FOOD INGREDIENTS AND PACKAGING UNIT

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

MINUTES OF THE 13TH PLENARY MEETING

Held on 28-30 April 2020

Meeting open for Observers
(Open session: 28 April 2020, 14:00-17:30)

(Agreed by written procedure on 20 May 2020)[1]

Participants

- Panel Members:

  José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Gott, Konrad Grob, Claude Lambré, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Vittorio Silano (Chair), Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis and Holger Zorn

- European Commission and/or Member States representatives:

  DG SANTE: Greta Borg, Catherine Evrevin, Bastiaan Schupp and Jonathan Briggs

- EFSA:

  Food Ingredients and Packaging (FIP) Unit: Claudia Roncancio Peña, Jaime Aguilera, Magdalena Andryszkiewicz, Eric Barthélémy, Anna Federica Castoldi, Consuelo Civitella, Cristina Croera, Fatima Den Ouden, Ana Gomes, Natalia Kovalkovicova, Alexandros Lioupis, Yi Liu, Simone Lunardi, Joaquim Manuel Maia, Ivana Nikodinoska, Irene Nuin, Foteini Pantazi, Sandra Rainieri, Ellen Van Haver, Katharina Volk and Francesca Werner

- Observers:

  Attending via web-streaming:

  Beneventi Elisa (BfR), Carella Maria (Coop), Carnio silvia (Mérieux NutriSciences), Cassart Michel (PlasticsEurope), Chuzhakina Kateryna (State Service of Ukraine on issues on food safety and consumer protection), Demaegdt Heidi (Sciensano), Dyekjaer Sidsel (CHEM Trust), Efimova Yulia (DSM), Eisert Ralf (BASF), Geiser Stefanie (EAS Strategies), Godts Francoise (DuPont), Jacquet Mélanie (Danone), Kramer Frank (INEOS Styrolution Group GmbH), Kroesche Christoph (EVONIK Industries), Lichtblauv Alexander (Clariant), Majer Alexander (BCW), Makrantoni Vaso (University of Edinburgh) Martati Erryana (Universitas Brawijaya Indonesia), Otter Rainer (BASF SE (observer for European Plasticisers/Cefic)), Prieto Arranz Miguel Angel (Cefic), Sarginson Nigel (ExxonMobil

[1] Adopted by written procedure

Chemical Europe In), Sghedoni Valentina (UNIMORE), Steijer Hans (RISE, Research Institutes of Sweden, Normpack), Vanova Hrncirik Romana (Meatable), Verhagen Bas (AB Enzymes), Vints Mark (Amcor), Yanık Feral (Labsgate Labor Kft)

OPEN SESSION

1. Welcome and apologies for absence

The Chair welcomed the participants in the meeting. No Apologies were received.

2. Guidelines for observers attending the open session

The Head of the FIP Unit 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[2] and the Decision of the Executive Director on Competing Interest Management[3,] 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 12th Plenary meeting held on 4-6 February 2020, Parma

The minutes of the 12th Plenary meeting held on 4-6 February 2020 were agreed by written procedure on 28th February 2020[4].

6. Report on written procedures since 12th Plenary meeting

The draft opinion on the safety assessment of the substance 2-hydroxyethyl methacrylate phosphate (renamed by the Panel "phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate") for use in

[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[4] https://www.efsa.europa.eu/sites/default/files/event/2020/12th-plenary-meeting-cep-panel-minutes.pdf

the manufacture of plastic food contact materials and articles (EFSA-Q2019-00390) was unanimously endorsed at the 12th Plenary meeting, subject to incorporation of changes as suggested during the meeting. Following the written procedure, it was adopted on 22 April 2020.

7. Scientific outputs submitted for discussion and possible adoption

7.1. Review and priority setting for substances that are listed without a specific migration limit in Table 1 of Annex 1 of Regulation 10/2011 (EFSA-Q-2019-00150)

EFSA was requested by the European Commission to review and set priorities for substances that are listed without a specific migration limit (SML) in Table 1 of Annex 1 of Regulation 10/2011, to ensure the authorisation is sufficiently protective to health. EFSA is expected to group them into high, medium and low priority to serve as a basis for future re-evaluations of individual substances and also to identify those substances for which an SML should not be needed. The use of existing knowledge on the chemistry and toxicology of these substances was required and therefore public databases and Union list searches were performed, along with the use of *in silico* prediction tools. The stepwise approach followed, the criteria applied for priority setting, the information sources and tools used, and the final results of this task were presented. The CEP Panel discussed the document and unanimously adopted the opinion on the closed session, subject to the incorporation of changes as suggested during the meeting.

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

8.2. EFSA including its Working Groups /Task Forces

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.

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.

8.4 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.

In relation to item 7.1 on the review and priority setting for substances that are listed without a specific migration limit in Table 1 of Annex 1 of Regulation 10/2011 (EFSA-Q-2019-00150), the following questions were received during the Plenary and answered as follows:

- From Mélanie Jacket (Danone): "Will a similar approach be developed to prioritise re-evaluation of substances with a restriction?"

  The Panel responded that no such activity is currently planned or on-going. It is possible that similar exercises may take place in the future, following requests from the Commission. Through the present prioritisation exercise and on other occasions, the EFSA FCM team has discussed with ECHA on the ways forward for priority setting for certain chemicals or groups of chemicals and this will probably continue in the future. It was also noted that the re-evaluation of substances has not been a standard practice in the field of FCM, in contrast to other related food safety areas such as the food additives and food flavourings and therefore a review and priority setting approach may also be needed for other FCM substances in the future.

- From Sidsel Dyekjaer (ChemTrust): "You say the ECHA data on plastic additives were not useful because different from what you needed. Can you shortly say what the difference was?"

  The Panel responded that the ECHA plastic additives initiative provided a very useful overview of plastic additives and it allowed constructive discussions and comparisons between the substances used in plastics in general and those listed in the FCM Union list. However, the current EFSA opinion focused only on those FCM substances which were evaluated before EFSA was created and which did not have an SML; for only a small fraction of these substances information was available through the ECHA plastics additive overview and therefore incorporation of this data into the overall FCM prioritisation methodology did not have a substantial effect. The exposure modelling approach undertaken by ECHA is based on the same principles as FCM migration modelling, making this an approach of common interest, however additional information required for modelling was not available for the majority of the substances of the present exercise (such as the additive function or the use levels in plastic, the type of plastic and the intended food contact use).

The Scientific Panel coordinators presented the question received in advance to the current plenary as follows:

- In relation to EFSA's update of the risk assessment of five phthalates for use in plastic food contact materials, the following question was received from Nigel Sarginson (ExxonMobil Chemical Europe Inc): "what is the scope, timing, status of new mandate on phthalates?"

  The Panel responded as follows: In December 2019, EFSA published its update of risk assessment of five phthalates used in plastic food contact materials, concluding on temporary Tolerable Daily Intakes. During the Open Plenary of the CEP Panel meeting in December 2019, the European Commission announced that a follow-up mandate would be sent to EFSA, in order for the uncertainties identified to be addressed. A draft mandate is currently under discussion between EFSA and the Commission, as well as in liaison with ECHA, in order to identify synergies between both agencies' work in the area of phthalates. Once the mandate is agreed, it will become publicly available in the EFSA's register of questions.

During the Plenary, the following questions were received on the same topic and answered as follows:

- From Nigel Sarginson (ExxonMobil Chemical Europe Inc): "when is it likely to become public".

  The Panel responded as follows: The draft mandate is currently under discussion between the various involved parties, i.e. DG SANTE, ECHA and EFSA. A date, when it will become available, cannot be anticipated.

- From Alexander Majer (BCW), "Will the mandate on phthalates cover the same substances or also additional alternative terephthalates? Is it possible to comment?"

  The Panel responded as follows: The scope, timing, details on inter-agencies collaboration and other aspects of the draft mandate are still under discussion and have to be agreed between EFSA, DG SANTE and ECHA. Therefore, at the current moment, no information on number and type of substances covered within this new mandate can be anticipated. It is not foreseen to enquire views from external stakeholders on the draft mandate.

- From Rainer Otter (BASF - European Plasticisers/Cefic): "Could you please explain the proposed allocation factor of 20% for phthalates"

  The Panel responded as follows: The opinion published in December 2019 reported the allocation factors, as currently set out for the some of the phthalates in Regulation (EU) No 10/2011. No specific recommendation was expressed on changing the allocation factors. In general, the question of whether to introduce allocations factors falls within the remit of risk managers (European Commission), who may decide on the need (or not) of these factors based on information provided in EFSA's scientific opinion or other aspects considered relevant.

EFSA gave feedback on the status of the mandate received from the EC for re-assessing the safety of styrene for use in food contact materials (EFSA-Q-2019-00686) following the new information that became available after the publication of the Monograph of the International Agency for Research on Cancer (IARC). In accordance with Article 12(3) of Regulation (EC) No 1935/2004, the EC asks EFSA to evaluate whether the authorisation of styrene (FCM 193) is still in accordance with the requirements of Reg. (EC) No 1935/2004. The FCM WG, in cooperation with the cross-cutting EFSA WG on Genotoxicity, is currently reviewing the IARC Monograph and the information available in the Technical dossier that was provided by a consortium of industry operators under the auspices of PlasticsEurope. The opinion is foreseen to be scheduled for possible adoption by the CEP Panel at their Plenary meeting in September 2020.

No other general questions were raised by the observers.

CLOSED SESSION

8.1 Scientific Panel(s) including their Working Groups

All the items discussed during the last two Plenaries of the Scientific Committee held in Parma on 18-20 February 2020 and 22-23 April 2020 were synthetically addressed by the Chair of the Panel.

8.3. European Commission

Nothing was reported.

9. Scientific outputs submitted for discussion and possible adoption

9.1 Food contact substance di(m-2,2',2''-nitrilotris(ethanol)-diperchlorato)dinatrium (EFSA-Q-2017-00444)

At its previous plenary meeting held in February 2020, the CEP Panel had adopted the scientific opinion on the safety assessment of the substance: di(m-2,2',2''-nitrilotris(ethanol)-diperchlorato)dinatrium (renamed by the Panel "(triethanolamine-perchlorate, sodium salt) dimer") for use in the manufacture of food contact materials.

During the preparation of the scientific output for publication EFSA became aware of an incorrect numerical value for the use levels of the substance in the final product and in the samples tested for migration, that was included in the dossier submitted. In accordance with the applicable EFSA SOP 12, the publication of the adopted scientific opinion was put on hold, and the opinion was included in the agenda of the current plenary meeting. At the current meeting, the Panel has withdrawn the scientific opinion previously adopted on 5 February 2020 and discussed the new text related to the assessment and to the conclusions. The Panel agreed with the revised dataset and updated the relevant text of the scientific opinion, also including an explanation for the changes made. The revised scientific opinion was discussed at the current plenary meeting and was unanimously adopted by the CEP Panel on 29 April 2020.

9.2 Food enzyme cyclomaltodextrin glucanotransferase from P*aenibacillus illinoisenis* strain 107 (EFSA-Q-2016-00523)

At its previous plenary meeting held in February 2020, the CEP Panel had adopted the scientific opinion on the safety assessment of the food enzyme cyclomaltodextrin glucanotransferase from Paenibacillus illinoisenis strain 107 for use in starch processing for trehalose production.

During the preparation of the scientific output for publication, EFSA became aware of an incorrect method used for detection of Escherichia coli in the food enzyme, that was included in the dossier submitted. In accordance with the applicable EFSA SOP 12, the publication of the adopted scientific opinion was put on hold, and the opinion was included in the agenda of the current plenary meeting. At the current meeting, the Panel has withdrawn the scientific opinion previously adopted on 4 February 2020 and discussed the new text related to the assessment. The Panel agreed with the revised dataset and updated the relevant text of the scientific opinion, also including an explanation for the changes made. The revised scientific opinion was discussed at the current plenary meeting and was unanimously adopted by the CEP Panel on 29 April 2020.

9.3 Food enzyme 4-α-D-{(1→4)α-D-glucano} trehalose trehalohydrolase/(1→4)-α-D-glucan 1-α-D-glucosylmutase from *Arthrobacter ramosus* (EFSA-Q-2016-00135/136)

At its previous plenary meeting held in February 2020, the CEP Panel had adopted the scientific opinion on the safety assessment of the food enzyme with 4-α-D-{(1→4)α-D-glucano} trehalose trehalohydrolase and (1→4)-α-D-glucan 1-α-D-glucosylmutase activity from Gryllotalpicola ginsengisoli strain S34, initially identified as Arthrobacter ramosus.

During the preparation of the scientific output for publication EFSA became aware of an incorrect numerical value for the starting material used for the determination of Escherichia coli, that was included in the dossier submitted. In accordance with the applicable EFSA SOP 12, the publication of the adopted scientific opinion was put on hold, and the opinion was included in the agenda of the current Plenary meeting. At the current meeting, the Panel has withdrawn the scientific opinion previously adopted on 4 February 2020 and discussed the new text related to the purity of the food enzyme and the conclusions. The Panel agreed with the revised dataset and updated the relevant text of the scientific opinion, also including an explanation for the changes made. The revised scientific opinion was discussed at the current plenary meeting and was unanimously adopted by the CEP Panel on 29 April 2020.

9.4 Process Veolia URRC for recycling post-consumer PET in food contact materials (EFSA-Q-2018-00768)

The draft opinion on the safety assessment of the recycling process: Veolia URRC for recycling post-consumer PET in food contact materials 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.

9.5 Food enzyme glucoamylase from the genetically modified *Trichoderma reesei* strain DP-Nzh38 (EFSA-Q-2016-00177)

The draft opinion on the safety assessment of the food enzyme glucoamylase from the genetically modified *Trichoderma reesei* strain DP-Nzh38 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.

9.6 Food enzyme endo-1,4-β-xylanase from a genetically modified *Trichoderma reesei* strain RF5427 (EFSA-Q-2013-00876/2014-00735)

The draft opinion on the safety assessment of the food enzyme: endo-1,4-β-xylanase from the genetically modified *Trichoderma reesei* strain RF5427 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.

9.7 Food enzyme with β-glucanase and β-xylanase activities from the *Trichoderma reesei* strain DP-Nya67 (EFSA-Q-2017-00085)

The draft opinion on the safety assessment of the food enzyme with β-glucanase and β-xylanase activities from the *Trichoderma reesei* strain DP-Nya67 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.

9.8 Food enzyme α-amylase from *Geobacillus stearothermophilus* strain DP-Gzb47(EFSA-Q-2016-00145)

The draft opinion on safety assessment of the food enzyme α-amylase from Geobacillus stearothermophilus (renamed as Parageobacillus thermoglucosidasius) strain DP-Gzb47 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.

9.9 Food enzyme lysophospholipase from a genetically modified *Aspergillus niger* strain NZYM-LP (EFSA-Q-2014-00919)

The draft opinion on safety assessment of the food enzyme lysophospholipase from the genetically modified *Aspergillus niger* strain NZYM-LP 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.

9.10 Food enzyme phospholipase A1 from the genetically modified *Aspergillus niger* strain NZYM-FP (EFSA-Q-2019-00639)

The draft opinion on safety assessment of the food enzymes phospholipase A1 from the genetically modified *Aspergillus niger* strain NZYM-FP 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.

8.5 New mandates

8.5.1 New questions since the previous meeting

The following new mandates have been received since the last Plenary meeting.

Food Sector	EFSA-Q-Number	Subject	Reception date
FCM	EFSA-Q-2020-00275	Request for safety evaluation of Genox® EP for use as additive in plastics	31/03/2020
REC	EFSA-Q-2020-00247	Request for safety evaluation of the Sicht-pack Hagner GmbH recycling process (Starlinger viscotec deCON)for food contact uses	16/03/2020
REC	EFSA-Q-2020-00231	Request for safety evaluation of the deSter BVBA recycling process (deSter) to produce recycled plastic for food contact uses	05/03/2020
REC	EFSA-Q-2020-00171	Request for safety evaluation of the PT Asiaplast Industries Tbk recycling process (Starlinger viscotec deCON)to produce recycled plastic for food contact uses	19/02/2020
REC	EFSA-Q-2020-00152	Request for safety evaluation of the Erreplast S.r.l. recycling process (Starlinger viscotec deCON) to produce recycled plastic for food contact uses	13/02/2020
REC	EFSA-Q-2020-00129	Request for safety evaluation of the SGR Société Générale de Recyclage recycling process (POLYMETRIX V-LEAN Super Clean)	05/02/2020

8.5.2 Valid questions since the previous meeting

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

Food Sector	EFSA-Q-Number	Subject	Valid on
REC	EFSA-Q-2020-00171	Request for safety evaluation of the PT Asiaplast Industries Tbk recycling process (Starlinger viscotec deCON)to produce recycled plastic for food contact uses	01/04/2020
REC	EFSA-Q-2020-00152	Request for safety evaluation of the Erreplast S.r.l. recycling process (Starlinger viscotec deCON) to produce recycled plastic for food contact uses	26/03/2020
REC	EFSA-Q-2020-00110	Request for safety evaluation of the Flight Plastics (UK) Ltd recycling process (Starlinger viscotec deCON) to produce recycled plastic for food contact uses	16/03/2020

REC	EFSA-Q-2020-00106	Request for safety evaluation of the Nosoplas recycling process (Starlinger iV+) to produce recycled plastic for food contact uses	12/03/2020
REC	EFSA-Q-2020-00048	Request for safety evaluation of the Somoplast - Riachi & Co recycling process (Starlinger viscotec deCON) to produce recycled plastic for food contact uses	25/02/2020
FCM	EFSA-Q-2019-00534	Request of the evaluation of 2-Methyl-1,8-octadiamine	28/02/2020
FCM	EFSA-Q-2019-00533	Request of the evaluation of Nonamethylenediamine	28/02/2020

8.5.3 Withdrawn questions since the previous meeting

The following question has been withdrawn since the last Plenary meeting.

Food Sector	EFSA-Q-Number	Subject	withdrawn on
ENZ	EFSA-Q-2015-00563	Request for EFSA to perform a scientific risk assessment on the food enzyme: Endo-1,4-beta-glucanase from a genetically modified strain of *Trichoderma reesei* (RF5261)	23/03/2020

8.6 Other scientific topics for information and/or discussion

Clarification for the applicants on the assessment of the possible presence of antimicrobial resistance genes in food enzymes

Regarding the assessment of the possible presence of antimicrobial resistance genes in food enzymes, the Panel would like to clarify the following:

When assessing the possible presence of antimicrobial resistance genes, the evaluation is done at the food enzyme level. Therefore, if the production strain carries antimicrobial resistance genes, absence of DNA from the production strain needs to be shown in the food enzyme.

Re-opening of guidance documents:

The CEP Panel was informed about the need to revise certain guidance documents within the Panel's remit in order to comply with the Regulation (EU) 2019/1381 which will enter into force on 27 March 2021. The new legal requirements introduced by this so-called Transparency Regulation will impact various areas of EFSA's work, including the handling of application dossiers in the context of regulated products, and therefore have to be correctly reflected in the guidance documents provided to applicants, so that both EFSA and the applicants can comply with the new requirements. The revision of the following guidance documents was therefore considered to be of high priority:

- Guidance on the Submission of a Dossier on Food Enzymes for Safety Evaluation (EFSA CEF Panel, 2009)
- Plastic FCM Note for Guidance (EFSA CEF Panel, 2008)

- Guidelines for recycling processes (EFSA AFC Panel, 2008)
- Guidelines for active and intelligent materials (EFSA CEF Panel, 2009)

10 Any Other business

None