

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

Minutes of the 75th Plenary meeting

Held on 5 to 7 June 2018, Parma (Italy)

(Agreed on 22/06/2018)¹

Participants

a) Panel Members

Claudia Bolognesi, Laurence Castle, Kevin Chipman, Jean-Pierre Cravedi², Karl-Heinz Engel³, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler⁴, Trine Husøy, Maria Rosaria Milana, Wim Mennes, Sirpa Kärenlampi, Gilles Rivière, Vittorio Silano (Chair), Jannavi Srinivasan⁴, Maria De Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle and Holger Zorn

b) Hearing Experts⁵:

- Henk van Loveren (for agenda items 6.1, 6.2 and 9)

c) European Commission and/or Member States representatives:

- DG SANTE: Miguel-Angel Granero Rosell

d) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Jaime Aguilera, Maria Anastassiadou, Magdalena Andryszkiewicz, Eric Barthélémy, Giovanni Bernasconi, Julia Cara Carmona, Anna Federica Castoldi, Cristina Croera, Ana Gomes, Christine Horn, Natalia Kovalkovicova, Alexandros Lioupis, Yi Liu, Joaquim Manuel Maia, Carla Martino, Claudia Roncancio Peña, Annamaria Rossi, Ellen Van Haver, Giorgia Vianello, Katharina Volk
- Data Unit: Davide Arcella

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Panel member Karla Pfaff.

2. Adoption of agenda

The agenda was adopted without any changes.

¹ Adopted by written procedure

² Not present on 7 June

³ Not present on 5 June

⁴ Participated via teleconference

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>

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, 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 the 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 74th Plenary meeting held on 7-8 March 2018, Parma

The minutes of the 74th Plenary meeting held on 7-8 March were agreed on 22 March 2018 by written procedure⁶.

5. Report on the written procedures since 74th Plenary meeting

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

6. Scientific outputs submitted for discussion and possible adoption

6.1 Beta-amylase from Barley (*Hordeum vulgare*) ([EFSA-Q-2014-00731](#))

As indicated in the previous minutes of the CEF Plenary meeting⁶, the section on allergenicity assessment of the opinion on beta-amylase from Barley⁷ was revised by the Working Group on Enzymes. The CEF Panel agreed with the revised version (see also section 9 regarding the approach taken by the Panel for the allergenicity assessment of food enzymes).

6.2 Alpha-amylase from a genetically modified strain of *Bacillus licheniformis* (NZYM-AN) ([EFSA-Q-2015-00084](#))

The draft opinion on the safety evaluation of the food enzyme alpha-amylase from a genetically modified strain of *Bacillus licheniformis* (NZYM-AN) was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.3 Alpha-amylase from a genetically modified strain of *Bacillus licheniformis* (NZYM-AV) ([EFSA-Q-2014-00794](#))

The draft opinion on the safety evaluation of the food enzyme alpha-amylase from a genetically modified strain of *Bacillus licheniformis* (NZYM-AV) was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.4 Alpha-amylase from a genetically modified strain of *Aspergillus niger* (NZYM-SB) ([EFSA-Q-2014-00413](#))

⁶ <http://www.efsa.europa.eu/en/events/event/180307-0>

⁷ <https://www.efsa.europa.eu/en/efsajournal/pub/4756>

The draft opinion on the safety evaluation of the food enzyme alpha-amylase from a genetically modified strain of *Aspergillus niger* (NZYM-SB) was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.5 Glucoamylase from a genetically modified strain of *Aspergillus niger* (NZYM-BF) ([EFSA-Q-2014-00307](#))

The draft opinion was not discussed due to lack of time.

6.6 Glucose oxidase from a genetically modified strain of *Aspergillus oryzae* (strain NZYM-KP) ([EFSA-Q-2013-00687](#))

The draft opinion on the safety evaluation of the food enzyme glucose oxidase from a genetically modified strain of *Aspergillus oryzae* (strain NZYM-KP) was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.7 Process-specific technical data used in the exposure assessment of food enzymes ([EFSA-Q-2018-00087](#))

This is the first delivery to the self-task of publishing the technical data used in the enzyme exposure estimation, and of developing process-specific estimation models. The technical data were presented to the members of the CEF Panel together with the main points for discussion. These data will be added as an addendum to the panel statement about food enzyme exposure assessment⁸ (published in 2016).

6.8 FGE.203 Revision 2 : [FL-no: 02.139, 02.153, 02.162, 02.188, 05.057, 05.064, 05.071, 05.081, 05.084, 05.101, 05.108, 05.125, 05.127, 05.140, 05.141, 05.173, 05.186, 05.194, 05.196, 09.573] ([EFSA-Q-2017-00003](#) to [-00022](#))

The draft opinion on the safety evaluation of the flavouring substances evaluated in FGE.203 Revision 2 was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.9 FGE.411: [FL-no: 16.133] ([EFSA-Q-2015-00820](#))

The draft opinion on the safety evaluation of the flavouring substance evaluated in FGE.411 was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel suggested some revisions of the opinion to be addressed by the Working Group on Flavourings before it can be adopted at a future plenary meeting.

6.10 Linpac recycling process ([EFSA-Q-2016-00550](#))

The draft opinion on the safety evaluation of the Linpac recycling process for polyethylene terephthalate (PET) was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts

⁸ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4581>

of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.11 Gneuss 1 recycling process ([EFSA-Q-2016-00705](#))

The draft opinion on the safety evaluation of the Gneuss 1 recycling process for PET was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.12 Gneuss 2 recycling process ([EFSA-Q-2016-00706](#))

The draft opinion on the safety evaluation of the Gneuss 2 recycling process for PET was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

6.13 Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) ([EFSA-Q-2017-00495](#))

The draft opinion on the safety evaluation of poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate for use in food contact materials was presented to the members of the CEF Panel together with the main points for discussion. The CEF Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7. New Mandates

7.1 New questions since the previous meeting

The following new mandates have been received since the last Plenary meeting: two for the safety assessment of food contact materials and four for the safety assessment of flavourings.

Food Sector	EFSA-Q-Number	Subject	Reception date
FCM	EFSA-Q-2018-00411	Request for safety evaluation of Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters for use as monomer (or additive) in plastics	14/05/2018
FCM	EFSA-Q-2018-00375	Request for the evaluation of a recycling process for poly(ethylene terephthalate) for direct food application (Bandera)	14/05/2018
FLAV	EFSA-Q-2018-00410	Request for evaluation as new flavouring substances of 2-Butyl-2-octenal (CAS 13019-16-4) (Ref FLA17-02)	19/03/2018
FLAV	EFSA-Q-2018-00409	Request for evaluation as new flavouring substances of 2-Octyl-2-dodecenal (CAS 25234-33-7)(Ref FLA17-02)	19/03/2018

FLAV	EFSA-Q-2018-00252	Request for evaluation as a new flavouring substance of the compound mixture of 3 and 4 butylthiophene-2-carbaldehyde (REF FL17-003)	19/03/2018
FLAV	EFSA-Q-2018-00251	Request for evaluation as new flavouring substances of 2-Hexyl-2-decenal (CAS 13893-39-5)(Ref FLA17-02)	19/03/2018

7.2 Valid questions since the previous meeting

The following questions have been considered valid for the start of the assessment since the last Plenary meeting: 77 for the safety assessment of flavourings and six for the safety assessment of enzymes.

Food Sector	EFSA-Q-Number	Subject	Valid on
FLAV	EFSA-Q-2018-00410	Request for evaluation as new flavouring substances of 2-Butyl-2-octenal (CAS 13019-16-4) (Ref FLA17-02)	04/05/2018
FLAV	EFSA-Q-2018-00409	Request for evaluation as new flavouring substances of 2-Octyl-2-dodecenal (CAS 25234-33-7)(Ref FLA17-02)	04/05/2018
FLAV	EFSA-Q-2018-00252	Request for evaluation as a new flavouring substance of the compound mixture of 3 and 4 butylthiophene-2-carbaldehyde (REF FL17-003)	04/05/2018
FLAV	EFSA-Q-2018-00251	Request for evaluation as new flavouring substances of 2-Hexyl-2-decenal (CAS 13893-39-5)(Ref FLA17-02)	04/05/2018
FLAV	EFSA-Q-2018-00220	FL 13.004 Allyl 2-furoate	16/04/2018
FLAV	EFSA-Q-2018-00219	FL 09.948 (2E)-2-nonenyl acetate	16/04/2018
FLAV	EFSA-Q-2018-00218	FL 09.947 (E,Z)-2,6-nonadienyl acetate	16/04/2018
FLAV	EFSA-Q-2018-00217	FL 09.866 Allyl valerate	16/04/2018
FLAV	EFSA-Q-2018-00216	FL 09.841 2-Hexenyl octanoate	16/04/2018
FLAV	EFSA-Q-2018-00215	FL 09.790 Allyl phenylacetate	16/04/2018
FLAV	EFSA-Q-2018-00214	FL 09-741 Allyl cinnamate	16/04/2018
FLAV	EFSA-Q-2018-00213	FL 09.719 Allyl anthranilate	16/04/2018
FLAV	EFSA-Q-2018-00212	FL 09.701 Allyl phenoxyacetate	16/04/2018
FLAV	EFSA-Q-2018-00211	FL 09.678 Pent-2-enyl hexanoate	16/04/2018
FLAV	EFSA-Q-2018-00210	FL 09.498 Allyl cyclohexanepropionate	16/04/2018
FLAV	EFSA-Q-2018-00209	FL 09.493 Allyl 2-methylcrotonate	16/04/2018
FLAV	EFSA-Q-2018-00208	FL 09.492 Allyl cyclohexanehexenoate	16/04/2018
FLAV	EFSA-Q-2018-00207	FL 09.489 Allyl isovalerate	16/04/2018
FLAV	EFSA-Q-2018-00206	FL 09.482 Allyl cyclohexaneacetate	16/04/2018
FLAV	EFSA-Q-2018-00205	FL 09.469 Allyl cyclohexanevalerate	16/04/2018
FLAV	EFSA-Q-2018-00204	FL 09.411 Allyl cyclohexanebutyrate	16/04/2018
FLAV	EFSA-Q-2018-00203	FL 09.410 Allyl 2-ethylbutyrate	16/04/2018
FLAV	EFSA-Q-2018-00202	FL 09.400 Hex-2-enyl phenylacetate	16/04/2018
FLAV	EFSA-Q-2018-00201	FL 09.399 (2E)-Hexenyl isovalerate	16/04/2018
FLAV	EFSA-Q-2018-00200	FL 09.398 Hex-(2E)-enyl hexanoate	16/04/2018
FLAV	EFSA-Q-2018-00199	FL 09.397 Hex-2-enyl formate	16/04/2018

FLAV	EFSA-Q-2018-00198	FL 09.396 Hex-2-enyl butyrate	16/04/2018
FLAV	EFSA-Q-2018-00197	FL 09.395 Hex-2(E)-enyl propionate	16/04/2018
FLAV	EFSA-Q-2018-00196	FL 09.394 Hex-2(E)-enyl acetate	16/04/2018
FLAV	EFSA-Q-2018-00195	FL 09.385 Hept-2-enyl acetate	16/04/2018
FLAV	EFSA-Q-2018-00194	FL 09.312 Allyl hexa-2,4-dienoate	16/04/2018
FLAV	EFSA-Q-2018-00193	FL 09.303 Hept-2-enyl isovalerate	16/04/2018
FLAV	EFSA-Q-2018-00192	FL 09.277 Oct-2(trans)-enyl butyrate	16/04/2018
FLAV	EFSA-Q-2018-00191	FL 09.276 Oct-2-enyl butyrate	16/04/2018
FLAV	EFSA-Q-2018-00190	FL 09.247 Allyl crotonate	16/04/2018
FLAV	EFSA-Q-2018-00189	FL 09.244 Allyl hexanoate	16/04/2018
FLAV	EFSA-Q-2018-00188	FL 09.146 Allyl undec-10-enoate	16/04/2018
FLAV	EFSA-Q-2018-00187	FL 09.119 Allyl octanoate	16/04/2018
FLAV	EFSA-Q-2018-00186	FL 09.109 Allyl nonanoate	16/04/2018
FLAV	EFSA-Q-2018-00185	FL 09.097 Allyl heptanoate	16/04/2018
FLAV	EFSA-Q-2018-00184	FL 09.054 Allyl butyrate	16/04/2018
FLAV	EFSA-Q-2018-00183	FL 06.072 1,1-Dimethoxyhex-2(trans)-ene	16/04/2018
FLAV	EFSA-Q-2018-00182	FL 06.031 1,1-Diethoxyhex-2-ene	16/04/2018
FLAV	EFSA-Q-2018-00181	FL 06.025 1,1-Diethoxynona-2,6-diene	16/04/2018
FLAV	EFSA-Q-2018-00180	FL 09.195 trans-2-Tridecenal	16/04/2018
FLAV	EFSA-Q-2018-00179	FL 05.191 trans-2-Decenal	16/04/2018
FLAV	EFSA-Q-2018-00178	FL 05.190 trans-2-Octenal	16/04/2018
FLAV	EFSA-Q-2018-00177	FL 05.189 2-Hexenal	16/04/2018
FLAV	EFSA-Q-2018-00176	FL 05.184 Undec-2(trans)-enal	16/04/2018
FLAV	EFSA-Q-2018-00175	FL 05.179 (E)-Tetradec-2-enal	16/04/2018
FLAV	EFSA-Q-2018-00174	FL 05.172 Nona-2(trans),6(trans)-dienal	16/04/2018
FLAV	EFSA-Q-2018-00173	FL 05.171 Non-2-enal	16/04/2018
FLAV	EFSA-Q-2018-00172	FL 05.150 Hept-2(trans)-enal	16/04/2018
FLAV	EFSA-Q-2018-00171	FL 05.144 Dodec-2(trans)-enal	16/04/2018
FLAV	EFSA-Q-2018-00170	FL 05.120 Dodeca-2,6-dienal	16/04/2018
FLAV	EFSA-Q-2018-00169	FL 05.114 4-Methylpent-2-enal	16/04/2018
FLAV	EFSA-Q-2018-00168	FL 05.111 Octa-2(trans),6(trans)-dienal	16/04/2018
FLAV	EFSA-Q-2018-00167	FL 05.109 2-Undecenal	16/04/2018
FLAV	EFSA-Q-2018-00166	FL 05.102 Pent-2-enal	16/04/2018
FLAV	EFSA-Q-2018-00165	FL 05.078 Tridec-2-enal	16/04/2018
FLAV	EFSA-Q-2018-00164	FL 05.076 Dec-2-enal	16/04/2018
FLAV	EFSA-Q-2018-00163	FL 05.073 Hex-2(trans)-enal	16/04/2018
FLAV	EFSA-Q-2018-00162	FL 05.072 trans-2-Nanenal	16/04/2018
FLAV	EFSA-Q-2018-00161	FL 05.070 2-Heptenal	16/04/2018
FLAV	EFSA-Q-2018-00160	FL 05.060 Oct-2-enal	16/04/2018
FLAV	EFSA-Q-2018-00159	FL 05.058 Nona-2(trans),6(cis)-dienal	16/04/2018
FLAV	EFSA-Q-2018-00158	FL 05.037 2-Dodecenal	16/04/2018
FLAV	EFSA-Q-2018-00157	FL 02.231 trans-2,cis-6-Nanodien-1-ol	16/04/2018
FLAV	EFSA-Q-2018-00156	FL 02.210 Undec-2-en-1-ol	16/04/2018
FLAV	EFSA-Q-2018-00155	FL 02.192 Oct-2-en-1-ol	16/04/2018
FLAV	EFSA-Q-2018-00154	FL 02.156 Hex-2(cis)-en-1-ol	16/04/2018
FLAV	EFSA-Q-2018-00153	FL 02.137 Dec-2-en-1-ol	16/04/2018
FLAV	EFSA-Q-2018-00152	FL 02.112 Non-2(cis)-en-1-ol	16/04/2018
FLAV	EFSA-Q-2018-00151	FL 02.090 Non-2(trans)-en-1-ol	16/04/2018

FLAV	EFSA-Q-2018-00150	FL02.050 Pent-2-en-1-ol	16/04/2018
FLAV	EFSA-Q-2018-00149	FL 02.049 Nona-2,6-dien-1-ol	16/04/2018
FLAV	EFSA-Q-2018-00148	FL 02.020 Hex-2-en-1-ol	16/04/2018
ENZ	EFSA-Q-2018-00115	Request for EFSA to perform a scientific risk assessment on the food enzyme D-psicose 3-epimerase from <i>Corynebacterium glutamicum</i> (strain FIS002)	04/04/2018
ENZ	EFSA-Q-2017-00091	Request for EFSA to perform a scientific risk assessment on the food enzyme preparation: Chymosin and pepsin from the abomasum of lactating lambs	12/03/2018
ENZ	EFSA-Q-2016-00514	Request for EFSA to perform a scientific risk assessment on the food enzyme: Glucan 1,4- β -glucosidase from <i>A. niger</i> (strain CICC2208.5)	12/03/2018
ENZ	EFSA-Q-2016-00513	Request for EFSA to perform a scientific risk assessment on the food enzyme: Alpha-amylase from <i>A. oryzae</i> (strain CICC2336)	12/03/2018
ENZ	EFSA-Q-2016-00512	Request for EFSA to perform a scientific risk assessment on the food enzyme: Alpha-amylase from <i>B. subtilis</i> (strain CICC10074)	12/03/2018
ENZ	EFSA-Q-2016-00511	Request for EFSA to perform a scientific risk assessment on the food enzyme: Aspergillopepsin I from <i>A. niger</i> (strain CICC2377)	12/03/2018

These questions were assigned to the respective working groups.

7.3 Withdrawn applications since the previous meeting

One application for the safety assessment of food contact materials and one application for the safety assessment of flavourings have been withdrawn since the last CEF Plenary meeting.

Food Sector	EFSA-Q-Number	Subject	withdrawn on
FLAV	EFSA-Q-2016-00869	Request for an evaluation of a new flavouring substance of 1-Methylnaphthalene, FL 01.014	19/04/2018
FCM	EFSA-Q-2013-00903	Request for the evaluation of the food contact material (antioxidant) phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethediyl)], C10-16 alkyl esters (CAS 1227937-46-3): Trade name (Doverphos) LGP-11	14/03/2018

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

The Chair of the Working Group (WG) on phthalates presented to the Panel members the updated mandate from the European Commission, to include the phthalates DINP and DIDP in EFSA's risk assessment, and the approach taken so far by the WG for re-evaluating the safety of the phthalates DBP, BBP and DEHP used in plastic food contact materials.

The Panel was informed about the establishment of a new WG on Bisphenol A to re-assess the TDI for BPA which was set on a temporary basis in 2015 by EFSA. Henk van Loveren has been nominated to chair this WG.

9. Other scientific topics for information and/or discussion

The CEF Panel discussed the approach to take for the Allergenicity assessment of food enzymes. The Panel considered that at present no validated methods are available to predict allergenicity of food enzymes and that allergenicity can conclusively be evaluated only when properly designed human studies are conducted.

Additionally, for food enzymes derived from genetically modified micro-organisms the name of the enzyme does not necessary mean that the sequence corresponds to the organism (or enzymes) considered in the dossier. The sequence is more relevant than the name and origin of the enzyme. Even if the food enzyme under assessment (or the protein for which sequence homology match is found) is not included in the databases of known allergens, allergenicity can still not be excluded.

If the protein under assessment (or the protein for which a sequence homology match was found) is included in the databases as known respiratory/skin allergens, the possibility of allergic reactions upon oral exposure cannot be excluded.

Additionally, quantifying the risk for allergenicity is not possible in view of the individual susceptibility to food allergens. Allergenicity can be ruled out only if the proteins are fully removed.

10. Any Other Business

The FIP Head of Unit expressed her gratitude to the Chair and the Panel members for their commitment and work provided during their CEF Panel mandate 2017-2018.

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 Roland Franz declared the following interest for agenda items 6.10. (Linpac recycling process), 6.11. Gneuss 1 recycling process and 6.12. Gneuss 2 recycling process. In general, in the area of PET recycling for food contact his lab has prepared numerous dossiers for industry for submission to and evaluation by the EFSA. Therefore a general conflict for PET recycling processes is declared, either because of direct involvement of his lab in the dossier or indirectly because of a possible market competition between the process under evaluation and the processes for which his lab has contributed.

With respect to the above mentioned agenda items 6.10, 6.11 and 6.12 his lab has contributed with technical-experimental work in support of these dossiers and prepared these dossiers for the petitioners. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁹ and the Decision of the Executive Director on Declarations of Interest¹⁰, and taking into account the specific matters discussed at the meeting in question, the interest declared on agenda items 6.10, 6.11 and 6.12 were deemed to represent a Conflict of Interest and result in exclusion of the expert from any discussion, voting or other processing of these agenda items.

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

¹⁰ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>