

**SCIENTIFIC PANEL
ON BIOLOGICAL HAZARDS
163rd Plenary Meeting**



12-13 July 2023
09:00-17:45/09:00-12:30
MINUTES - Agreed on 27 July 2023

Location: Webconference

Attendees:

■ Panel Members:

Ana Allende, Avelino Alvarez-Ordóñez, Declan Bolton, Sara Bover-Cid, Marianne Chemaly, Alessandra De Cesare, Lieve Herman, Friederike Hilbert, Konstantinos Koutsoumanis, Roland Lindqvist, Maarten Nauta, Romolo Nonno, Giuseppe Ru, Luisa Peixe, Marion Simmons, Panagiotis Skandamis, Elisabetta Suffredini

■ Hearing Experts¹:

Not applicable

■ European Commission and/or Member States representatives:

Kris De Smet (DG Health and Food Safety, Unit G4; item 6.4)

■ EFSA:

BIOHAW Unit:

Ruben Barcia, Kateryna Chuzhakina, Sandra Correia, Maria Teresa Da Silva Felicio, Beatriz Guerra, Michaela Hempen, Ernesto Liebana, Joana Lourenco, Winy Messens, Angel Ortiz-Peláez, Valentina Rizzi, Eleonora Sarno, Ancuta Cezara Simon, Pietro Stella, Frank Verdonck

MESE Unit:

Laura Martino (item 6.8)

■ Observers:

Not applicable

■ Others:

Not applicable

1. Welcome and apologies for absence

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 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/sites/default/files/corporate_publications/files/expertselection.pdf



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.

4. Agreement of the minutes of the 162nd Plenary meeting held on 7 and 8 June 2023

The minutes of the 161st Plenary meeting held on 26 and 27 April 2023 were agreed by written procedure on 22 June 2023⁴.

5. Scientific outputs submitted for possible adoption or endorsement

No document was submitted for possible adoption or endorsement.

6. Scientific outputs submitted for discussion

6.1. Statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes' (EFSA-Q-2023-00096)⁵

Last (5th) Working Group (WG) meeting took place on 5 June by web-meeting. This subject was also discussed during part of the QPS WG meeting on 27 June. The Public Consultation was launched on 2 May and remained open until 2 June⁶. A total of 75 submissions were received with more than 150 comments/questions. The chair presented the main ongoing discussions being carried out by the WG experts, on the reply to those comments/questions and on possible amendments to the text of the statement. Next WG meeting will take place on 20 September by web-meeting. A PC Report will be prepared and published with the Panel Statement. The deadline for possible adoption of the Panel Statement and acceptance of the Public Consultation report is 30 September 2023.

6.2. 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)⁷

Last meeting took place on 27 June by web-meeting. EFSA coordinator and WG chair presented to the Panel the follow up of the proposals for the new challenges/themes to be included in this Opinion. The next WG meeting will be on 4 September. The QPS

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/en/events/162nd-biohaz-panel-plenary-meeting>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00096>

⁶ <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l09000006r4Ki/pc0434>

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00054>



opinion document will be presented to the BIOHAZ Panel for possible adoption in December 2025.

6.3. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 19: Suitability of taxonomic units notified to EFSA until September 2023 (EFSA-Q-2021-00771)⁸

Last WG meeting took place on 27 June by web-meeting. Until the end of June, 31 notifications were received from April 2023; 26 of these will not be evaluated for the following reasons: 11 notifications are related to microorganisms that are excluded from QPS evaluation (10 are notifications of filamentous fungi, 1 of *Enterococcus faecium*), and 15 are related to TUs that already have QPS status and did not require further evaluation. Five of the other 5 TUs notified within this period will be evaluated for a possible QPS status: *Serratia marcescens*, *Weizmannia faecalis*, *Clostridium tyrobutyricum*, *Burkholderia ubonensis* (already notified and evaluated in 2019) and *Ensifer adhaerens* (already notified and evaluated in 2021). The new ELS exercise will be launched at the beginning of July. The deadline is 30 December 2023.

6.4. Scientific opinion on microbiological hazards associated with the use of water in post-harvest handling and processing operations of fresh and frozen fruits, vegetables and herbs (EFSA-Q-2021-00374, EFSA-Q-2023-00073, EFSA-Q-2023-00074, EFSA-Q-2023-00075 and EFSA-Q-2023-00076), including associated outsourcing activities (OC/EFSA/BIOCONTAM/2021/02)⁹

The last WG meeting took place by web-meeting on 4 to 5 July 2023 in Parma. The WG Chair presented the full Part 1 opinion discussing all comments received from the Panel. Most of these comments were immediately addressed and a few will be considered by the WG in their last review of the draft opinion before planned adoption at the next plenary meeting. The next WG meeting will be in Parma on 7 September 2023. The Chair also presented briefly all modifications that have been applied to the previously approved protocol by the WG during the execution of the assessments. The Panel agreed with the presented protocol modification table which will be published together with the previously approved protocol as an Annex; Section 2 (Data and Methodologies) of the scientific opinion will reflect and explain the assessment made considering the changes applied to the protocol. The deadline for the adoption of the Part 1 Scientific Opinion is 30 October 2023 (although actual adoption might be anticipated to September 2023) and for the Parts 2, 3, 4 and 5 Scientific Opinions is 31 December 2024.

6.5. Scientific opinion on the persistence of microbiological hazards in food and feed production and processing environments (EFSA-Q-2022-00217)¹⁰

The last WG meeting was held on 9 June 2023 in Parma. An update was given of the whole assessment. Feedback was given on the suggestions that were raised at the previous plenary meeting on the assessment question 6 “*What are the perspectives of integrating the information gathered in the previous AQs in risk assessment?*”. The persistence in the extended version of the two-linked-compartments model would be considered through the parameter representing the change in the population size in the non-food contact surface of the production environment. Further, this assessment would: (i) describe the available persistence models and data needs; (ii) include the

⁸ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00771>

⁹ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00374>

¹⁰ <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00217>



hazards *L. monocytogenes* and *Salmonella*, and (iii) describe in a narrative way the use of the top-down approach. The next WG meeting will be held on 24 July 2023 by web-conference. The deadline for adoption of the Scientific Opinion is 31 December 2023.

6.6. Scientific opinion on the public health aspects of *Vibrio* spp. related to the consumption of seafood in the EU (EFSA-Q-2022-00826)¹¹

No WG meeting was held since last plenary meeting. The WG chair gave an update of the work ongoing for some of the assessment questions. The next WG meeting will be held by web-conference on 17 July 2023. The deadline for adoption of this Scientific Opinion is 30 June 2024.

6.7. Request for scientific and technical assistance to evaluate the application of the Czech Republic to be recognised as having a negligible risk of classical scrapie (EFSA-Q-2023-00088)¹²

The WG Chair presented the report for the first time to the Panel for information. The draft report and the model had been shared with the Panel in advance. The comments made before the plenary had been addressed in the report. The WG chair went through the different sections of the report, including the results, which are final. The conclusion and recommendations are the sections least elaborated but will be reviewed by the WG in the next meeting on Tuesday 29 August 2023. The chair of the Panel recommended to explain better how the results are presented in tabular format and not to preclude the cut-off for decision to grant the status of the country, since this is a risk management decision. The WG Chair clarified this was agreed with the EC for previous evaluations and the results are summarised now in the same way. The report will be presented for endorsement to the September plenary.

6.8. Request for scientific and technical assistance regarding the impact of the proposed revised Australia's microbiological monitoring programme for beef and sheep meat exported to the EU (EFSA-Q-2023-00058)¹³

The WG received the data and model used in the Australian equivalence submission. The next step is to run the simulations with the Australian model and with a new model developed by the WG to assess the impact of the proposed changes to the monitoring system for beef and sheep carcasses exported to the EU. The comparison will be restricted to Australian carcass monitoring data from EU-listed slaughterhouses. The data include Aerobic Plate Count and *E. coli* (cfu/cm²) and presence/absence of *Salmonella*. In the proposed system, *Salmonella* monitoring is discontinued. The next WG meeting is 14 July 2023. The deadline for this mandate is 31 December 2023.

6.9. Request for a re-evaluation of certain aspects of the EFSA scientific opinion of April 2010 on risk assessment of parasites in fishery products, based on new scientific data (EFSA-Q-2023-00090)¹⁴

The third meeting on the WG took place on 17 June. The Chair of the WG reminded the BIOHAZ Panel about the Terms of Reference (ToRs) of the mandate. He presented

¹¹ <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00826>

¹² <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00088>

¹³ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00058>

¹⁴ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00090>



the draft protocol containing ToRs interpretation, the problem formulation, i.e. the translation of the ToRs into assessment questions (AQs) and sub-questions (SQs), where applicable, as well as the methods that will be applied for conducting the assessment. The protocol was approved. The fourth WG meeting will be held on 17 July 2023. The outputs to address the mandate will be two scientific opinions of the BIOHAZ Panel, one with deadline March 2024 and one with deadline December 2024.

6.10. Request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins (EFSA-Q-2023-00105)¹⁵

The EFSA BIOHAW Unit informed the Panel about WG composition and the areas of expertise identified key for this mandate. He also thanked the two panel members who expressed interest to become WG members but were not selected. The work plan was briefly described with the first WG meeting taking place on Monday 17 July 2023 and two more meetings to be held in 2023. Considering the deadline for this mandate is September 2024, and given EFSA decision to transfer TSE mandates from the BIOHAZ Panel to the AHW Panel from 1 July 2024, the thorough reading and adoption of the scientific opinion will be done by the AHW Panel whereas previous discussions including the first reading will be done by the BIOHAZ Panel. The chair of the WG will remain throughout the lifespan of the mandate. It will be discussed internally how to provide information to the AHW panel at earlier stages.

7. New mandates

7.1. Application alternative ECN method tunnel composting (EFSA-Q-2023-00448)¹⁶

The BIOHAW unit informed the Panel of the arrival of a new ABP application submitted by the Belgian competent authority on behalf of the European Compost Network (ECN). It is a revised application of the one evaluated in 2020 with negative result. The dossier is being subject to the completeness check with deadline for validation or request for information of 4 August 2023. The BIOHAW unit also informed the Panel of the tender call launched by EFSA in February 2023 to provide support to EFSA in the risk assessment of alternative methods for the use and disposal of animal by-products and derived products. The framework partnership agreement (FPA) was signed on 10 July 2023 with a consortium of six institutions led by the Universidad Politecnica de Cartagena (Spain). The FPA is for four years and for each application offered to the contractor a specific grant agreement (SGA) will be signed. The BIOHAW unit will inform the Panel of the validation of the application if and when the completeness check is finished.

¹⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00105>

¹⁶ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00448>



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

8.1. Scientific Committee

The BIOHAZ Panel Chair briefly reported the outcome of the last meeting of the Scientific Committee¹⁷, indicating that there were no point of major interest for the BIOHAZ Panel.

8.2. European Commission

EFSA staff from BIOHAZ Unit briefly reminded the Panel about upcoming requests for scientific advice by EFSA in the remit of the BIOHAZ Panel, and about some topics at discussion within the European Commission in relation to past EFSA BIOHAZ Scientific Opinions.

9. Other topics for information and/or discussion

9.1. Implementation of the guidance on uncertainty analysis in scientific assessments

Discussion on this agenda item was postponed to the next plenary meeting.

9.2. Topics of scientific concern in the area of biological hazards and preparedness

EFSA staff from BIOHAZ Unit updated the Panel on the feedback received from the European Commission (DG SANTE) in relation to the ideas collected and discussed at the previous plenaries on possible activities aimed at improving future preparedness to food safety incidents. EFSA will now consider possible activities for the future, using the EFSA Focal Point operational framework 2023-2027.

9.3. Update on EFSA Guidance on protocol development for EFSA's scientific assessments

The WG on Guidance on protocol development for EFSA generic scientific assessments held a web-conference on 26-27 June and 5 July 2023. The comments received through the public consultation of the draft guidance document¹⁸ were addressed. The revised version of the guidance document was approved by the WG and it will be presented for possible adoption at the Scientific Committee meeting on 21-21 September 2023.

9.3. Update on the EMA expert groups on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, and on the establishment of a list of antimicrobials which shall not be used or which may be used subject to certain conditions

Panel member Luisa Peixe updated the Panel on the EMA scientific advice on the establishment of a list of antimicrobials which shall not be used in accordance with

¹⁷ <https://www.efsa.europa.eu/en/events/114th-plenary-meeting-scientific-committee-open-observers>

¹⁸ <https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l09000006qpC7/pc0398>



Articles 112, 113 and 114 of Regulation (EU) 2019/6 or which shall be used in accordance with these articles subject to certain conditions¹⁹, adopted by the EMA Committee for Veterinary Medicinal Products (CVMP) on 15 June 2023.

10. Any other business

No other topic was discussed.

¹⁹ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/scientific-advice-under-art1076-regeu2019/6-establishment-list-antimicrobials-which-shall-not-be-used-accordance-art-112-113-114-which-shall_en.pdf