ("BTB, PRT, Valplastic, Fellinger B and BariQ) (agenda item 6.9), Buhler C technology ("Buhler C'' and "FENC'') (agenda item 6.11), 'PRT' based on the recoSTAR PET-FG technology (agenda item 6.12) and "RPET Nosinyec" (agenda item 6.10) and his employer has carried out some experimental migration testing for the petitioner of the dossier on polyacrylic acid, sodium salt, crosslinked (agenda item 6.8). 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, 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.