SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

182nd Panel Plenary meeting – OPEN to observers

3-4 December 2025 09:00-17:00 / 09:00-13:00 MINUTES - Agreed on 18 December



Location: Parma and Web-Conference

Attendees:

o Panel Members:

Ana Allende, Avelino Alvarez-Ordóñez, Valeria Bortolaia, Sara Bover-Cid, Alessandra De Cesare, Wietske Dohmen, Laurent Guillier, Lieve Herman, Liesbeth Jacxsens, Maarten Nauta, Lapo Mughini-Gras, Jakob Ottoson, Luisa Peixe, Fernando Pérez-Rodríguez, Panagiotis Skandamis, Elisabetta Suffredini

Hearing Experts¹:
 None

- European Commission and/or Member States representatives:
 Sandrine Amsler, Kris De Smet, Gunilla Eklund (EC DG SANTE), Maja Desgree Du Lou (EC DG ENV) participation to selected agenda items
- o EFSA:

Laura Cabral, Sandra Correia, Beatriz Guerra, Gulnara Guluzade, Ernesto Liebana, Winy Messens, Valentina Rizzi, Eleonora Sarno, Pietro Stella, Megan Tumulty, Natisha Vatwani, Frank Verdonck, Anna Zdanowicz (BIOHAW Unit); Marta Bisaschi (CSO); Anthony Smith (COM unit)

Others:Observers (see Annex 1)

1. Welcome and apologies for absence

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ 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.

¹ As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pd



4. Panel members introduction

The BIOHAZ Panel members briefly introduced themselves to the observers.

5. Presentation of Guidelines for observers

EFSA BIOHAZ Panel Coordinator introduced the EFSA Guidelines for observers, including the rules for attending the meeting, and explained when in the agenda specific slots for answering questions from the observers have been placed.

6. Agreement of the minutes of the 181st Panel Plenary meeting held on 22-23 October 2025, in Parma

The minutes of the 181st Panel plenary meeting were agreed by written procedure on 5 November 2025. During the plenary EFSA staff brought to the attention of the Panel the need to update the minutes of the 181st Plenary meeting to add agreement expressed by the Panel during the 181st Plenary meeting on a correction to be brought to the QPS Panel Statement part 21. The Panel agreed with the change proposed in the minutes.

7. Scientific outputs submitted for adoption/endorsement

7.1 Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA. 23: Suitability of taxonomic units notified to EFSA until September 2025 (EFSA-Q-2023-00053)

Last WG meeting was held on 21 October in Parma. A total of 47 notifications were received between April and September 2025 (inclusive): 28 as feed additives, 11 as food enzymes, food additives and flavourings, 6 as novel foods, none as PPPs and 2 as food contact materials. From these, 43 were not evaluated for the following reasons: 18 involved taxonomic units (TU) excluded from the QPS evaluation (9 filamentous fungi and 9 *E. coli*) and 25 belong to TUs that already have a QPS status. Of the remaining 4 notifications, *Heyndrickxia faecalis* (previously *Weizmannia faecalis*) had already been evaluated for a possible QPS status in a previous Panel Statement. The other 2 TUs included, *Microchloropsis gaditana* and *Bacillus thermoamylovorans* (both notified for the first time), was assessed for a possible QPS status in this Panel Statement. An additional TU, *Aurantiochytrium acetophilum* (not evaluated previously), was included in response to an internal request. Their assessment for a possible QPS status was discussed and agreed by the Panel. The summaries of the ELS cycle for each TU were also agreed. The Statement was adopted by the BIOHAZ Panel.

7.2 Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA (EFSA-Q-2023-00054)

Last WG meeting was held on 21 October in Parma. The WG Chair presented the main changes made by the WG in all sections of the document with focus on the section on the bacteriophages consideration as it was the last to be developed. The summaries of the 3-years cycle concerning the ELS, the new notifications and the QPS recommendations were also presented. A new section with a summary of the notifications received for the QPS Panel Statement part 1 until part 23 was also presented. The overall draft opinion was discussed and finally adopted by the BIOHAZ Panel.

7.3 Scientific opinion on the microbiological safety of ungulates meat intended to be frozen (<u>EFSA-Q-2024-00663</u>) and on frozen meat of ungulates: defrosting (<u>EFSA-Q-2024-00711</u>)



The last WG meetings were held on 7 November and on 17-18 November 2025. The WG Chair presented in detail the draft opinion, focusing on the recent amendments introduced by the WG, also in reply to the comments by the Panel during the October plenary. The draft conclusions, abstract and summary were revised in detail, and few final modifications were made to the text during the discussion. The opinion was adopted by the Panel. The EC representative thanked the Panel and the WG for addressing the mandate.

8. Scientific outputs submitted for discussion

8.1 Scientific opinion(s) on the current status of the occurrence and spread of carbapenemase-producing Enterobacterales in the food chain in the EU/EFTA

No additional meeting of the WG has taken place since the last plenary. The WG continues supervising the outcomes of the FPA Carba-R-ales project providing advice, and addressing any emerging issue related to the topic. The duration of the activities of the whole mandate is up to the end of 2027, where an updated scientific opinion will be released.

8.2 Request for a scientific opinion on the implementation of point 2 of Annex V of Regulation (EU) 2025/40 on Packaging and Packaging Waste (EFSA-Q-2025-00456)

The second and third WG meetings took place on 5 November 2025, and on 25 and 28 November 2025. The Panel was informed about the addition of the definition of unprocessed fresh fruits, vegetables and herbs (FVHs) in the clarifications of the mandate. It refers to "any harvested FVHs as well as those submitted to specific postharvest handling operations that can be performed at the moment of harvest or in the packing house (e.g., sorting, elimination of external leaves, removal of the dirt), to make the product market ready." The protocol was presented, addressing the comments made and following discussion, and was approved by the Panel. A call for data "Unprocessed fresh produce packaging" will be launched to offer interested parties (e.g., food business operators, national food authorities, research institutions, academia) and/or other stakeholders, the opportunity to submit documented information relevant to the mandate. The draft questionnaire was presented to the Panel and comments were received that will be discussed with the WG at their next meeting on 9 December 2025. The deadline for delivery of the scientific opinion is end of November 2026.

8.3 Request for a scientific opinion on Food Safety Culture and its microbiological food safety impact in the EU (<u>EFSA-Q-2025-00553</u> and <u>EFSA-Q-2025-00554</u>)

As anticipated in previous plenary meetings, a mandate on food safety culture has been received by EFSA from the European Commission. The WG coordinator informed the Panel about the decision, taken in consultation with the BIOHAZ Panel Chair, that the mandate needs to be carried out by a new Working Group. After informing the Panel, and in consultation with the BIOHAZ Panel Chair, Liesbeth Jacxsens was nominated Chair of the Working Group. The WG Chair and the WG coordinator presented the mandate, its terms of reference and the provisional planning ahead to the Panel. Two scientific opinions are expected as output, the deadlines for their adoption are end of December 2026 and end of April 2027. The need for a third opinion (part 3 of the mandate) will be agreed with the European Commission at later stage, depending on the findings of the first two.

8.4 Update on the adoption of the scientific opinion on the risk of infection with highly pathogenic avian influenza virus affecting dairy cows in the United States of America (EFSA-Q-2024-00712)



Following the endorsement of the sections of the opinion under the remit of the BIOHAZ Panel by the BIOHAZ Panel at their previous meeting, the whole opinion was adopted by the AHAW panel on 19 November 2025.

8.5 Update on the adoption of the guidance on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin (EFSA-Q-2024-00020)

Following the endorsement of the sections of the opinion under the remit of the BIOHAZ Panel by the BIOHAZ Panel at their 180th plenary meeting, the whole opinion was adopted by the FCM panel by written procedure on 1 December 2025.

9. Update on new mandates

EFSA Staff briefly updated the Panel on the reception of a new mandate from the European Parliament on the health risks posed by microplastics (including nanoplastics) in food, water and air. The Mandate will be of primary competence of the CONTAM Panel, with the contribution of the BIOHAZ Panel. The BIOHAZ Panel should cover the role of micro- and nanoplastics as vectors for human foodborne microbiological hazards in food of plant and animal origin. Deadline of the Mandate is end of December 2027.

10. Feedback from the Scientific Committee, other Scientific Panels, EFSA and the European Commission

10.1 Scientific Committee

The Panel Chair reported to the Panel the main topics discussed during the 128th Plenary meeting of the Scientific Committee (SC), that took place on 26 and 27 November 2025⁴, in particular: an update on the work on the guidance on critical appraisal of evidence for food and feed safety assessment, the guidance on the use of biomarkers of effect in risk assessment, an update on activities related to social science (which include the exchanges and possible future support to the BIOHAZ Panel within the mandate on food safety culture), the SC mandate on risk benefit of fish in relation to contaminants, and other activities of the SC, the revision of the guidances on weight of evidence and biological relevance, an update on the initiative aimed at reducing length and improving readability of scientific opinions, an update on the project on guidance architecture and on the programme of the SC for updating or creating new cross-cutting guidances. During the SC plenary, the PPR and the BIOHAZ Panel Chairs presented the activities and workplan of their Panels.

10.2 European Commission

No discussion took place under this agenda item.

11. Other topics for information and/or discussion

11.1 Topics of scientific concern in the area of biological hazards

Nothing to report under this agenda item.

⁴ https://www.efsa.europa.eu/en/events/128th-plenary-meeting-scientific-committee-open-observers



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

Two questions were made by observers that attended the meeting:

- 1. <u>Question:</u> For a genetically modified microorganism (GMM) used in production, where the strain was obtained without full documentation of the genetic modifications, is it sufficient to perform a whole-genome comparison between the production strain and its declared parental strain to identify all modifications? If not, could you clarify what additional analyses or information EFSA would expect to ensure a complete characterisation of the genetic changes?
 - Answer: For applying the QPS approach in the risk assessment, the genetic modification needs to be assessed and considered as safe. For this, Chapter 3.5 of the Micro Guidance needs to be followed⁵. The assessment of the genetic modification must be based on information of all inserted sequences (3.5.1.1) and of other modifications (3.5.1.2). The structure of the genetic modification(s) should be done by comparing the WGS data for the GMM with those of the non-genetically modified reference strain. This should be done for bacteria, viruses, yeasts and filamentous fungi (3.5.2.1). When the WGS data are not required (e.g. microalgae and other protists) or are available but do not allow characterisation of the genetic modification, all the modification steps should be described (3.5.2.2). For further details on the WGS analysis, the applicant should refer to the EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain⁶ and its future updates.
- 2. <u>Question:</u> Is it possible to consult or conference with the QPS team before the submission of a dossier for regulated product?

Answer: Applicants can contact EFSA for General Pre-Submission Advice (GPSA), according to what explained on EFSA website⁷. Please note that the QPS assessment process is only triggered internally by EFSA after receiving an application for market authorisation. It cannot be triggered directly by an applicant. The BIOHAZ Panel and the BIOHAW Unit are not responsible for the assessment of applications related to microorganisms assessed within the QPS assessment, therefore any GPSA on future applications need to be made to the EFSA Units responsible for the assessment of such applications. An interactive multimedia tool explaining the QPS process is available on EFSA website⁸.

13. AOB

ESA staff updated the Panel on the reception of a new EC mandate to EFSA requesting technical specifications on harmonised monitoring of antimicrobial resistance (AMR) in zoonotic and indicator bacteria isolated from food-producing animals and food for the period 2028-2034. The Mandate is allocated to the BIOHAW Unit (BIOMO Team), an ad hoc WG is being set up, and the deadline to produce the scientific report is end of December 2026. The BIOHAZ Panel will be updated on the progress of the work from time to time, just for information. No action from the Panel is required.

Following to the resignation of Panel member Elisabetta Suffredini as of 31 December 2025 from the Panel, the EFSA Panel and EFSA staff thanked Elisabetta Suffredini for her active and excellent contribution to the activities of the BIOHAZ Panel.

Annex I List of Observers

Online:

⁵ https://doi.org/10.2903/j.efsa.2025.9705

⁶ https://doi.org/10.2903/j.efsa.2024.8912

⁷ https://www.efsa.europa.eu/en/applications/about/services

⁸ https://www.efsa.europa.eu/en/applications/qps-assessment



A total of 9 observers attended the meeting (out of 21 registered observers)

Observer	Affiliation
Aarieke DE JONG	Netherlands Food and Consumer Product Safety Authority - Office for Risk Assessment and Research (NVWA-BuRO)
Dragan FLORENTINA	Mega Image
Elina KOSKINEN	Orion Corporation
Aikaterini KOUDOUNA	Tsakalidis Analysis & Testing
Solomon NTSOERENG	University of The Free State
Nicoleta PASECINIC	Kerry Ingredients & Flavours Ltd
Georgia Danae TZIMEAS	Undeclared affiliation, Food Safety MSc Graduate
Kathleen Slingerland	Farmless
Hua Zhu	Baseclear