

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

## Minutes of the 66<sup>th</sup> Plenary meeting

Held on 31 January to 2 February 2017, EFSA (Parma)

(Agreed on 15 February 2017)<sup>1</sup>

### Participants

#### a) Panel Members

Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler<sup>2</sup>, Trine Husøy<sup>3</sup>, Maria Rosaria Milana<sup>4</sup>, Wim Mennes, Sirpa Orvokki Kärenlampi, André Penninks, Vittorio Silano, Andrew Gilbert Smith, Maria De Fátima Tavares Poças<sup>2</sup>, Detlef Wölflé, Holger Zorn<sup>2</sup>, Corina-Aurelia Zugravu

#### b) European Commission and/or Member States representatives:

- DG SANTE: Miguel-Angel Granero Rosell<sup>2</sup>

#### c) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Margarita Aguilera-Gomez, Maria Anastassiadou, Eric Barthélémy, Mary Carfi, Anna Federica Castoldi, Cristina Croera, Zoltán Diveki, Alexandros Lioupi, Yi Liu, Joaquim Manuel Maia, Carla Martino, Claudia Roncancio Peña, Claudio Putzu, Annamaria Rossi, Siiri Saarna, Ellen Van Haver, Katharina Volk
- Scientific Committee and Emerging Risks (SCER): Andrea Germini
- Additives and Products or Substances used in Animal Feed (FEEDAP): Jaime Aguilera

### 1. Welcome and apologies for absence

The Chair welcomed the participants and two new trainees Claudio Putzu and Siiri Saarna that recently joined the FIP Unit.

Apologies were received from Christina Tlustos.

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<sup>1</sup> Adopted by written procedure

<sup>2</sup> Participated via teleconference

<sup>3</sup> Participated via teleconference on 1 February 2016

<sup>4</sup> Participated on 1 February 2016



## 2. Adoption of agenda

Agenda item 6.7 was removed from the agenda. The remainder of the agenda was adopted without further changes.

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest,<sup>6</sup> 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. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

## 4. Agreement of the minutes of the 65<sup>th</sup> Plenary meeting held on 30 November – 1 December 2016, Brussels (Belgium)

The minutes of the 65<sup>th</sup> Plenary meeting held on 30 November – 1 December 2016 were agreed on 20 December 2016 by written procedure<sup>7</sup>.

## 5. Report on the written procedures since 65<sup>th</sup> 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 Evaluation of isooctadecanamide ([EFSA-Q-2014-00651](#))

The draft opinion on the safety evaluation of isooctadecanamide (renamed as 'mixture of methyl-branched and linear C14-C18 alkanamides, derived from fatty acids') 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

### 6.2 FGE.49 Revision 1: [FL-no: 16.016] caffeine ([EFSA-Q-2011-01015](#)) and [FL-no: 16.032] theobromine ([EFSA-Q-2011-00049](#))

The draft opinion on the safety evaluation of the flavouring substances evaluated in FGE.49 Revision 1 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

### 6.3 FGE.210 Revision 3: [FL-no: 07.134] Alpha-damascone ([EFSA-Q-2016-00308](#)); [FL-no: 07.130] Delta-damascone ([EFSA-Q-2016-00309](#)); [FL-no: 07.225] cis-1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)but-2-en-1-one ([EFSA-Q-2016-00310](#)); [FL-no: 07.226] tr-1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)but-2-en-1-one ([EFSA-Q-2016-00311](#)); [FL-no: 07.231] alpha-damascenone ([EFSA-Q-2016-00312](#))

Upon request from the WG on Flavourings, the CEF Panel discussed some issues that are critical for the safety assessment of the flavouring substances evaluated in FGE.210. In the present revision of FGE.210, additional genotoxicity data submitted by the applicant

<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>6</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>7</sup> <http://www.efsa.europa.eu/en/events/event/161130b>



for alpha-damascone were evaluated. The results for two samples of alpha-damascone were contradictory, with one sample proving positive but a second sample proving negative results in an *in vivo* Comet assay in the liver. Therefore, the concern for genotoxicity raised by the chemical structure of the substance and by equivocal *in vitro* data could not be ruled out on the basis of the submitted *in vivo* studies on alpha-damascone [FL-no: 07.134]. The CEF Panel requires additional information from the applicant to be able to conclude on the safety of the flavouring substance [FL-no: 07.134] and the four structurally related substances [FL no: 07.130, 07.225, 07.226 and 07.231]. The scientific evaluation of the flavouring substance will be suspended, awaiting the submission of the additional information requested.

**6.4 FGE.57 Revision 1: [FL-no: 02.067] Isopulegol ([EFSA-Q-2014-00339](#)); [FL-no: 07.067] Isopulegone ([EFSA-Q-2014-00340](#)); [FL-no: 09.219] Isopulegyl acetate ([EFSA-Q-2014-00341](#)); [FL-no: 07.127] p-Mentha-1,4(8)-dien-3-one ([EFSA-Q-2014-00346](#))**

The draft opinion on the safety evaluation of the flavouring substances evaluated in FGE.57 Revision 1 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

**6.5 FGE.302: [FL-no: 16.119] N-(2-methylcyclohexyl)-2, 3, 4, 5, 6-pentafluorobenzamide ([EFSA-Q-2014-00060](#))**

The draft opinion on the safety evaluation of the flavouring substance evaluated in FGE.302 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

**6.6 FGE.07 Revision 5: [FL-no: 02.131] But-3-en-2-ol ([EFSA-Q-2016-00467](#)); [FL-no: 02.187] Non-1-en-3-ol ([EFSA-Q-2016-00470](#)); [FL-no: 07.161] Hex-1-en-3-one ([EFSA-Q-2016-00471](#)); [FL-no: 07.210] 1-Nonene-3-one ([EFSA-Q-2016-00472](#))**

The draft opinion on the safety evaluation of the flavouring substances evaluated in FGE.07 Revision 5 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

**6.7 Evaluation of Märkische Faser recycling process ([EFSA-2016-00139](#))**

This agenda item was removed from the agenda as the Working Group on Recycling Plastics decided at their last working group meeting (17-18 January 2017) to ask the applicant for additional data to allow the risk assessment to be completed.

## **7. New Mandates**

### **7.1 New applications since the previous meeting**



The following new mandates have been received since the last Plenary meeting: nine for the safety assessment of enzymes, one for the safety assessment of food contact materials and 22 for the safety assessment of flavourings.

Food Sector	EFSA-Q-Number	Subject	Reception date
ENZ	2016-00863	Request for EFSA to perform a scientific risk assessment on the food enzyme: Cyclomaltodextrin glucanotransferase from <i>Geobacillus stearothermophilus</i>	20/12/16
ENZ	2016-00866	Request for EFSA to perform a scientific risk assessment on the food enzyme: Ficin from <i>Ficus glabrata</i>	20/12/16
ENZ	2016-00867	Request for EFSA to perform a scientific risk assessment on the food enzyme: Bromelain from <i>Ananas comosus</i>	20/12/16
FLAV	2016-00869	Request for an evaluation of a new flavouring substance of 1-Methylnaphthalene, FL 01.014	20/12/16
FLAV	2017-00001	Request for an evaluation of a new flavouring substance of Naringenin (CAS: 480-41-1)	20/12/16
FLAV	2017-00003	FL 02.139 Deca-2,4-dien-1-ol	20/12/16
FLAV	2017-00004	FL 02.153 Hepta-2,4-dien-1-ol	20/12/16
FLAV	2017-00005	FL 02.162 Hexa-2,4-dien-1-ol	20/12/16
FLAV	2017-00006	FL 02.188 Nona-2,4-dien-1-ol	20/12/16
FLAV	2017-00007	FL 05.057 Hexa-2(trans),4(trans)-dienal	20/12/16
FLAV	2017-00008	FL 05.064 Trideca-2(trans),4(cis),7(cis)-trienal	20/12/16
FLAV	2017-00009	FL 05.071 Nona-2,4-dienal	20/12/16
FLAV	2017-00010	FL 05.081 2,4-Decadienal	20/12/16
FLAV	2017-00011	FL 05.084 Hepta-2,4-dienal	20/12/16
FLAV	2017-00012	FL 05.101 Penta-2,4-dienal	20/12/16
FLAV	2017-00013	FL 05.108 Undeca-2,4-dienal	20/12/16
FLAV	2017-00014	FL 05.125 Dodeca-2,4-dienal	20/12/16
FLAV	2017-00015	FL 05.127 Octa-2(trans),4(trans)-dienal	20/12/16
FLAV	2017-00016	FL 05.140 Deca-2(trans),4(trans)-dienal	20/12/16
FLAV	2017-00017	FL 05.141 Deca-2,4,7-trienal	20/12/16
FLAV	2017-00018	FL 05.173 Nona-2,4,6-trienal	20/12/16
FLAV	2017-00019	FL 05.186 2,4-Octadienal	20/12/16
FLAV	2017-00020	FL 05.194 tr-2, tr-4-Nonadienal	20/12/16
FLAV	2017-00021	FL 05.196 tr-2, tr-4-Undecadienal	20/12/16
FLAV	2017-00022	FL 09.573 Hexa-2,4-dienyl acetate	20/12/16



ENZ	2017-00041	Request for EFSA to perform a scientific risk assessment on the food enzyme: Lactoperoxidase from bovine milk	16/01/17
ENZ	2017-00042	Request for EFSA to perform a scientific risk assessment on the food enzyme: Pancreatin from porcine pancreas	16/01/17
ENZ	2017-00043	Request for EFSA to perform a scientific risk assessment on the food enzyme: Pancreatin from porcine pancreas and duodenum	16/01/17
ENZ	2017-00044	Request for EFSA to perform a scientific risk assessment on the food enzyme preparation: Chymosin and pepsin from stomachs of lambs and kids (young goats)	16/01/17
ENZ	2017-00045	Request for EFSA to perform a scientific risk assessment on the food enzyme preparation: chymosin, pepsin and gastricsin from stomachs (abomasum) of kids (young goats)	16/01/17
ENZ	2017-00048	Request for EFSA to perform a scientific risk assessment on the food enzyme obtained from the Cardoon flowers (Cynara cardunculus var. sylvestris)	16/01/17
FCM	2017-00054	Request for the evaluation of a substance: Active mixture Spongel	18/01/17

## 7.2 Valid applications since the previous meeting

The following applications have been considered valid for the start of the assessment since the last Plenary meeting: six for the safety assessment of food contact materials and eight for the safety assessment of flavourings.

Food Sector	EFSA-Q-Number	Subject	Valid on
FCM	2016-00680	Request for safety evaluation of Coexpan Montonate recycling process (Starlinger viscotec deCON technology)	12/12/16
FLAV	2016-00720	FL 12.009 Diallyl trisulfide	15/12/16
FLAV	2016-00721	FL 12.013 Dimethyl trisulfide	15/12/16
FLAV	2016-00722	FL 12.020 Methyl propyl trisulfide	15/12/16
FLAV	2016-00723	FL 12.023 Dipropyl trisulfide	15/12/16
FLAV	2016-00724	FL 12.045 Methyl allyl trisulfide	15/12/16
FLAV	2016-00725	FL 12.074 Diallyl polysulfides	15/12/16
FLAV	2016-00726	FL 12.155 Methyl ethyl trisulfide	15/12/16
FLAV	2016-00727	FL 12.280 Diisopropyl trisulfide	15/12/16
FCM	2016-00486	Request for the re-evaluation of Morssinkhof-plastics recycling process	19/12/16
FCM	2016-00705	Request for safety evaluation of Gneuss Kunststofftechnik recycling process (Gneuss 1 technology)	20/12/16
FCM	2016-00706	Request for safety evaluation of Gneuss Kunststofftechnik recycling process (Gneuss 2 technology)	20/12/16



FCM	2016-00741	Request for safety evaluation of Coexpan Deutschland recycling process (EREMA basic technology)	6/01/17
FCM	2016-00510	Request for the evaluation of an additive: reaction product of stearyl-diethanol-amine with C18 saturated fatty acids	12/01/17

These applications were assigned to the respective working groups.

### 7.3 Withdrawn applications since the previous meeting

A withdrawal request for the following application on food contact materials was received by EFSA since the last CEF Plenary meeting.

Food Sector	EFSA-Q-Number	Subject	withdrawn on
FCM	2015-00411	Request for safety evaluation of VINNAPAS® LL 8324 for use as additive in plastics.	5/01/17

## 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 on 16-17 November 2016. The Chair provided feedback on the main issues discussed.

#### 8.1.2 CEF Standing Working Group on Recycling Plastics

No updates were provided.

#### 8.1.3 CEF Standing Working Group on Genotoxicity

The CEF Panel members were informed about a technical hearing that was held on 24 January 2017 with representatives from the European Flavour Association (EFFA) to provide clarifications on a new proposed *in vitro* test for genotoxicity testing.

#### 8.1.4 CEF Standing Working Group on Food Contact Materials

The CEF Panel members were informed about the on-going trial exercise for the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee<sup>8</sup> in the field of food contact materials (FCM). The quantitative and qualitative approaches as applied by the FCM Working Group for identifying and assessing the uncertainties linked to the toxicity data of an opinion on FCM were presented. The FCM Working Group will address the uncertainties linked to the non-toxicity data of the opinion at their next meeting.

#### 8.1.5 CEF Standing Working Group on Flavourings

No updates were provided.

<sup>8</sup> <http://www.efsa.europa.eu/en/topics/topic/uncertainty>



#### **8.1.6 CEF Standing Working Group on Food Enzymes**

No updates were provided.

#### **8.2 EFSA including its Working Groups /Task Forces**

No updates were provided.

#### **8.3 European Commission**

No updates were provided.

### **9. Other scientific topics for information and/or discussion**

The CEF Panel was informed about the new Guidance Document on the characterisation of microbial strains and feed additives obtained by them, currently being developed by the Working Group on Genetically Modified Microorganisms (GMM)<sup>9</sup> of the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel). It was explained that this new guidance will cover products consisting of non-genetically modified (non-GM) microorganisms (e.g. probiotics) and products obtained by fermentation of microorganisms (both genetically modified and non-GM). The document will cover the characterisation of the strain and of those aspects of the product linked to the production strain, but will not cover the safety of the product as such. The safety assessment of products like food enzymes, flavourings and additives obtained by fermentation of GMMs will fall under the remit of other Panels (CEF, ANS<sup>10</sup>). Therefore, the different Panels concerned will be requested to endorse the corresponding section of the document regarding the detection of recombinant DNA in products, prior to the release of the guidance document for public consultation.

### **10. Any Other Business**

The CEF Panel agreed with the changes EFSA intends to bring into the Note for Guidance for FCM substances. This document needs to be revised to update the information that is obsolete or not in line with other EFSA guidance documents. EFSA aims at publishing the revised version of this Note for Guidance together with the new EFSA administrative guidance document on plastic food contact materials by the end of February 2017.

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<sup>9</sup> <https://ess.efsa.europa.eu/doi/doiweb/wg/681851>

<sup>10</sup> EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)