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

Minutes of the 65th Plenary meeting

Held on 30 November and 1 December 2016, Brussels (Belgium)

(Agreed on 20 December 2016)[1]

Meeting open to Observers

OPEN SESSION

30 November 2016, 10:00-18:00

Participants

a) Panel Members

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

b) Observers: Izabela Blaszkiewicz (Unilever), Jan Demyttenaere (EFFA, European Flavour Association), Krassimira Kazashka-Hristozova (FEFCO, European Federation of Corrugated Board Manufactures), Blanca Sanchez (Alonso & Asociados), Bettina Schnabel (Association of the cutlery and flatware industries), Rachida SEMAIL (Keller and Heckman), Elisa SETIEN (FECC, European Federation of Chemical Distributors), Maria Jose Trave (BUDENHEIM IBERICA SLU), Angeliki Vlachou (FoodDrinkEurope)

c) European Commission and/or Member States representatives:

- DG SANTE: Miguel-Angel Granero Rosell[2], María Iglesia[2], Bastiaan Schupp, Luis Vivas-Alegre

d) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Maria Anastassiadou[2], Eric Barthélémy[3], Mary Carfi[2], Anna Federica Castoldi, Cristina Croera[3], Yi Liu[3], Claudia Roncancio Peña, Annamaria Rossi, Ellen Van Haver
- Evidence Management Unit: Davide Arcella[3]
- EXREL Unit: Stephen Pagani[2]

[1] Adopted by written procedure
[2] Participated on 30 November 2016
[3] Participated on 1 December 2016

1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies were received.

2. Brief introduction of Panel members and Observers

The Chair welcomed the observers.

The Chair invited all the participants to the meeting to briefly introduce themselves.

3. Presentation of the *EFSA Guidelines for Observers*

The Head of FIP Unit presented the rules for observers to be followed during and after the open plenary meeting. Observers were given the possibility to send questions when submitting their registration and these questions would be answered in a dedicated session at the end of the day. Observers were also informed that the Chair would grant opportunity for additional questions at the end of each discussion topic.

4. Adoption of agenda

The agenda was adopted without any changes.

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director on Declarations of Interest,[5] 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.

6. Agreement of the minutes of the 64th Plenary meeting held on 13-15 September 2016, Parma (Italy)

The minutes of the 64th Plenary meeting held on 25-27 October 2016 were agreed on 15 November by written procedure[6].

7. Report on the written procedures since 64th Plenary meeting

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

8. Scientific outputs submitted for discussion and possible adoption

8.1 FGE.216 Revision 2: [FL-no: 05.062] 2-phenylcrotonaldehyde (EFSA-Q-2015-00199), [FL-no: 05.099] 5-methyl-2-phenylhex-2-enal (EFSA-Q-2015-00201), [FL-no: 05.100] 4-methyl-2-phenylpent-2-enal (EFSA-Q-2015-00202), [FL –no: 05.175] 2-phenylpent-2-enal (EFSA-

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[6] http://www.efsa.europa.eu/en/events/event/161025

Q-2015-00203) and [FL-no: 05.222] 2-phenyl-4-methyl-2-hexenal (EFSA-Q-2015-00204)

The status of the evaluation of genotoxicity of the flavouring substances of FGE.216 was presented to the members of the CEF Panel together with the main points for discussion. The comments and suggestions made will be considered by the working group on Genotoxicity.

8.2 FGE.63 Revision 3: [FL-no: 07.102] pent-1-en-3-one (EFSA-Q-2016-00462), [FL-no: 07.081] oct-1-en-3-one (EFSA-Q-2016-00463),[FL-no: 02.023] oct-1-en-3-ol (EFSA-Q-2016-00464), [FL-no: 02.099] pent-1-en-3-ol (EFSA-Q-2016-00465), [FL-no: 02.104] hex-1-en-3-ol (EFSA-Q-2016-00466), [FL-no: 02.136] dec-1-en-3-ol (EFSA-Q-2016-00468), [FL-no: 02.155] 1-hepten-3-ol (EFSA-Q-2016-00469), [FL-no: 09.281] oct-1-en-3-yl acetate (EFSA-Q-2016-00473) and [FL-no: 09.282] oct-1-en-3-yl butyrate (EFSA-Q-2016-00474)

The draft opinion on the safety evaluation of the flavouring substances evaluated in FGE.63 Revision 3 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.

8.3 FGE.407: [FL-no: 16.130] 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid (EFSA-Q-2015-00244)

The draft opinion on the safety evaluation of the flavouring substances evaluated in FGE.407 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.

9. New Mandates

9.1 New applications since the previous meeting

The following new mandates have been received 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	Reception date
FCM	2016-00680	Request for safety evaluation of Coexpan Montonate recycling process (Starlinger viscotec deCON technology)	27/10/2016
FLAV	2016-00727	FL 12.280 Diisopropyl trisulfide	3/11/2016
FLAV	2016-00726	FL 12.155 Methyl ethyl trisulfide	3/11/2016
FLAV	2016-00725	FL 12.074 Diallyl polysulfides	3/11/2016
FLAV	2016-00724	FL 12.045 Methyl allyl trisulfide	3/11/2016
FLAV	2016-00723	FL 12.023 Dipropyl trisulfide	3/11/2016
FLAV	2016-00722	FL 12.020 Methyl propyl trisulfide	3/11/2016

FLAV	2016-00721	FL 12.013 Dimethyl trisulfide	3/11/2016
FLAV	2016-00720	FL 12.009 Diallyl trisulfide	3/11/2016
FCM	2016-00706	Request for safety evaluation of Gneuss Kunststofftechnik recycling process (Gneuss 2 technology)	8/11/2016
FCM	2016-00705	Request for safety evaluation of Gneuss Kunststofftechnik recycling process (Gneuss 1 technology)	8/11/2016
FCM	2016-00704	Request for safety evaluation of Krones recycling process (Krones Pellet technology)	8/11/2016
FCM	2016-00741	Request for safety evaluation of Coexpan Deutschland recycling process (EREMA basic technology)	17/11/2016
FCM	EFSA-Q-2016-00779	Request for safety evaluation of Technip Zimmer recycling process (Technip Zimmer technology)	23/11/2016

9.2 Valid applications since the previous meeting

The following applications have been considered valid for the start of the assessment since the last Plenary meeting: nine for the safety assessment of enzymes and one mandate related to the safety assessment of bisphenol A.

Food Sector	EFSA-Q-Number	Subject	Validation date
ENZ	2016-00575	Request for EFSA to perform a scientific risk assessment on the food enzyme: 3-Phytase from *Aspergillus niger* (strain PHY93-08)	14/11/2016
ENZ	2016-00576	Request for EFSA to perform a scientific risk assessment on the food enzyme: Alpha-amylase from *Aspergillus niger* (strain AS 29-286)	14/11/2016
ENZ	2016-00577	Request for EFSA to perform a scientific risk assessment on the food enzyme: Invertase and Exo-beta-glucosidase from *Aspergillus niger* (strain IN 319)	14/11/2016
ENZ	2016-00578	Request for EFSA to perform a scientific risk assessment on the food enzyme: Alpha-galactosidase from *Aspergillus niger* (strain AGS614)	14/11/2016

ENZ	2016-00579	Request for EFSA to perform a scientific risk assessment on the food enzyme: Lactase from *Aspergillus oryzae* (strain GL 470)	14/11/2016
ENZ	EFSA-Q-2016-00656	Request for EFSA to perform a scientific risk assessment on the food enzyme: Pectinase from *Rhizopus oryzae* (strain MC3-3-9)	21/11/2016
ENZ	EFSA-Q-2016-00655	Request for EFSA to perform a scientific risk assessment on the food enzyme: Aspergillopepsin I from A*spergillus niger* (strain AP 233)	21/11/2016
ENZ	EFSA-Q-2016-00654	Request for EFSA to perform a scientific risk assessment on the food enzyme: Triacylglycerol lipase from *Aspergillus niger* (strain NL 151)	21/11/2016
ENZ	EFSA-Q-2016-00658	Request for EFSA to perform a scientific risk assessment on the food enzyme: chymosin and pepsin from stomachs of calves and cows	24/11/2016
FCM	EFSA-Q-2016-00635	Re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs and protocol for the risk assessment strategy	28/11/2016

These applications were assigned to the respective working groups.

9.3 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	Withdrawal date
FCM	EFSA-Q-2013-00425	Request for the evaluation of Additive: Benzenepropanamide 3,5-bis(1,1 -dimethylethyl) - 4hydroxy-, N-C16-18-alkyl derivs	28/10/2016

Noteworthy, a scientific opinion on Benzenepropanamide 3,5-bis(1,1 -dimethylethyl) – 4-hydroxy-, N-C16-18-alkyl derivs (EFSA-Q-2013-00425) was adopted by the CEF Panel at its Plenary Meeting of 18 March 2015. Its publication was put on hold pending the receipt from the applicant of the permission from a (different) data owner to use some specific data to support the application. In the absence of submission by the applicant of such declaration or, alternatively, of the data required, the CEF Panel could only decide to withdraw the adoption of the opinion. Both the applicant and the Member State concerned filed to EFSA a withdrawal request for this application on 11 and 28 October 2016, respectively.

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

10.1 Scientific Committee and Scientific Panel including their Working Groups

10.1.1 CEF SWG Recycling Plastics

The chair of the WG informed the Panel members and the observers about number of recycling processes currently under evaluation by the WG.

10.1.2 CEF Standing Working Group on Genotoxicity

The chair of the WG informed the Panel members and the observers about the number of existing flavouring substances and the number of new applications for which the genotoxicity data are looked at by the WG.

10.1.3 CEF Standing Working Group on Food Contact Materials

The chair of the WG informed the Panel members and the observers about the number of FCM substances currently under evaluation by the WG and the on-going trial exercise for the implementation of the principles of the Uncertainty guidance from the EFSA Scientific Committee[7] in the field of food contact materials.

10.1.4 CEF Standing Working Group on Flavourings

The chair of the WG informed the Panel members and the observers about the number and status of flavouring applications that are under assessment by the WG.

10.1.5 CEF Standing Working Group on Food Enzymes

The chair of the WG informed the Panel members and the observers about the number and status of food enzyme applications that are under assessment by the WG, as well as the on-going call-for-data[8] concerning technical factors specific for the baking and brewing processes.

10.2 EFSA including its Working Groups /Task Forces

The Panel members and the observers were informed about an EFSA WG that has been established following an EFSA internal mandate to develop a protocol for bisphenol A (BPA) assessment. This WG will also be in charge of executing the tasks as foreseen by the first step of the external mandate received from the European Commission[9].

10.3 European Commission

The Head of DG Santé E2 "Food processing technologies and novel foods" made a presentation on on-going and coming work of relevance to EFSA with regard to flavourings, enzymes and food contact materials.

11. Other scientific topics for information and/or discussion

There were no other scientific topics for discussion.

[7] http://www.efsa.europa.eu/en/topics/topic/uncertainty
[8] https://www.efsa.europa.eu/en/data/call/161110
[9] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00635

12. Answers to questions received in writing from Observers (in application of the *EFSA Guidelines for Observers*)

Angeliki Vlachou (FoodDrinkEurope):

- Question 1: *Could you please provide an indicative programme of the upcoming evaluations and publications of Opinions for flavourings?*

In 2016, five new flavouring substances were under evaluation in the CEF flavouring working group (FGE.406, FGE.407, FGE.408, FGE.410, FGE.411). The draft opinion on FGE.407 has been adopted during this plenary meeting. FGE.411 is expected to be submitted for discussion and possible adoption in the first half of 2017. For three out of the five new applications (FGE.406, FGE.408 and FGE.410) concerning the evaluation of flavouring substances, requests for additional data have been addressed to the applicants.

For four 'other flavourings' (FGE.500, FGE.501, FGE.502, FGE.503) and one smoke flavouring (RS1003) additional data have been requested to the applicants.

With regard to flavouring substances under evaluation according to Regulation (EC) 1565/2000 five FGEs (FGE.49Rev1, FGE.07Rev5, FGE.57Rev1, FGE.74Rev4 and FGE.302) are expected to be finalised in the first half of 2017; for approximately twenty FGEs, additional data are requested to the applicants.

For the flavouring substances with a structural alert for genotoxicity, the following FGEs contain substances which are under evaluation: FGE.210 (5 substances), FGE.216 (5 substances) and FGE.226 (1 substance). Additional data are requested directly to the applicant for FGE.204 (16 substances), FGE.208 (5 substances), FGE.215 (7 substances), FGE.217 (9 substances) and FGE.222 (8 substances). Six FGEs dealing with the evaluation of flavouring substances according to Regulation (EC) 1565/2000 are currently in stop-the-clock (FGE.13Rev3, FGE.21Rev6, FGE.67Rev3, FGE.76Rev2, FGE.77rev3 and FGE.93Rev2). For the substances of FGE.200 (74 substances) and FGE.201 (12 substances), additional data have been requested via publication in the scientific opinion.

- Question 2: *Could you please provide an indicative programme of the upcoming evaluations and publications of Opinions for enzymes?*

The scientific statement on exposure assessment of food enzymes has been published on the Authority's webpage. The prioritisation of the evaluation of food enzymes is under discussion with the European Commission. The evaluation of enzymes derived from plants and animals is on-going.

During the meeting, further questions were raised in relation to the different topics of the agenda. A question concerned the procedural follow-up of application FGE.216 Revision 2 (agenda item 8.1). In relation to agenda item 10.1.3, an observer requested clarification with regard to the legal status of the Note for Guidance[10] for food contact materials (FCM) versus the EFSA Scientific Opinion describing the recent developments in the safety assessment of substances used in FCM[11]. The latter one provides the European Commission with a scientific basis for any possible revision of Regulation 10/2011, which concerns plastic materials and articles intended to come into contact with food. In contrast, the Note for Guidance remains the right reference point for petitioners presenting an application for the safety assessment of a substance to be used in FCM. Following the information provided on the activities of the EFSA WG to develop a

[10] http://www.efsa.europa.eu/en/efsajournal/pub/21r
[11] https://www.efsa.europa.eu/en/efsajournal/pub/4357

protocol for hazard assessment for BPA (agenda item 10.3), an observer questioned the amount of work foreseen for this substance compared to other FCM substances. As a temporary TDI for BPA was set by EFSA in 2015 (which reflected the uncertainties involved), the availability of a suitable protocol would require the re-evaluation of the safety of BPA in order for a full TDI to be set. In addition, the protocol that is being developed for BPA is part of a broader, overarching, EFSA project (PROMETHEUS)[12], which has the objective of developing new methodologies for risk assessment. In this context, the BPA hazard assessment protocol would be one of the case studies. Another question related to the definitions of EFSA Scientific Outputs and Supporting Publications, which can be retrieved from the Authority's webpage.

13. Any Other Business

There was no other business.

The Chair closed the open session by thanking the participants and the observers for their attention and contribution.

[12] https://www.efsa.europa.eu/en/efsajournal/pub/4121

CLOSED SESSION

1 December 2016, 08:30-16:00

Items under point 14 and 15 are closed to Observers due to confidential business information/proprietary data

14. Scientific outputs submitted for discussion and/or possible adoption

14.1 Evaluation of Tungsten Oxide (EFSA-Q-2014-00726)

The draft opinion on the safety evaluation of Tungsten Oxide 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

14.2 Evaluation of Isooctadecanamide (EFSA-Q-2014-00651)

The draft opinion on the safety evaluation of Isooctadecanamide 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 identified the need for some revisions of the opinion before it can be adopted at the next plenary meeting.

15. Other scientific topics for information and/or discussion

15.1 Dietary exposure for the β-amylase from soybean whey (EFSA-Q-2016-00085)

Upon request from the WG on Enzymes, the CEF Panel discussed the exposure assessment of the opinion on the safety evaluation of β-amylase food enzyme obtained from soybean whey. The exposure section of the draft opinion will be further elaborated by the WG following the recommendations from the CEF Panel.