

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

Minutes of the 54th Plenary Meeting

Held on 17-19 March 2015, Parma (Italy)

(Agreed on 5 May 2015)

Participants

a) Panel Members

Claudia Bolognesi, Laurence Castle,¹ Jean-Pierre Cravedi,¹ Karl-Heinz Engel, Paul Fowler, Konrad Grob, Rainer Gürtler, Maria Rosaria Milana, André Penninks, Fátima Poças,² Vittorio Silano, Andrew Smith, Detlef Wölfle

b) Hearing Experts:³

- Sirpa Kärenlampi⁴

c) European Commission and/or Member States representatives:

- Miguel-Anguel Granero Rosell⁵ (DG SANTE)
- Bastiaan Schupp (DG SANTE)

d) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Margarita Aguilera-Gomez, Maria Anastassiadou, Magdalena Andryszkiewicz, Eric Barthélémy, Mary Carfi, Anna Federica Castoldi, Maria Correia, Cristina Croera, Marina Goumenou, Georges Kass, Joaquim Manuel Maia, Claudia Roncancio Peña, Annamaria Rossi, Kim Rygaard Nielsen, Rositsa Serafimova, Anne Theobald

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Trine Husøy, Wim Mennes, Christina Tlustos, Fidel Toldrà, Holger Zorn.

¹ Participated on 18-19 March 2015

² Participated on 17-18 March 2015

³ 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>

⁴ Participated on 17 March 2015 via teleconference

⁵ Participated via teleconference

2. Adoption of agenda

The agenda was adopted without any changes.

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, 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 ADoI or the SDoI, 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 53rd Plenary meeting held on 27-29 January 2015, Parma (Italy)

The minutes of the 53rd Plenary meeting held on 27-29 January were agreed.⁸

5. Report on the written procedures since 53rd Plenary meeting

No scientific outputs were adopted by written procedure since the last plenary meeting.

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁸ <http://www.efsa.europa.eu/en/events/event/150127a.htm>

6. Scientific outputs submitted for discussion and possible adoption

6.1 Alpha-amylase from a GM strain of *Bacillus licheniformis* (NZYM-AC) ([EFSA-Q-2013-00586](#))

The rapporteurs introduced the technical, toxicological and GMM parts of the draft opinion to the members of the CEF Panel and presented the main points for discussion. A preliminary discussion took place and the CEF Panel asked the WG on Enzymes for some additional clarifications. A revised draft opinion will be presented at a future plenary for discussion and possible adoption.

6.2 Amyloglucosidase from a genetically modified strain of *Aspergillus niger* (NZYM-BR) ([EFSA-Q-2013-00686](#))

The rapporteurs introduced the technical, toxicological and GMM parts of the draft opinion to the members of the CEF Panel and presented the main points for discussion. One question related to the subchronic 90-day study was raised and the Panel suggested that the WG on Enzymes requests clarification from the applicant. A revised draft opinion will be presented at a future plenary for discussion and possible adoption.

6.3 Recycling process PET-M (PET recycling) ([EFSA-Q-2010-00093](#))

The Chair of the WG Recycling Plastic introduced the draft opinion on the safety assessment of the recycling process PET-M 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 [opinion](#) is available on the Authority's webpage.

6.4 Coveris recycling process for Poly(ethylene terephthalate) for the manufacture of materials and articles in contact with food ([EFSA-Q-2014-00530](#)) and Envaplaster recycling process for Poly(ethylene terephthalate) for direct food application (EREMA basic) ([EFSA-Q-2014-00714](#))

The Chair of the WG Recycling Plastic introduced the draft opinion on the safety assessment of the recycling processes Coveris and Envaplaster 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 [opinion](#) is available on the Authority's webpage.

6.5 Self-tasking on a scientific opinion on guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation ([EFSA-Q-2011-00107](#))

The Chair of the WG Food Contact Materials presented the draft opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. The CEF Panel discussed the approach and made some recommendations. A modified draft opinion will be presented at the next CEF Plenary meeting.

6.6 Zinc oxide, nano particles for use as an additive in plastics ([EFSA-Q-2014-00308](#))

The rapporteur introduced the draft opinion on the safety assessment of zinc oxide nanoparticles 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 [opinion](#) is available on the Authority's webpage.

6.7 Benzenepropanamide 3,5-bis(1,1-dimethylethyl)-4hydroxy-, N-C16-18-alkyl derivs. ([EFSA-Q-2013-00425](#))

The rapporteur introduced the draft opinion on the safety assessment of benzenepropanamide 3,5-bis(1,1-dimethylethyl)-4hydroxy-, N-C16-18-alkyl derivatives and presented the main points for discussion.

The draft opinion was discussed. Following the discussion, the opinion was modified accordingly and adopted.

6.8 Tetraethyl orthosilicate (TEOS) for use as monomer in plastics ([EFSA-Q-2012-01011](#)) and Hexamethyldisilazane (HMDS) for use as monomer in plastics ([EFSA-Q-2013-00029](#))

The rapporteurs introduced the draft opinion on the safety assessment of tetraethyl orthosilicate (TEOS) and hexamethyldisilazane (HMDS) and presented the main points for discussion. The CEF Panel asked the WG Food Contact Materials for some additional clarifications. A revised draft opinion will be presented at a future plenary for discussion and possible adoption.

6.9 FGE.78 Revision 2

The rapporteur presented the draft opinion on the flavouring substances in FGE.78 Rev2. 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 [opinion](#) is available on the Authority's webpage.

6.10 FGE.25 Revision 3

The rapporteur presented the draft opinion on the flavouring substances in FGE.25 Rev3. 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 [opinion](#) is available on the Authority's webpage.

6.11 FGE.21 Revision 5

The rapporteur presented the draft opinion on the flavouring substances in FGE.21 Rev5. 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 [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 four new mandates for the safety assessment of enzymes, two new mandates for the safety assessment of a plastics recycling process, four new mandates for the safety assessment of food contact materials and two new mandates for the safety assessment of flavourings had been received since the last Plenary meeting.

7.1 New applications since the previous meeting

Food Sector	EFSA-Q-Number	Subject
ENZ	EFSA-Q-2015-00127 until 2015-00131	Request for EFSA to perform a scientific risk assessment on the food enzymes: Pullulanase from a genetically modified strain of <i>Bacillus subtilis</i> , Glucoamylase from a genetically modified strain of <i>Aspergillus niger</i> , Chymosin from a genetically modified strain of <i>Kluyveromyces lactis</i> , Pectin lyase from a genetically modified strain of <i>Aspergillus niger</i> and Triacylglycerol lipase from pregastric tissues of cattle, goat and sheep
ENZ	EFSA-Q-2015-00093 until 2015-00097	Request for EFSA to perform a scientific risk assessment on the food enzymes: Beta-galactosidase from a genetically modified strain of <i>Bacillus licheniformis</i> , Mannan endo-1,4-beta-mannosidase (β -mannanase) from a genetically modified strain of <i>Trichoderma reesei</i> , Transglutaminase from <i>Streptoverticillium mobaraense</i> , Maltogenic amylase from a genetically modified strain of <i>Bacillus subtilis</i> and Glucanase from <i>Streptomyces violaceoruber</i>
ENZ	EFSA-Q-2015-00083 until 2015-00087	Request for EFSA to perform a scientific risk assessment on the food enzymes: Beta-amylase from wheat (<i>Triticum</i> spp.), Alpha-amylase from a genetically modified strain of <i>Bacillus licheniformis</i> , Chymosin from a genetically modified strain of <i>Kluyveromyces lactis</i> , Polygalacturonase from a genetically modified strain of <i>Aspergillus niger</i> , Pectinesterase from a genetically modified strain of <i>Aspergillus niger</i>
ENZ	EFSA-Q-2015-00063 until 2015-00067	Request for EFSA to perform a scientific risk assessment on the food enzymes: Asparaginase from a genetically modified strain of <i>Aspergillus oryzae</i> , Xylanase from a genetically modified strain of <i>Bacillus licheniformis</i> , Xylanase from a genetically modified strain of <i>Bacillus subtilis</i> , Protease complex consisting of trypsin, chymotrypsin, elastase and carboxypeptidase from pig pancreas, and Cellulase from <i>Trichoderma viride</i>
REC	EFSA-Q-2015-00114	Request for safety evaluation of recycling process of Sumilon Eco PET SARM to produce recycled plastic for food contact uses
REC	EFSA-Q-2015-00003	Request for the evaluation of a recycling process for poly(ethylene terephthalate) for direct food application

FCM	EFSA-Q-2015-00121	Request to evaluate Methanone,(2,4-difluorophenyl)(4-fluorophenyl)
FCM	EFSA-Q-2015-00020	Request to evaluate 2,3,3,4,4,5,5-Heptafluoropentene-1 polymer with ethene and tetrafluoroethene for use as monomer in plastics
FCM	EFSA-Q-2015-00104	Request for the safety evaluation of active substance Biocork sulphites-active caps
FCM	EFSA-Q-2015-00091	Request to re-evaluate 2,4-di-t-amylphenol (hydrolysis product of Weston 705)
FLAV	EFSA-Q-2015-00138 and 2015-00139	Request for re-evaluation of flavouring substance from FGE.213 (FGE.19 subgroup 2.7)
FLAV	EFSA-Q-2015-00082	Request for an evaluation of a new flavouring substance, (S)-1-(3-(((4-amino-2,2-dioxido-1H-benzo[c][1,2,6]thiadiazin-5-yl)oxy)methyl)piperidin-1-yl)-3-methylbitan-1-one

7.2 Valid applications since the previous meeting

Applications considered valid for the start of the assessment:

Food Sector	EFSA-Q-Number	Subject	Valid on
ENZ	EFSA-Q-2014-00921	Request for EFSA to perform a scientific risk assessment on the food enzyme: Phospholipase from a genetically modified strain of <i>Aspergillus oryzae</i> (NZYM-PP)	12/02/2015
ENZ	EFSA-Q-2014-00922	Request for EFSA to perform a scientific risk assessment on the food enzyme: Maltogenic amylase from a genetically modified strain of <i>Bacillus subtilis</i> (NZYM-OC)	12/02/2015
ENZ	EFSA-Q-2014-00411	Request for EFSA to perform a scientific risk assessment on a food enzyme: Phospholipase A2 from a genetically modified strain of <i>Trichoderma reesei</i> (RF8793)	23/02/2015
ENZ	EFSA-Q-2014-00733	Request for EFSA to perform a scientific risk assessment on the food enzyme: Xylanase from GM <i>Bacillus subtilis</i> (LMGS-28355)	23/02/2015
ENZ	EFSA-Q-2015-00046	Request for EFSA to perform a scientific risk assessment on the food enzyme: Maltogenic amylase produced by a genetically modified strain of <i>Bacillus subtilis</i> (NZYM-SO)	02/03/2015
FCM	EFSA-Q-2014-00637	Request for evaluation of Terrachim recycling process for Poly (ethylene terephthalate) for direct food application (Vacurema Prime)	06/02/2015

FCM	EFSA-Q-2015-00050	Request to evaluate new monomer 2,3,3,4,4,5,5-heptafluoro-1-pentene	27/02/2015
FCM	EFSA-Q-2015-00061	Request for the evaluation of (Butadiene – styrene – methyl methacrylate – butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate	06/03/2015
FLAV	EFSA-Q-2015-00060	Request for re-evaluation of flavouring substance from FGE.210 (FGE.19 subgroup 2.4) FL 07.061 allyl alpha-ionone	04/02/2015

These applications were assigned to the respective working groups.

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 and its Working Groups

The Scientific Committee Plenary was held 18-19 February 2015. A presentation was made by the Chair.

8.1.3. CEF SWG Food Enzymes

The secretariat informed the CEF Panel about the modalities of the meetings of the SWG on Enzymes and proposed to nominate a second vice Chair who could chair meetings related to the topic of genetically modified microorganism. Lieve Herman was nominated by the Chair of the CEF Panel as second vice Chair of the SWG Enzymes.

8.2 EFSA including its Working Groups /Task Forces

EFSA reported on the publication of a document of the Technical University of Denmark (DTU) dated 20 February 2015 entitled 'Evaluation of EFSA's new scientific opinion on bisphenol A (BPA)'. In this document an alternative (lower) TDI for BPA is proposed. Following a discussion at the Advisory Forum, a decision was taken that EFSA's and DTU's experts would meet to discuss the issue, following the provisions of Article 30 of Regulation (EC) No 178/2002.

9. Other scientific topics for information and/or discussion

10. Any Other Business

No other business was raised.

Annex

List of flavouring substances and corresponding EFSA Q numbers for the FGEs referred to in the minutes

FGE.78 Revision 2: FL 01.007 beta-caryophyllene ([EFSA-Q-2013-00185](#)), FL 01.003 Pin-2(10)-ene ([EFSA-Q-2013-00186](#)), FL 01.004 Pin-2(3)-ene ([EFSA-Q-2013-00187](#)), FL 01.009 Camphene ([EFSA-Q-2013-00188](#)), FL 01.017 Valencene ([EFSA-Q-2013-00189](#)), FL 01.024 beta-Bourbonene ([EFSA-Q-2013-00190](#)), FL 01.026 1(5),7(11)-Guaiadiene ([EFSA-Q-2013-00191](#)), FL 01.029 delta-3-Carene ([EFSA-Q-2013-00192](#)) FL 01.008 Myrcene ([EFSA-Q-2013-00845](#)), FL 01.018 beta-Ocimene ([EFSA-Q-2013-00846](#)), FL 01.040 alpha-farnesene ([EFSA-Q-2013-00847](#)), FL 01.061 undeca-1,3,5-triene ([EFSA-Q-2013-00848](#))

FGE.25 Revision 3: FL 01.059 4(10)-thujene ([EFSA-Q-2013-00193](#)), FL 01.035 2,6-Dimethylocta-2,4,6-triene ([EFSA-Q-2013-00849](#)), FL 01.064 cis-3,7-Dimethyl-1,3,6-octatriene ([EFSA-Q-2013-00850](#)), FL 01.070 1-Octene ([EFSA-Q-2013-00851](#))

FGE.21 Revision 5: FL 15.045 2-Butylthiophene ([EFSA-Q-2013-00861](#)), FL 15.076 2-Hexylthiophene ([EFSA-Q-2013-00862](#)), FL 15.093 2-Octylthiophene ([EFSA-Q-2013-00863](#)), FL 15.096 sec-Pentylthiophene ([EFSA-Q-2013-00864](#)), FL 15.040 2-acetylthiophene ([EFSA-Q-2014-00119](#)), FL 15.074 5-ethylthiophene-2-carbaldehyde ([EFSA-Q-2014-00120](#)), FL 15.097 2-propionylthiophene ([EFSA-Q-2014-00121](#))

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST:

- a) In the SDoI submitted for this meeting, Dr Detlef Woelfle declared the following interest: He has prepared working documents (SDS) for 6.8. Tetraethyl orthosilicate (TEOS) for use as monomer in plastics (EFSA-Q-2013-00425) and Hexamethyldisilazane (HMDS) for use as monomer in plastics (EFSA-Q-2013-00029) under contract with EFSA. 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, 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 is discussed or in anyway processed by the Panel.