SCIENTIFIC PANEL ON FOOD CONTACT MATERIALS, ENZYMES AND PROCESSING AIDS (CEP) OPEN to Observers
44th CEP Panel meeting

11-13 June 2024
14:00-18:00 /09:00-18:00 / 09:15-15:30
MINUTES (Agreed on 26 June 2024)

Location: EFSA, Parma

Attendees:

- CEP Panel Members:
José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Gott, Claude Lambré, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Henk Van Loveren, Laurence Vernis and Holger Zorn
- European Commission: Martinus Nagtzaam, Catherine Evrevin, Bastiaan Schupp, Jonathan Briggs
- EFSA:
Food Ingredients and Packaging (FIP) Unit: Jaime Aguilera, Zainab Al Harraq, Magdalena Andryszkiewicz, Eric Barthélémy, Daniele Cavanna, Gian Luca Colombo, Daniele Comandella, Ana Criado, Valeriu-Georghe Curtui, Roos de Nijs, Julia Fontan Vela, Arianna Gallo, Natalia Kovalkovicova, Alexandros Lioupis, Yi Liu, Simone Lunardi, Remigio Marano, Eleonora Marini, Silvia Peluso, Sandra Rainieri, Laura Sanmartín, Elisa Savini, Vasiliki Sfika, Katharina Volk and Kyriaki Xiftou

- Hearing experts: Joop De Knecht (item 7.8)

- Observers: Azens Jean-Jacques (Carton Ondulé de France / Association Club MCAS), Bahl Martin (Novonesis), Bothe Sarah (PPM), Carre Patrick (Terres Inovia), Ciccone Marianna (Alma Mater Studiorum - University of Bologna), Craigen Tracey (Amano Enzyme EU), Eisert Ralf (BASF SE), Guder Tina (Ajinomoto), Güneş Zeynep Saliha (Research asistana), Honkanummi Anni (AB Enzymes), Hooper Jeremy (MARS WRIGLEY), Kanisova Daniela (Amano Enzyme EU), Mackenzie-Wade Daniel (AAK-FEDIOL representative), Makkonen Jenny (Biosafe Biological Safety Solutions Ltd Oy), Mostardini Francesca (Università degli studi di Parma), Mulrine Colleen (Food Standards Agency in Northern Ireland), Pasecinic Nicoleta (KERRY TASTE & NUTRITION), Pescador Paula (Biosafe Ltd/Oy), Pronk Marja (RIVM (National Institute for Public Health and the Environment)), Ribera Daniel (Cargill France), Scetar Mario (University of Zagreb Faculty of foodtechnology and biotechnology), Teoh Keng Ngee (Ajinomoto Europe), Van Hoeck Els (Sciensano), Verhagen Bas (AB Enzymes), Vints Mark (Amcor), Voutilainen Minna (Biosafe Ltd/Oy), Waegeneers Nadia (Sciensano)

OPEN SESSION

1. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Christina Tlustos and Konrad Grob for whole meeting, and from Pier Sandro Cocconcelli on the 11th June.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence1 and the Decision of the Executive Director on Competing Interest Management2, EFSA screened the Annual Declarations of Interest filled out by the Panel 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.

4. Agreement of the minutes of the 43rd CEP Panel meeting held on 16-17 April 2024 via web-conference

The minutes of the 43rd CEP Panel meeting were agreed by written procedure on 10 May 2024.

5. Report on written procedures since 42nd Plenary meeting

None

6. Feedback from the Scientific Committee/Panel(s), EFSA, European Commission

6.1 Scientific Committee

The Chair reported the main points discussed during the 118th and 119th Scientific Committee Plenary, held from 10th to 11th April and from 29th to 30th May 2024, respectively.

The chair also reported the harmonisation on the use of term "margin of exposure" and "margin of safety".

Experts participating to cross cutting WGs reported activities on the biomarkers of effect, genotoxicity and nanotechnologies.

The safety assessment of mixtures of natural origin to manufacture food contact materials was also presented to the Panel.

6.2 European Commission

None

6.3 Update from CEP Panel Working groups

6.3.1. CEP WG on Food Contact Materials

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

The major achievements of the WG on Food Contact Materials from 2018 to 2024 were presented to the Panel and the observers. An update on the activities related to the risk assessment of styrene was also presented.

The progress on dossier evaluation is recorded in the **minutes of the WG**.

6.3.2. CEP WG on Recycling of Plastic

The major achievements of the WG on Recycling of plastic from 2018 to 2024 were presented to the Panel and the observers.

The progress on dossier evaluation is recorded in the **minutes of the WG.**

6.3.3. CEP WG on the evaluation of substances used to remove microbial contamination from products of animal origin

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

6.3.4. CEP WG on Enzymes

The major achievements of the WG on Enzymes from 2018 to 2024 were presented to the Panel and the observers.

The progress on dossier evaluation is recorded in the **minutes of the WG.**

6.3.5. CEP WG on Extraction Solvents

The major achievements of the WG on Extraction Solvents from 2018 to 2024 were presented to the Panel and the observers. An overview of the activities related to the work that is being carried out on hexane was also presented.

The progress on the evaluation is recorded in the **Minutes of the WG**.

6.3.6 CEP WG on Phthalates

The major achievements of the WG on Phthalates from 2018 to 2024 were presented to the Panel and the observers.

The progress on the evaluation is recorded in the **Minutes of the WG**.

6.4 Updates from EFSA

The FIP unit presented the results of the Experts Feedback Survey 2023.

The FIP unit also explained the rationale behind the split of the CEP Panel into two Panels (FCM and FEZ Panel) as of the 1st of July 2024.

7. Scientific outputs submitted for discussion and possible adoption

7.1. Scientific guidance on the criteria for the evaluation of post-consumer mechanical PET recycling EFSA-Q-2023-00351

The CEP Panel discussed all parts of the Guidance. The Guidance was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

Questions from observers and Answers from EFSA (in application of the guidelines for Observers)

The following questions were collected from the online registration form and answered by EFSA during the plenary meeting.

Q1 - *On the ongoing work on reassessing hexane: 1) What is the available evidence on the possible MOAH contamination through hexane (recycling/recirculation)? 2) Are there new available information on exposure of EU consumers and on toxicological data vs. what was available for the previous assessment of hexane?*

Reply: Currently hexane is authorised as an extraction solvent (Directive 2009/32/EC) based on a safety evaluation that was carried out by the SCF in 1996. The terms of reference of the mandate sent by EC are to assess the need for a re-evaluation of hexane, not to already perform a full risk assessment. This means that what the EFSA CEP Panel is currently doing is to consider if there is new relevant information on the different steps of a Risk Assessment (chemistry, exposure, toxicity), which would suggest that the SCF evaluation should be reconsidered.

Among those elements are:

- the precise identity (specifications) of the compound used as an extraction solvent,
- the evidence about a possible propagation of contaminants from hexane to food during the extraction process,
- the evaluation of the exposure,
- the identification of new toxicity data on hexane that became available after the SCF opinion.

Q 2. *As we are currently finalising a scientific review on alternative solvents in oil processing, the question arose: Is there any new toxicological information on the suspected reproductive toxicity of hexane, as described by many suppliers in their safety data sheets?*

Reply: Following the terms of reference of the EC mandate, EFSA is considering if there is a need for a re-evaluation of hexane. Performing a full re-evaluation, including a complete appraisal of all recent toxicity studies, is not the current goal of this activity.

A potential full re-evaluation may consider effects other than neurotoxicity, which was the focus of the 1996 SCF opinion, as in the meantime other studies on hexane toxicity, including consideration of other endpoints such as reproductive toxicity, have been carried out and are available. Their relevance and reliability remain to be evaluated.

Q 3. *Do we have new data on the health risks that hexane could pose via the protein meals fed to farm animals, and sufficient measurements to establish the residue levels found in animal feed troughs?*

Reply: Although the EFSA CEP Panel is aware that some products of the food extraction process using hexane are used in animal feed, it is not in its remit to assess the safety of use of hexane as an extraction solvent in feed.

The following question was received from observers in the plenary meeting, and answered by EFSA in the meeting.

Q 4 - *Will the CEP working group for the need to reevaluate hexane consider the topics of contamination with MOAH by hexane and safety of use of hexane separately? Because those MOAH*

contaminants from mineral oils are not originated in the used hexane as solvent, they are brought into the extraction process from the solvent recovery process.

Reply: information about the ongoing activity of PPM and MRI was included in the mandate by the Commission, so we are aware of the findings of this research. In the current drafting of the answer to EC, the WG is considering the topic of potential MOAH contamination and how this could impact the safety –not only based on the research activity but also including other considerations.
MOAH contamination has been recently addressed by the EFSA CONTAM Panel, which included considerations on levels in edible oils.

CLOSED SESSION

7.2. Recycling process Guolong (EREMA Basic)
EFSA-Q-2022-00287
Due to time constrain, the opinion was not discussed during the meeting and will be submitted to the Panel for possible adoption by written procedure, once EFSA completes the public consultation and reaches a decision to the confidentiality requests formulated by the applicant.

7.3. Recycling process Ecopackaging (EREMA Basic)
EFSA-Q-2022-00298
Due to time constrain, the opinion was not discussed during the meeting and will be submitted to the Panel for possible adoption by written procedure, once EFSA completes the public consultation and reaches a decision to the confidentiality requests formulated by the applicant.

7.4. Recycling process Palamidis (EREMA Basic)
EFSA-Q-2022-00494
Due to time constrain the opinion was not discussed during the meeting and will be submitted to the Panel for possible adoption by written procedure.

7.5. Recycling process KGL (EREMA Basic)
EFSA-Q-2022-00837
Due to time constrain the opinion was not discussed during the meeting and will be submitted to the Panel for possible adoption by written procedure.

7.6. Recycling process Lietpak (EREMA MPR)
EFSA-Q-2023-00278
Due to time constrain the opinion was not discussed during the meeting and will be submitted to the Panel for possible adoption by written procedure.

7.14. Recycling process Fucine Film (Reifenhäuser)
EFSA-Q-2021-00715
The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

OPEN SESSION

7.7. Internal mandate: catalogue of AMR genes in species of *Bacillus* by means of a bioinformatic tool implementing the EFSA criteria regarding intrinsic and acquired AMR genes
EFSA-Q-2023-00741
EFSA presented and explained all parts of the Technical report. The CEP Panel provided some suggestions for improvement. The Technical Report was unanimously endorsed, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.8. Revision of the Guidance on Decontamination substances
EFSA-Q-2024-00020

The following parts of the guidance were presented to the CEP panel and discussed:

- technical data on the substance,
- consumer exposure assessment to the substance,
- toxicological and ecotoxicological impact of the substance.

The changes and issues highlighted by the Panel will be discussed by the WG.

7.9. Protease from the non-genetically modified *Bacillus amyloliquefaciens* (strain AE-NP)_Extension of use
EFSA-Q-2023-00004
The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.10. Protease from the non-genetically modified *Aspergillus melleus* (strain AE-P)_Extension of use
EFSA-Q-2023-00356
The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.11. Laccase from the non-genetically modified *Trametes hirsuta* strain AE-OR_Extension of use
EFSA-Q-2023-00383
The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.12. Alpha-amylase from the non-genetically modified *Bacillus licheniformis* (strain AE-TA)_Extension of use
EFSA-Q-2023-00305
The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.13. Alpha-L-rhamnosidase from the non-genetically modified *Penicillium decumbens* (strain AE-HP)_Extension of use
EFSA-Q-2023-00359
The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

CLOSED SESSION

7.15. Safety assessment of the substances "wax, rice bran, oxidized" and "wax, rice bran, partially saponified" for use in food contact materials
EFSA-Q-2022-00452
The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously endorsed. The adoption will take place in the future, once EFSA completes the public consultation and reaches a decision to the confidentiality requests formulated by the applicant.

7.16. Beta-glucosidase from the non-genetically modified *Penicillium multicolor* strain AE-GLY
EFSA-Q-2015-00273
The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.17. Asparaginase from genetically modified strain *Aspergillus niger* EFSA-Q-2013-00895 and EFSA-2021-00276

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.18. Subtilisin from the non-genetically modified *Bacillus paralicheniformis* strain AP-01 EFSA-Q-2022-00601

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.19. 3-Phytase from the non-genetically modified *Aspergillus niger* strain PHY93-08 EFSA-Q-2016-00575

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

7.20. Triacylglycerol lipase from the non-genetically modified *Penicillium caseifulvum* strain AE-LRF by Amano Enzyme Inc. EFSA-Q-2014-00545

The CEP Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

8. AoB

Scientific opinion on the safety assessment of the mucorpepsin from the non-genetically modified *Rhizomucor miehei* strain M19-21(EFSA-Q-2022-00201)

The thermolabile form of the food enzyme was evaluated and adopted in February 2024. Following the publication of the scientific opinion[3], the applicant requested clarification on the outcome of the evaluation for the native form of the food enzyme, which was described in the additional data received during the scientific risk assessment, but not included in the published scientific opinion. The Panel agreed to amend the scientific opinion to include the native form of the food enzyme.

The revised opinion will be re-published, acknowledging the amendment in compliance with EFSA standard operating procedures.

Correction of 4 Scientific opinions on the safety assessment of EREMA technology, used to recycle post-consumer PET into food contact materials

In view of the reception of precise raw data on the percentage of contaminated flakes used in a Challenge test, and consequent update of calculations resulting in different % of allowed recycled PET for the manufacture of materials and articles intended to be used in contact with food, the Panel agreed to amend the following opinions: ON 3462 (with regard to EFSA-Q-2012-00236)[4]; ON 4842 (EFSA-Q-2015-00679)[5]; ON 8518 (EFSA-Q-2022-00286)[6] and ON 8519 (EFSA- Q-2022- 00267)[6].

The abovementioned revised opinions will be re-published acknowledging the amendments in compliance with EFSA standard operating procedures

[3] Adopted by the CEP Panel on 1 February 2024 and published on 26 February 2024
[4] Adopted by the CEF Panel on 4 November 2013 and published on 22 November 2013
[5] Adopted by the CEF Panel on 4 May 2017 and published on 14 June 2017
[6] Adopted by the CEP Panel on 7 December 2023 and published on 11 January 2024