

9/10 April 2025

09:15-17:15/ 09:15-17:15

MINUTES - Agreed on 10th April 2025

Location: Teleconference

Attendees:

- Panel Members:

José Manuel Barat Baviera, Claudia Bolognesi, Francesco Catania, Gabriele Gadermaier, Ralf Greiner, Baltasar Mayo, Alicja Mortensen, Yrjö Roos, Marize De Lourdes Marzo Solano, Monika Sramkova, Hendrik van Loveren, Laurence Vernis, Holger Zorn (Chair)

- Hearing Experts¹:

Not Applicable

- European Commission and/or Member States representatives:

EC: Catherine Evrein

- EFSA:

Food Ingredients and Packaging (FIP) Unit: Jaime Aguilera, Magdalena Andryszkiewicz, Laura Cabo Sanmartin, Daniele Cavanna, Valeriu-Georghe Curtui, Ana Criado, Cristina Fernández-Fraguas, Ana Gomes, Natalia Kovalkovicova, Yi Liu, Simone Lunardi, Alexia Ollier, Jeroen Pasch, Silvia Peluso, Maria Chiara Sicuri, Valentina Tokić

- Others:

Eleonora Marini participated as ISA (Individual Scientific Advisor)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s with Risk Assessment". No Conflicts of Interest related to the issues discussed in these meetings 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 8th FEZ Panel Plenary meeting held on 11-13 March 2025, in Parma

¹ As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": <https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf>

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



The minutes of the 8th Panel plenary meeting were agreed by written procedure on 13th March 2025.

5. Report on written procedure

No written procedures to report.

6. Scientific outputs submitted for discussion/adoption

6.1 Extension of use of the food enzyme endo-polygalacturonase from a genetically modified *Trichoderma reesei* strain RF6197 ([EFSA-Q-2024-00676](#))

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

6.2 Extension of use of the food enzyme pectin esterase from a genetically modified *Trichoderma reesei* strain RF6201 ([EFSA-Q-2024-00677](#))

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

6.3 Prolyl oligopeptidase from a genetically modified *Trichoderma reesei* strain DP-Nyq99 as a new food enzyme ([EFSA-Q-2023-00906](#))

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

6.4 Acetolactate decarboxylase from a genetically modified *Bacillus subtilis* strain DP-Ezz65 as a new food enzyme ([EFSA-Q-2024-00069](#))

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

6.5 4- α -Glucanotransferase from a genetically modified strain of *Bacillus amyloliquefaciens* (strain MAS) ([EFSA-Q-2017-00405](#))

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

6.6 Serine protease (Chymotrypsine) from a genetically modified strain of *B. licheniformis* (strain NZYM-RH) ([EFSA-Q-2014-00292](#))

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

6.7 Phospholipase A1 from a genetically modified *Trichoderma reesei* strain DP-Nzk98 as a new food enzyme ([EFSA-Q-2024-00065](#))

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



6.8 Follow-up opinion linked to EFSA-Q-2014-00114 - Leucyl aminopeptidase from a non-genetically modified *Aspergillus* sp. strain AE-MB (EFSA-Q-2024-00210)

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

6.9 Pullulanase from a non-genetically modified *Klebsiella pneumoniae* strain AE-PUL as a new food enzyme (EFSA-Q-2023-00567)

Following the adoption of this scientific opinion in March 2025⁴, EFSA discovered that due to administrative error, the new genotoxicity test submitted as additional data was not available for the Panel in March 2025. In the present Plenary meeting, the Panel evaluated the new genotoxicity test, revised the corresponding section, and adopted the revised opinion unanimously. The revised opinion will be published, acknowledging the amendment in compliance with EFSA standard operating procedures.

6.10 Mannan endo-1,4- β -mannosidase from *A. niger* - data package Amano Enzyme Inc. (EFSA-Q-2022-00576)

The FEZ Panel discussed and finalised the draft scientific opinion. After amendments, the draft opinion will be presented at the next available FEZ plenary meeting for further discussion and possible adoption.

6.11 Maltogenicc amylase from a genetically modified *Escherichia Coli* strain MLAVSC as a new food enzyme (EFSA-Q-2024-00034)

The FEZ Panel discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant.

6.12 Pullulanase from a genetically modified *Bacillus licheniformis* strain DP-Dzp107 as a new food enzyme (EFSA-Q-2024-00088)

The FEZ Panel discussed and finalised the draft scientific opinion. After amendments, the draft opinion will be presented at the next available FEZ plenary meeting for further discussion and possible adoption.

6.13 Endo-1,4-beta-xylanase from a genetically modified *Trichoderma reesei* strain DP-Nzd72 as a new food enzyme (EFSA-Q-2024-00085)

The FEZ Panel discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant.

6.14 Cellulase from *Trichoderma citrinoviride* Strain X31 - data package Shin Nihon Chemical Co., Ltd (EFSA-Q-2023-00297)

Not discussed due to lack of time.

6.15 Amidase from a genetically modified *Escherichia coli* strain SP-a as a new food enzyme (EFSA-Q-2024-00307)

⁴ chrome-extension://efaidnbmninnbpcjpcglclefindmkaj/https://www.efsa.europa.eu/sites/default/files/2025-03/FEZ%20PLM%208_%20Minutes.pdf



The FEZ Panel discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant.

6.16 Lysozyme from albumen of hens' egg (*Gallus gallus domesticus*) as a new food enzyme (EFSA-Q-2024-00309)

The involved experts discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant

7. Other scientific topics for information/discussion

None

8. Update on new Mandates

None

9. Feedback from the Scientific Committee/ Scientific Panels/EFSA/ EC

9.1 Scientific Committee

The Chair updated the Panel on topics discussed during the most recent Scientific Committee meeting.

9.2 European Commission

Not applicable

9.3 Scientific Panel(s) including their Working Groups

Not applicable

10. Any other business

The Panel discussed the letter received from AMFEP on the 27th of March on the acceptability of substitute toxicological studies. A reply from EFSA will be sent to AMFEP.

11. Preparatory meeting/s with Risk Assessment

Since the last FEZ Plenary meeting, five preparatory meetings chaired by EFSA staff were held as follows.

11.1 Preparatory meeting on Allergenicity, 1st of April from 08.15 to 11.45

11.1a Attendees:

- o FEZ Panel Members:
Gabriele Gadermaier, Hendrik van Loveren
- o EFSA:



Food Ingredients and Packaging (FIP) Unit: Magdalena Andryszkiewicz, Cristina Fernández-Fraguas, Silvia Peluso (chair), Alexia Ollier

11.2 Preparatory meeting on dietary exposure, 4th of April from 09.00 to 13.00

11.2a Attendees:

o FEZ Panel Members:

José Manuel Barat Baviera, Ralf Greiner, Holger Zorn, Yrjö Roos

o EFSA:

Food Ingredients and Packaging (FIP) Unit: Daniele Cavanna (chair), Yi Liu, Maria Chiara Sicuri, Valentina Tokić, Jeroen Pasch

11.3 Preparatory meeting on toxicology , 1st of April from 14.00 to 18.00

11.3a Attendees:

o FEZ Panel Members:

Claudia Bolognesi, Alicja Mortensen, Marize De Lourdes Marzo Solano, Monika Sramkova, Hendrik van Loveren

o EFSA:

Food Ingredients and Packaging (FIP) Unit: Ana Criado (chair), Natalia Kovalevich, Valentina Tokić, Daniele Volpi

11.4 Preparatory meeting on technology, 4th of April from 14.00 to 17.30

11.4a Attendees:

o FEZ Panel Members:

José Manuel Barat Baviera, Ralf Greiner, Holger Zorn

o EFSA:

Food Ingredients and Packaging (FIP) Unit: Magdalena Andryszkiewicz, Cristina Fernández-Fraguas (chair), Jeroen Pasch, Valentina Tokić

11.5 Preparatory meeting on microbiology, 2nd of April from 14.00 to 18.00

11.5a Attendees:

o FEZ Panel Members:

Baltasar Mayo, Laurence Vernis

o EFSA:

Food Ingredients and Packaging (FIP) Unit: Jaime Aguilera, Yi Liu, Simone Lunardi (chair), Silvia Peluso



11.6 Discussion points

Different sections of a draft opinion were discussed in the respective preparatory meetings. The combined outcome is reported below.

11.6.1 Serine protease (with trypsin specificity) from a genetically modified strain of *Fusarium venenatum* (NZYM-FG) ([EFSA-Q-2014-00412](#))

The involved experts discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant.

11.6.2 Serine endopeptidase from a genetically modified *Trichoderma reesei* strain AR-201 as a new food enzyme ([EFSA-Q-2023-00367](#))

The involved experts discussed the draft scientific opinion and will continue the discussion at the next available FEZ plenary meeting.

11.6.3 Alpha amylase from a non-genetically modified *Aspergillus oryzae* strain CCTCC M2023235 as a new food enzyme ([EFSA-Q-2024-00451](#))

The involved experts discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant.

11.6.4 Triacylglycerol lipase from a genetically modified *Aspergillus niger* strain PLR as a new food enzyme ([EFSA-Q-2024-00206](#))

The involved experts discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant.

11.6.5 Cellulase and Endo-1,3(4)-beta-glucanase from *Trichoderma reesei* DP-Nzc104 - data package Genencor International, B.V. ([EFSA-Q-2023-00229](#))

The involved experts discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant.

11.6.6. Asparaginase from a non-genetically modified *Saccharomyces cerevisiae* strain AcryleasTM Pro (ARY-2) as a new food enzyme ([EFSA-Q-2024-00076](#))

The involved experts discussed the draft scientific opinion and will continue the discussion at the next available FEZ plenary meeting.

11.6.7. Prolyl oligopeptidase from a genetically modified *Aspergillus niger* strain NZYM-MR as a new food enzyme ([EFSA-Q-2024-00638](#))

The involved experts discussed the draft opinion and concluded that additional information is required in order to proceed with the safety assessment of this food enzyme. A request for additional information will be sent to the applicant.

12. Next meeting

The next meeting will be held on 20-21 May 2025, via teleconference.