FOOD INGREDIENTS AND PACKAGING UNIT

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

MINUTES OF THE 11TH PLENARY MEETING

Held on 10-12 December 2019

Meeting open for Observers
(Open session: 10 December 2019, 14:00-17:30h)

(Agreed by written procedure on 10 January 2020)[1]

Participants

- Panel Members:

  José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli[2], Riccardo Crebelli, Konrad Grob[3], Evgenia Lampi, Alicja Mortensen, Gilles Rivière[4], Vittorio Silano (Chair), Inger-Lise Steffensen, Christina Tlustos[5], Henk van Loveren[6], Laurence Vernis[7] and Holger Zorn

- European Commission and/or Member States representatives:

  DG SANTE: Catherine Evrevin and J. Briggs have participated via web-conference

- EFSA:

  Food Ingredients and Packaging (FIP) Unit: Claudia Roncancio Peña, Jaime Aguilera, Magdalena Andryszkiewicz, Eric Barthélémy, Anna Federica Castoldi, Consuelo Civitella, Cristina Croera, Ana Gomes, Natalia Kovalkovicova, Alexandros Lioupis, Yi Liu, Simone Lunardi, Joaquim Manuel Maia, Irene Nuin, Foteini Pantazi and Sandra Rainieri

- Observers:

  Attending via web-streaming:

  Bas Verhagen (Puratos), Ralf Eisert (BASF SE), Ana Paula Fedel (Vitopel do Brasil), Giovanna Soviero (Consultant), Aurora Bertamini (Coster Tecnologie Speciali SpA), Ana Giannini (Chemours), Sidsel Dyekjær (CHEM Trust), Manon Ombredane (Keller and Heckman LLP), Riccardo Soldesti (Università di Parma – Student), Stefanie Geiser (EAS Strategies), Mark Vints (Amcor), Monica Opole (Senior Consultant), Michela Mastrantonio (Cefic- European Plasticisers),

1 Adopted by written procedure
2 Apologised the 1st and 2nd day AM, by TC the 2nd day PM
3 Apologised the 3rd day.
4 By TC.
5 By TC
6 Apologised the 1st day
7 By TC

Rainer Otter (BASF SE), Ajay Pawar (Kanashi Biotech Pvt Ltd), Tobias Eltze (BASF SE), Bellagha Amina (Rimasse), Mercedes Garcia (Eroski s Coop), Alexander Majer (Burson Cohn & Wolfe), Flavia De Marta (Elanco), Susanna Andersson (RISE AB/Normpack), Elisa Beneventi (BfR), Nigel Sarginson (ExxonMobil Chemical Europe Inc), Amel Alliouche (Banque), Sofiya Shopova (BfR-EU-FORA - fellowship), Cristina Colciar (University of Agricultural Sciences and Veterinary Medicine, Cluj-Napoca), Aberl Jackson Deule (Tanzania Medicines and Medical Devices Authority), Johan Nouwen (ECHA), Irantzu Garmendia (Cefic), Michel Cassart (Plasticseurope), Kacper Wróbel, Kürşat Sütçü (The Ministry of Agriculture and Forestry), Ana Laur (Moldova's National Food Safety Agency) and Victoria-Eliza Chirnitchi (PlasticsEurope)

OPEN SESSION

1. Welcome and apologies for absence

The Chair welcomed the participants in the meeting. Apologies were received from David Gott for the entire plenary, from H. van Loveren for the 1st day, from K. Grob for the 3rd day and from Pier Sandro Cocconcelli for the 1st day and the morning of the 2nd day.

2. Guidelines for observers attending the open session

The Scientific Panel coordinator introduced 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 meeting. Observers were also informed that the Chair would grant opportunity for additional questions at the end of each discussion topic.

3. Adoption of agenda

The agenda was adopted without changes.

4. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence[8] and the Decision of the Executive Director on Competing Interest Management[9], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

5. Agreement of the minutes of the 10th Plenary meeting held on 23-24 October 2019, Parma

[8] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[9] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The minutes of the 10th Plenary meeting held on 23-24 October 2019 were agreed by written procedure on 8th November 2019[10].

6. Report on written procedures since 10th Plenary meeting

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

7. Scientific topic(s) for discussion

7.1. Process specific technical data used in exposure assessment of food enzyme – 2019 update (EFSA-Q-2018-00585)

The updated version of the document entitled "Process specific technical data used in exposure assessment of food enzyme was presented to the members of the CEP Panel together with the main points for discussion. More food processes were added in 2019, together with a FEIM-cereal calculator for open access. The CEP Panel discussed the document and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7.2. Specific Migration Limits (SML) for substances used in plastic Food Contact Materials (FCM) – Review (EFSA-Q-2019-00150)

The review of substances used in plastic FCM without specific migration limit (SML), including the methodology and criteria applied to assign substances into low, medium and high priority groups, was presented to the Panel for discussion and feedback. EFSA is requested to identify those substances for which an SML would be necessary, grouping them in high, medium and low priority, which will serve as the basis for future re-evaluation of individual substances. The use of existing knowledge on the chemistry and toxicology of these substances is needed for the priority setting and therefore the task includes searches in relevant public databases, Union lists and the use of predictive tools. The draft opinion will be elaborated by the WG following the recommendations from the Panel.

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

8.1 Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

All the items discussed during the Plenary Scientific Committee held in Parma on 4-5 December 2019 were synthetically addressed by the Chair of the Panel.

8.2 Scientific Committee and Scientific Panel(s) including their Working Groups

8.2.1 CEP WG on Enzymes

No additional issues were brought to the attention of the CEP Panel further to what is already recorded in the minutes of the WG.

[10] http://www.efsa.europa.eu/sites/default/files/event/190205-m.pdf

8.2.2 CEP WG on Food Contact Materials

No additional issues were brought to the attention of the CEP Panel further to what is already recorded in the minutes of the WG.

8.2.3 CEP WG on Recycling Plastic

No additional issues were brought to the attention of the CEP Panel further to what is already recorded in the minutes of the WG.

8.2.4 CEP WG on BPA re-evaluation

No additional issues were brought to the attention of the CEP Panel further to what is already recorded in the minutes of the WG.

8.2.5 EFSA WG on BPS

EFSA provided an update on the work of the Bisphenol S WG, a work done in collaboration with the European Chemicals Agency (ECHA) and the Belgian Competent Authority under REACH.

Bisphenol S is in fact regulated in the EU under different regulatory frameworks and evaluated by different authorities. Therefore, EFSA, ECHA and the Belgian Competent Authority under REACH established a coordination group to align the evaluation of the new studies generated under REACH. Aim of this coordination group is to promote inter agencies and Member States cooperation avoiding duplication of work and possible divergent opinions.

Therefore, following the submission of new toxicological studies (an Extended One Generation Reproductive Toxicity Study and a Toxicokinetic study) under REACH, the European Commission sent a mandate to EFSA to assess these new studies and if this new data affects the current authorization of Bisphenol S as Food Contact Material. An *ad hoc* Working Group was then established, and it is now preparing a Scientific Technical Report which is planned to be discussed in the CEP Panel meeting in the first quarter of 2020.

8.2.6 Feedback from the Scientific Committee

8.3 EFSA including its Working Groups/Task Forces

JECFA is conducting a public consultation on the evaluation of enzyme preparations used in foods, until 31 January 2020.

8.4 European Commission

No feedback provided.

8.5 Questions from and answers to Observers (in application of the guidelines for Observers)

The Chair opened the floor to any additional question from the observers attending the meeting. The Scientific Panel coordinator presented the questions received in advance to the current plenary and provided answers.

- In relation to agenda item 7.2, the following notes and questions were received from Sidsel Dyekjær (CHEM Trust): (a) Beware that ECHA may characterise substances as "of no concern" because it does not look at FCM (higher exposure possible). (b) Did you look at neurotox/immunotox effects?

(c) How do you define endocrine disruptors? (d) Will this work be published? Very interesting presentation.

The Panel responded as follows: (a) The comment on ECHA evaluations and their applicability to FCM substances will be considered. (b) The substances listed for prioritisation were checked against the OpenFoodTox database of EFSA and no neurotoxic/immunotoxic effects were found. (c) The observer was directed to the "Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009", https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5311 for details on endocrine disruptor identification and definitions. It was noted that within the context of the current prioritisation exercise, the ECHA database was searched for evaluations of possible endocrine disruptor properties, as these are applied by ECHA. (d) Once finalised and adopted by the Panel, the opinion will be published (foreseen for April 2020).

- In relation to EFSA's update of the risk assessment of five phthalates for use in plastic food contact materials[11], the following notes and questions were received from Nigel Sarginson (ExxonMobil Chemical Europe Inc):

  (a) How does EFSA ensure that the full robust weight of evidence scientific data and interpretation is included in its opinions and scientific reports? How does EFSA ensure consistency and coherence with the opinions of other EU agencies e.g. ECHA? Significant concerns were raised by the draft phthalates opinion with respect to these two aspects. Have these points been addressed in the final opinion? I did submit questions on the key topics of how does EFSA ensure the full robust weight of evidence of scientific data is incorporated into EFSA opinions - I note that the final opinion still states that weight of evidence and comprehensive review were not possible due to the ToR and time limitations. The final opinion also points to the opinion being "temporary" due to the limitations of the mandate and the uncertainties. Can it then be concluded this opinion should not be the basis for any regulatory action? And that further scientific review is needed?

  The Panel responded as follows: As stated in the opinion, the assessment is considered as temporary due to limited scope of the mandate and the uncertainties identified. Nonetheless, the outcome of the present assessment is more protective for human health as compared to the past EFSA evaluations as it considers the possible cocktail effect of substances acting on the same target and by the same mechanism. Therefore, a group TDI, though temporary, has been proposed as opposed to individual TDIs.
  Whether this opinion will be used for regulatory actions is a question for the European Commission (EC) rather than for EFSA.
  The EC will send EFSA a more comprehensive mandate to address the areas of uncertainties.

  (b) How does EFSA ensure consistency and coherence with the opinions of other EU agencies e.g. ECHA? On the question of consistency and coherence - what is the basis for NOT following the ECHA opinion on DINP

[11] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5838

which was a robust weight of evidence assessment conducted over 3 years, and which concluded that DINP is very different to DEHP, DBP and BBP with respect to reproductive effects, and that changes in testosterone were reversible and did not lead to adverse effects.

The Panel responded as follows: There was engagement of the European Chemicals Agency (ECHA) throughout the evaluation process. Two ECHA scientific officers actively participated in the meetings of the Phthalates Working Group and of the CEP Panel along our risk assessment process.
The data considered in two ECHA opinions were the main source of data for EFSA's opinion.
EFSA and ECHA work under different regulatory frameworks and specifically the opinion of ECHA on DINP aimed at the classification of the substance which is hazard-based as opposed to EFSA performing risk assessment and putting the risk of the substance in the context of co-exposure to other substances during vulnerable periods of development. The classification process is a binary process, either a substance is classified or not classified, based on its intrinsic properties and independent of the exposure.
The EFSA CEP Panel acknowledged in its opinion the ECHA's RAC (2018) conclusion that no classification of DINP is warranted either for effects on sexual function and fertility or for developmental toxicity. ECHA, like EFSA, reported some transient effects of DINP on the reproductive system (e.g. reduction of testosterone content or production in pup testes). These effects were not leading to a permanent adverse outcome and as such they were deemed not sufficient to trigger the classification of DINP as reproductive toxicant.
EFSA noted that DINP's transient effect on fetal testosterone production could not be ignored in a risk assessment scenario considering co-exposure to DINP and Repro 1B-classified phthalates (DBP, BBP, DEHP, which act via the same mechanism) during sensitive windows of susceptibility. Therefore, the CEP Panel decided to group DBP, BBP, DEHP and DINP into a temporary group-TDI based on similar reproductive effects, i.e. reduction of fetal testosterone.
These perceived differences with respect to DINP toxicological assessment are thus a reflection of the different regulatory contexts of ECHA's classification as opposed to EFSA's cumulative risk assessment.
Last but not least, ECHA has agreed with EFSA on the absence of diverging views prior to the publication of EFSA opinion.

(c) EFSA concludes that exposures to DEHP, DBP and BBP (as well as DINP and DIDP) from food are well within the TDI. Yet ECHA concluded that exposures to DEHP, DBP, BBP (and also DIBP) were above the DNEL (TDI equivalent) and hence ECHA recommended broad restrictions on DEHP, DBP, BBP and DIBP which were accepted by the European Commission. Does the final EFSA opinion address this lack of consistency and coherence? Just to add these significant issues of consistency and coherence create significant uncertainty and lack of a stability for further development (and investment) in substances in the EU - also creates uncertainties for other stakeholders and consumers - this is why it is so important! Does the final EFSA phthalates opinion explain why there these differences in conclusions with ECHA re: grouping of DINP / safety of the SVHC phthalates DEHP, DBP, BBP and DIBP?

Just to add that for the ECHA restrictions food was a significant source of exposure to DEHP, DBP, BBP (and DIBP).

The Panel responded as follows: ECHA and EFSA considered different sets of substances and different sources of exposure. Thus, the presumed inconsistency can be explained by these two main factors.
As regards the exposure to DEHP, BBP, DBP and DIBP, ECHA based its assessment on human biomonitoring data covering all sources of exposure. On this basis, it concluded that there is a health risk for the European population.
EFSA's exposure assessment instead focused on a different set of phthalates (DEHP, BBP, DBP, DINP and DIDP) and on the dietary route only. Based on this scenario, EFSA concluded that the exposure of consumers is below the temporary group-TDI for DEHP, BBP, DBP and DINP and the individual TDI for DIDP.
Explanations of the work of EFSA and ECHA are provided in the opinion.
Concerning food as a source of exposure, the CEP Panel considers that these estimates of dietary exposure for the individual phthalates are quite well aligned with the published estimates that used different approaches (Total Diet Studies (TDS) for the UK, Ireland and France) and are consistent with the estimates for the individual phthalates reported by ECHA.

No other general questions were raised by the observers, in addition to some clarifications on the points discussed during the open session of the plenary.

8.6 New Mandates

8.6.1 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 one for the safety assessment of enzymes.

Food Sector	EFSA-Q-Number	Subject	Reception date
FCM	EFSA-Q-2019-00648	Request for safety evaluation of the Veolia recycling process (Starlinger iV+)to produce recycled plastic for food contact uses	11/10/2019
ENZ	EFSA-Q-2019-00639	Request for EFSA to perform a scientific risk assessment on the food enzyme phospholipase A1 produced by a genetically modified strain of *Aspergillus niger* (strain NZYM-FP)	07/10/2019
FCM	EFSA-Q-2019-00631	Request for the safety evaluation of Sodium percarbonate (14,9%)on active and intelligent materials	04/10/2019

8.6.2 Valid questions since the previous meeting

The following question have been considered valid for the start of the assessment since the last Plenary meeting.

Food Sector	EFSA-Q-Number	Subject	Reception date
FCM	EFSA-Q-2019-00390	Application for authorisation of 2-hydroxyethyl methacrylate phosphate as a monomer for use in the manufacture of plastic food contact materials and articles	09/10/2019

8.6.3 Withdrawn questions since the previous meeting

Food Sector	EFSA-Q-Number	Subject	withdrawn on

None

8.7 Other scientific topics for information and/or discussion

None

CLOSED SESSION

7.3. Request for EFSA to perform a scientific risk assessment on the food enzyme: Glucan 1,4-alpha-maltohydrolase from a genetically modified strain of *Bacillus licheniformis* (DP-Dzr50) (EFSA-Q-2016-00096)

The draft opinion on the food enzyme: Glucan 1,4-alpha-maltohydrolase from a genetically modified strain of *Bacillus licheniformis* (DP-Dzr50) was presented to the members of the CEP Panel together with the main points for discussion. The CEP Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7.4. Request for EFSA to perform a scientific risk assessment on a food enzyme: endo-1,4-beta-xylanase from *D. dimorphosporum* (DXL) (EFSA-Q-2014-00355/356)

The draft opinion on the food enzyme: endo-1,4-beta-xylanase from *D. dimorphosporum* (DXL) was presented to the members of the CEP Panel together with the main points for discussion. The CEP Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7.5. Request for EFSA to perform a scientific risk assessment on a food enzyme: endo 1,4-beta xylanase from a genetically modified strain of *A. acidus* (RF 7398) (EFSA-Q-2014-00165)

The draft opinion on the food enzyme: endo 1,4-beta xylanase from a genetically modified strain of *A. acidus* (RF 7398) was presented to the members of the CEP Panel together with the main points for discussion. The CEP Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7.6. Request for EFSA to perform a scientific risk assessment on a food enzyme: Xylanase from a genetically modified strain of *T. reesei* (RF5703) (EFSA-Q-2014-00410)

The draft opinion on the food enzyme: Xylanase from a genetically modified strain of *T. reesei* (RF5703) was presented to the members of the CEP Panel together with the main points for discussion. The CEP Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7.7. Request for EFSA to perform a scientific risk assessment on the food enzyme: Amylase from *B. amyloquefaciens* (strain BANSC) (EFSA-Q-2014-00730)

The draft opinion on the food enzyme: Amylase from *B. amyloquefaciens* (strain BANSC) was presented to the members of the CEP Panel together with the main points for discussion. The CEP Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7.8. Request for EFSA to perform a scientific risk assessment on the food enzyme: Glucan 1,4-alpha-maltohydrolase from a genetically modified strain of *Bacillus licheniformis* (DP-Dzr50) (EFSA-Q-2016-00096)

The draft opinion on the food enzyme: Glucan 1,4-alpha-maltohydrolase from a genetically modified strain of *Bacillus licheniformis* (DP-Dzr50) was presented to the members of the CEP Panel together with the main points for discussion. The CEP Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7.9. Request for EFSA to perform a scientific risk assessment on the food enzymes: *Beta-galactosidase* from a genetically modified strain of *Escherichia coli* (BglA MCB3) (EFSA-Q-2015-00622)

The draft opinion on the food enzyme: Beta-galactosidase from a genetically modified strain of *Escherichia coli* (BglA MCB3) was presented to the members of the CEP Panel together with the main points for discussion. The CEP Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

7.10. Request for safety evaluation of Bis(2-ethylhexyl)-cyclohexane-1,4-dicarboxylate, CAS-Nr.:84731-70-4, for its use as additive in plastics (Hanwha chemical) (EFSA-Q-2018-00549)

The draft opinion on food contact material: Bis(2-ethylhexyl)-cyclohexane-1,4-dicarboxylate, CAS-Nr.:84731-70-4, for its use as additive in plastics (Hanwha chemical) was presented to the members of the CEP Panel together with the main points for discussion. The CEP Panel discussed the different parts of the risk assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

9. Any Other business

None