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

## Minutes of the 3rd Plenary meeting

**Held on 23-25 October 2018, Parma (Italy)**

**Meeting open to Observers**

**(Open session: 24 October 2018, 14:00-18:00;**

**25 October 2018, 09:00-13:00)**

**(Agreed on 16/11/2018)**[1]

### Participants

**a) Panel Members**

José Manuel Barat Baviera, Claudia Bolognesi, Beat Johannes Brüschweiler, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Gott[2], Konrad Grob, Evgenia Lampi, Alicja Mortensen, Gilles Rivière, Vittorio Silano (Chair), Inger-Lise Steffensen, Christina Tlustos, Henk van Loveren and Holger Zorn[3]

**b) Hearing Experts[4]:**

- Laurence Castle (for agenda item 10.1); Panagiotis Skandamis[2] (for agenda item 9.1)

**c) European Commission and/or Member States representatives:**

- DG SANTE: Verena Haider[2] (for agenda item 9.1)

**d) EFSA:**

- Food Ingredients and Packaging (FIP) Unit: Jaime Aguilera, Magdalena Andryszkiewicz, Giovanni Bernasconi, Julia Cara Carmona, Anna Federica Castoldi, Ana Gomes, Christine Horn, Natalia Kovalkovicova, Alexandros Lioupis, Yi Liu, Joaquim Manuel Maia, Carla Martino, Claudia Roncancio Peña, Ellen Van Haver, Giorgia Vianello, Katharina Volk
- DATA Unit: Davide Arcella; Claudia Cascio
- BIOCONTAM Unit: Winy Messens

[1] Adopted by written procedure
[2] Attended by teleconference
[3] Not present on 23 October 2018
[4] 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

**e) Observers[5] (in brackets affiliation):**

- Attending physically in Parma: Nigel Sarginson (ExxonMobil Chemical Inc.)
- Attending via webstreaming: Estefania Boix (Keller and Heckman LLP), Ronan Cariou (LABERCA-Oniris), Judith Eisinger (Università di Bologna), Stefanie Geiser (EAS Strategies), Hanna Gustafsson (Perstorp AB), Jennifer Hirter (PMI), Rita Piedade (DuPont), Maarten Roggeman (ECHA), Kate Trollope (EU Food Policy)

**CLOSED SESSION**

**23 October 2018, 13:30-18:00**

**24 October 2018, 09:00-13:00**

Items under point 6 were closed to Observers due to confidential business information/proprietary data

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Panel member Laurence Vernis.

## 2. Adoption of agenda

The agenda was adopted without any changes.

## 3. Declarations of Interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[6] and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declarations of Interest[7]. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting when asking for Oral Declarations of Interest.

## 4. Agreement of the minutes of the 2nd Plenary meeting held on 26-27 September 2018, Brussels

The minutes of the 2nd Plenary meeting held on 26-27 September were agreed on 15 October 2018 by written procedure[8].

## 5. Report on written procedures since the 2nd Plenary meeting

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

[5] http://www.efsa.europa.eu/en/stakeholders/observers
[6] http://www.efsa.europa.eu/en/corporate/pub/policyonindependence
[7] http://www.efsa.europa.eu/en/corporate/pub/independencepolicy17
[8] http://www.efsa.europa.eu/en/events/event/180926-2

## 6. Scientific outputs submitted for discussion and possible adoption

### 6.1 Acetolactate decarboxylase from a genetically modified strain of *Bacillus licheniformis* (NZYM-JB) (EFSA-Q-2016-00031)

The draft opinion on the safety evaluation of the food enzyme acetolactate decarboxylase from a genetically modified strain of *Bacillus licheniformis* (NZYM-JB) 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.

### 6.2 Maltogenic amylase from a genetically modified strain of *Bacillus subtilis* (NZYM-OC) (EFSA-Q-2014-00922)

The draft opinion on the safety evaluation of the food enzyme maltogenic amylase from a genetically modified strain of *Bacillus subtilis* (NZYM-OC) 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.

### 6.3 Maltogenic amylase from a genetically modified strain of *Bacillus subtilis* (NZYM-SO) (EFSA-Q-2015-00046)

The draft opinion on the safety evaluation of the food enzyme maltogenic amylase from a genetically modified strain of *Bacillus subtilis* (NZYM-SO) 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.

### 6.4 Xylanase from a genetically modified strain of *Aspergillus oryzae* (NZYM-FA) (EFSA-Q-2013-00789)

The draft opinion on the safety evaluation of the food enzyme xylanase from a genetically modified strain of *Aspergillus oryzae* (NZYM-FA) 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.

### 6.5 Endo-1,4-beta-xylanase from a genetically modified strain of *Trichoderma reesei* (DP-Nzd22) (EFSA-Q-2014-00667)

The draft opinion on the safety evaluation of the food enzyme endo-1,4-beta-xylanase from a genetically modified strain of *Trichoderma reesei* (DP-Nzd22) 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.

### 6.6 RecyPET Hungaria recycling process (EFSA-Q-2017-00092)

The draft opinion on the safety evaluation of the RecyPET Hungaria recycling process for polyethylene terephthalate (PET) 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.

**OPEN SESSION**

**24 October 2018, 14:00-18:00**

**25 October 2018, 09:00-13:00**

## 7. Welcome and 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.

## 8. Presentation of the EFSA Guidelines for Observers[9]

The rules for observers to be followed during and after the open plenary meeting were presented. Observers were able to send questions along their registration and were given the opportunity for raising additional questions at the end of each discussion topic.

## 9. Scientific outputs submitted for discussion and possible adoption

### 9.1 Evaluation of the safety and efficacy of lactic and acetic acids to reduce microbiological surface contamination on pork carcasses and pork cuts (EFSA-Q-2017-00666)

In accordance with Art 29 of Regulation (EC) No 178/2002, the EC asked EFSA to evaluate the safety and the efficacy of lactic and acetic acids intended to be used individually by food business operators during the processing to reduce microbial surface contamination on pork carcasses and cuts. The Chair of the Working Group (WG) on the evaluation of substances used to reduce microbial contamination from products of animal origin, Alicja Mortensen, presented the assessment related to the toxicological safety of the two organic acids and the risk related to their release into the environment, whereas the vice-Chair, Panagiotis Skandamis, presented the assessment endorsed by the BIOHAZ Panel regarding the efficacy of lactic and acetic acids treatments and the potential emergence of reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials linked to the use of these organic acids.
The CEP Panel discussed the different parts of the risk assessment and concluded that there is enough evidence to show that lactic and acetic acids and their possible uses as decontaminants are safe for human health and for the environment, and that they do not promote horizontally transferable reduced susceptibility to lactic or acetic acid or resistance to therapeutic antimicrobials. Regarding the efficacy assessment, the Panel concluded that:

a) for lactic acid the efficacy could only be demonstrated in the following conditions: i) spraying of pork carcasses when compared to untreated controls; ii) dipping of pork meat cuts when compared to water treatment. On the other hand, the Panel could not conclude whether lactic acid was more efficacious than water treatment when spraying pork carcasses and/or pork meat cuts.

[9] https://www.efsa.europa.eu/sites/default/files/observersguidelines.pdf

b) for acetic acid, due to the limited available data, the Panel could not conclude on the efficacy of acetic acid treatments of pork carcasses and/or pork meat cuts.

Regarding the assessed uses, the Panel stressed the need to adhere to good hygiene practices and hazard control measures – a recommendation that actually applies to each step of the food chain. The Panel unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

## 10. Other scientific topics for information and/or discussion

### 10.1 Update of the risk assessment for di-butylphthalate (DBP, FCM No 157), butyl-benzyl-phthalate (BBP, FCM No 159), bis(2-ethylhexyl)phthalate (DEHP, FCM No 283), di-isononylphthalate (DINP, FCM No 728) and di-isodecylphthalate (DIDP, FCM No 729) (EFSA-Q-2017-00588/-00589/-00590; EFSA-Q-2018-00800/-00801)

The Chair of the WG on phthalates, Laurence Castle, presented to the Panel members the progress made by the WG on the re-evaluation of the safety of five phthalates (DBP, BBP, DEHP, DINP and DIDP) authorised for use in plastic food contact materials (FCMs). This mandate from the European Commission follows the publication in 2017 of an opinion of the European Chemicals Agency (ECHA) on DBP, BBP, DEHP, along with DIBP, which is however not authorised for use in plastic FCM, in the context of a restriction dossier under Annex XV of the REACH Regulation. EFSA's re-evaluation should determine whether, based on the data package used by ECHA, the opinion and the authorisation of DBP, BBP and DEHP under Regulation (EU) No 10/2011 are still in accordance with the FCM regulation. Two other phthalates (DINP and DIDP), which were not addressed in the ECHA assessment of 2017 but were assessed by EFSA back in 2005, have been included in the mandate as well, as they are also authorised for use in plastic FCMs.

The Panel discussed aspects of the toxicological assessment as well as the exposure assessment carried out so far by the WG, in collaboration with the EFSA's DATA Unit. The Panel noted the complexity of the combined assessment of the different phthalates, both in terms of toxicology and exposure. The Panel's discussion focused on the possibility of grouping some of these phthalates under a group TDI, and on the approach for the exposure assessment and its related limitations. These issues will be further addressed by the WG at its next meeting. The Panel and the observers were also informed that once revised and endorsed by the Panel, the opinion will undergo public consultation.

## 11. New Mandates

### 11.1 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.

| Food Sector | EFSA-Q-Number | Subject | Reception date |
|---|---|---|---|
| FCM | EFSA-Q-2018-00811 | Request for safety evaluation of Poly Recycling AG recycling process (Starlinger PET direct iV+) to produce recycled plastic for food contact uses | 18/10/2018 |
| FCM | EFSA-Q-2018-00768 | Request for safety evaluation of Veolia Beteilingungsgesellschaft mbH recycling process (URRC) | 08/10/2018 |

### 11.2 Valid questions since the previous meeting

The following questions have been considered valid for the start of the assessment since the last Plenary meeting: three for the safety assessment of food contact materials.

| Food Sector | EFSA-Q-Number | Subject | Valid on |
|---|---|---|---|
| FCM | EFSA-Q-2018-00549 | 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) | 12/10/2018 |
| FCM | EFSA-Q-2018-00529 | Request for safety evaluation of Jász-Plasztik Kft recycling process (Vacurema prime technology) | 09/10/2018 |
| 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 | 27/09/2018 |

### 11.3 Withdrawn applications since the previous meeting

Two applications for the safety assessment of food enzymes have been withdrawn since the last Plenary meeting.

| Food Sector | EFSA-Q-Number | Subject | withdrawn on |
|---|---|---|---|
| ENZ | EFSA-Q-2015-00562 | Request for EFSA to perform a scientific risk assessment on the food enzyme: Endo-1,3(4)-beta-glucanase from a genetically modified strain of *Bacillus subtilis* (CBS 613.94) | 04/10/2018 |
| ENZ | EFSA-Q-2014-00202 | 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. niger* (CBS 612.94) | 25/09/2018 |

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

### 12.1 Scientific Committee and Scientific Panel including their Working Groups

#### 12.1.1 Scientific Committee and its Working Groups

There hasn't been a Scientific Committee meeting since the last Plenary meeting.

#### 12.1.2 CEP Working Groups

The Chairs of the respective CEP WGs (BPA re-evaluation; Decontamination substances; Food Enzymes; Food Contact Materials; Phthalates; and Recycling Plastics) informed the Panel members and the observers about the latest developments, the possible challenges the WG might be facing, and where relevant, the number of ongoing applications under evaluation.

The minutes of the last WG meetings are published on the EFSA website.

## 13. Answers to questions from Observers (in application of the EFSA Guidelines for Observers)

In relation to agenda item 10.1, the following question was received from Nigel Sarginson (ExxonMobil Chemical Inc.) in advance to the meeting:

- With respect to the risk assessment of the phthalates (DBP, BBP and DEHP) what is the status on the assessment of the two substances which were added via an updated mandate in May 2018, namely DINP and DIDP? More specifically will the opinion on DINP from March 2018 of the Risk Assessment Committee (RAC) of the ECHA, concluding no CLP classification required based on the lack of any significant adverse reproductive effects in animal studies be taken into account in the assessment? Similarly will the data on DIDP showing a lack of any significant adverse reproductive effects be taken into account? Is it still proposed to have the same deadline for DINP and DIDP as for DEHP, DBP and BBP, and will there be a commenting period?

It was clarified that the WG on phthalates is aware of the ECHA RAC opinion on DINP of March 2018. Still, some discussion is needed at the WG level as regard to which of the five substances under evaluation should be included in a possible group-TDI based on common toxicological target, e.g. the reproductive system. Once the opinion is revised and endorsed by the Panel, it will be published for public consultation. Following this step, the opinion will be further revised according to the comments, if applicable, and then brought back to the Panel for adoption. The final output will contain the assessment of all five phthalates.

The observer provided some comments on the 2018 ECHA RAC opinion on DINP, summarising the main considerations that led to the overall conclusion that classification for DINP was neither warranted for effects on sexual function and fertility, nor for developmental toxicity. During the discussion on the approach for exposure assessment, the observer made reference to a paper by Koch et al. (2016) in which intake estimates of certain phthalates were studied. He commented on the declining trend observed for the intake of phthalates, which is expected to further decrease once further restrictions in use will come into place. EFSA replied that this article is part of the same data package used for developing the ECHA RAC opinion on DBP, BBP, DEHP and DIBP (2017), and therefore its findings are being taken in due consideration in the current EFSA safety re-evaluation.

The Chair asked whether additional questions were raised by the observers attending the meeting remotely. There were no additional questions.

## 14. 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 contributions.