SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

168th Panel Plenary meeting

13-14 March 2024 09:00-17:45 / 09:00-15:00 MINUTES - Agreed on 27 March 2024



Location: Parma
Attendees:

o Panel Members:

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

Hearing Experts¹:

None

- European Commission and/or Member States representatives:
 EC: Martial Plantady (items 6.4, 6.5, 8.3), Gunilla Eklund (item 7)
- o EFSA:

Angela Botteon, Alessandro Broglia, Sandra Correia, Maria Teresa Da Silva Felicio, Sofia Fusco, Martin Goudjihounde, Beatriz Guerra, Michaela Hempen, Ernesto Liebana, Winy Messens, Angel Ortiz-Peláez, Valentina Rizzi, Mirko Rossi, Maria Sanz Zapata, Eleonora Sarno, Pietro Stella, Frank Verdonck (BIOHAW Unit)

Laura Martino (MESE Unit) (item 6.5), Fulvio Barizzone (MESE Unit) (item 9.1)

Others:None

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

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

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4. Agreement of the minutes of the 167th Panel Plenary meeting held on 24-25 January 2024

The minutes of the 167th Panel plenary meeting were agreed by written procedure on 8 February 2024.

5. Scientific output(s) submitted for adoption/endorsement

No scientific outputs were submitted for adoption or endorsement.

5.1 Scientific opinion on 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 (<u>EFSA-Q-2023-00090</u>)

The last working group (WG) meeting of took place on 1 March (web-conference). The draft scientific opinion was presented for possible adoption. The Chair of the WG presented the changes done since the last plenary. Comments received by the Panel members prior the plenary had been addressed satisfactorily. Minor additional requests were adjusted during the Plenary discussion. A final review of the conclusions, summary and abstract was conducted and the opinion was then adopted by the Panel. A second scientific opinion of the BIOHAZ Panel will be developed to address ToR4- Whether any particular species of wild caught fish originating from specific fishing grounds could be regarded as not representing a health hazard with regards to the presence of parasites of public health importance of the mandate. The deadline for the adoption of this second opinion is December 2024.

5.2 Application alternative method ECN tunnel composting (EFSA-Q-2023-00448)

The WG Chair presented the draft opinion for possible adoption. Minor comments submitted by Panel members before the plenary had been addressed to the satisfaction of the Panel. Minor additional changes were made during the discussion. A final review of the conclusions, summary and abstract was conducted and the opinion was then adopted by the Panel.

6. Scientific Output submitted for discussion

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

The last WG meeting took place on 22 January by web-meeting. No changes since last plenary. Tasks were assigned for next meeting which will be on 22 March by web-meeting. The deadline for adoption of the Scientific Opinion is 31 December 2025.

6.2 Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 20: Suitability of taxonomic units notified to EFSA until March 2024 (<u>EFSA-Q-2021-00772</u>)

The last WG meeting took place on 22 January by web-meeting. Seventy-five notifications were received between October and January 2023 (inclusive): 47 as feed additives, 18 as food enzymes, food additives and flavourings, 10 as novel foods and none as PPPs. From these 75, 21 were not evaluated because belong to taxonomic units excluded from the QPS evaluation

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(10 filamentous fungi, 1 Enterococcus faecium, 9 E. coli and 1 Streptomyces aureofaciens), and 47 belong to taxonomic units that already have a QPS status. Of the remaining 7 notifications, 2 are non-QPS but were just evaluated for a possible QPS status: Serratia marcescens and Weizmannia faecalis. One was notified at genus level so cannot be assessed for the QPS status. The other 4 will be evaluated for a possible QPS status: Akkermansia muciniphila, Microbacterium arborescens, Rhizobium radiobacter (synonym Agrobacterium radiobacter) and Actinomadura roseirufa. The screening at title/abstract level was done with the AI classifiers tool in parallel with an expert. The full-text phase for possible safety concerns was also finalised. Next WG meeting will take place on 22 March by web meeting. The draft Panel statement will be presented for possible adoption before 31 June 2024.

6.3 Scientific opinion on microbiological hazards associated with the use of water in postharvest handling and processing operations of fresh and frozen fruits, vegetables and herbs – parts 2-5 (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)

The last WG meeting took place on 27 February 2024. The WG Chair presented the approach followed by the WG to draft the Fresh-whole FVHS sector-specific opinion, addressing the comments received from the Panel on the current draft. The Panel endorsed the approach followed by the WG and agreed that the other two sector-specific opinions (Fresh-cut FVHs and Frozen FVHs) should also follow the same structure and be developed applying similar data analyses of each sector-specific WASHTOP sub dataset. The Panel also suggested to use an alternative approach to the OR (Odds ratio) analyses, namely CART (Classification and regression trees) which may be more adequate for the WASHTOP dataset and this will be explored. The Chair informed the Panel that the last deliverables from the WASHTOP tender (OC/EFSA/BIOCONTAM/2021/02) were submitted to EFSA on 4 March and the last meeting with all consortium partners to present and discuss their final results will take place on 21-22 March. Some Panel members gave a few comments on the final external scientific report and these will be discussed with WASHTOP. The Panel members may still provide comments on the final deliverables until 18 March. The next WG meeting will be a physical meeting in Parma on 15 to 16 April 2024. The deadline for the adoption of the three sector-specific scientific opinions (Fresh-whole, Fresh-cut and Frozen FVHs) and the "Model" scientific opinion is 31 December 2024.

6.4 Scientific opinion on the public health aspects of *Vibrio* spp. related to the consumption of seafood in the EU (<u>EFSA-Q-2022-00826</u>)

The last WG meeting was held on 13 February 2024 by web-conference. The WG chair presented the draft opinion to the BIOHAZ Panel, apart from the section dealing with the knowledge gaps and the priorities for future research related to *Vibrio* spp. in seafood and aquatic environments. The following sections were presented for possible endorsement: (i) Occurrence of the relevant Vibrio spp. in seafood placed or intended to be placed on the EU market (SQ1.2), (ii) Analytical methods for the detection, enumeration and characterisation of the relevant *Vibrio* spp. in seafood (SQ1.3); (iii) Pathogenicity to humans and virulence factors of the relevant *Vibrio* spp. (SQ1.5); (iv) Antimicrobial resistance in the relevant *Vibrio* spp. isolated from seafood and from seafood-borne infections (SQ1.6-1.7) and (v) Risk assessment modelling options for the health impact of relevant *Vibrio* spp. in seafood in the EU. These were endorsed apart for point (iv). The next WG meeting will be held on 11 April 2024 by web-conference. The deadline for adoption of this Scientific Opinion is 30 June 2024.

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6.5 Scientific report of EFSA on the impact of the proposed revised Australia's microbiological monitoring programme for beef and sheep meat exported to the EU (EFSA-Q-2023-00058)

Since the last plenary meeting, two WG meetings have taken place on 26 February and 12 March. The two independent codes developed by the WG members to assess the impact of the revised program produced similar outputs, meaning that the models are reliable and then are validated for the assessment. The model outputs were presented separately for different combinations of species (beef/sheep), bacteria type (APC/E. coli) and boning system (hot/cold) to reflect the microbiological criteria in the current system and allow a comparison to the proposed one. This led to 5 distinctive models: APC in beef, APC in sheep, E. coli in cold boned beef, E. coli in hot boned beef and E. coli in sheep. The models were presented as number of alerts per 1 million animals over five years. The draft has been submitted for the first reading during this Panel plenary meeting and the comments from the Panel members will be addressed during the next WG meeting on the 8 April. The deadline for this mandate is extended to 30 June 2024.

6.6 Scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins (<u>EFSA-Q-2023-00105</u>)

The WG Chair presented the draft opinion and the probabilistic model for first reading. The layout and contents of the draft opinion were explained following the rationale of the assessment questions of the protocol. The WG Chair went through the comments submitted to the opinion before the plenary and addressed those made during the plenary. It was emphasised by the Panel that the exposure and risk other than via the oral route (food or feed) should not considered by the working group since it is out of the remit of the BIOHAZ panel or EFSA altogether. The use of unpublished data for one parameter of the ovine model was discussed. The chair explained the uniqueness of the data and how they will be applied for a hypothetical model scenario of gelatine produced by ovine bones. It was acknowledged that unpublished data have been used in the context of other scientific opinions. Some Panel members recommended to discuss the validity of the results of the model since some parameters seem to account for variability as well as for uncertainty, and to eliminate model outputs that make inferences at population level. Overall, the Panel agreed with the implementation of the approaches explained in the protocol. The eighth meeting of the working group is scheduled on Monday 8 April 2024 and the ninth on Monday 15 April 2024. Both meetings will take place before the next plenary on 29-30 April 2024, where the draft opinion will be submitted for thorough reading.

6.7 Request for a scientific opinion on the evaluation of the safety and efficacy of peroxyacetic acid (PAA) to reduce microbiological surface contamination on beef carcasses, half carcasses and quarter carcasses (<u>EFSA-Q-2022-00626</u>)

There is no update on this item since the previous plenary meeting.

6.8 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 (<u>EFSA-Q-2024-00020</u>)

The BIOHAZ Panel was provided with an update on the work related to the self-tasking mandate for a revision of the Guidance document 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 intended for human consumption⁴. Of note is that the work on the self-task mandate by the Scientific Committee to deliver an EFSA guidance document on the risk

⁴ https://open.efsa.europa.eu/guestions/EFSA-Q-2024-00020

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assessment of microorganisms used in the food chain to be applied across sectors will be of relevance for the revision of the decontamination guidance document. This is the case for biological substances proposed for the removal of microbial surface contamination of foods of animal origin. A WG meeting will be held on 24 April 2024 by web-conference. The current deadline for adoption by the CEP Panel is end of March 2025.

7. New mandates

7.1 Request for a scientific opinion on the equivalence of an alternative heat treatment process of feathers and down (<u>EFSA-O-2024-00169</u>)

EFSA received a mandate from the European Commission (EC) on 06 March 2024, requesting a scientific opinion concerning the equivalence of the heat treatment process of feathers and down consisting of dry heat to a temperature of 100°C or higher for at least thirty (30) minutes, with the treatment set up in Chapter VII, Point C of Annex XIII to Regulation (EU) No 142/2011, in terms of inactivation of relevant pathogens. The background and mandate were presented to the BIOHAZ Panel, and it was decided to assign it to the BIOHAZ WG on applications for alternative methods of use or disposal of animal by-products or derived products. After informing the Panel and in consultation with the BIOHAZ Panel Chair, Alessandra De Cesare was nominated Vice-Chair of the Working Group and will take care of chairing the meetings related to this mandate. EFSA will deliver the output by 31 January 2025.

7.2 Self-task mandate of the BIOHAZ panel on the current status of the occurrence and spread of carbapenemase-producing Enterobacterales in the food chain in the EU/EFTA (<u>EFSA-Q-2024-00149</u>)

After a request from the BIOHAZ Panel, EFSA approved on 19 February a self-task Mandate for the assessment on the "Current status of the occurrence and spread of carbapenemase-producing Enterobacterales in the food chain in the EU/EFTA". The EFSA BIOHAW Unit 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, Luisa Peixe was nominated Chair of the Working Group. Deadline for the Mandate is 30 June 2027.

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

8.1 Scientific Committee

EFSA Staff from the BIOHAW Unit updated the Panel about the presentation of the BIOHAZ work programme made by the BIOHAZ Panel Chair at the last Scientific Committee meeting on 5-6 February 2024⁵.

8.2 European Commission

EFSA Staff from the BIOHAZ Unit updated the Panel in relation to recent changes in European Commission DG SANTE staff responsible for topics related to the BIOHAZ area.

8.3 Update on Rapid Outbreak Assessments and related activities

⁵ https://www.efsa.europa.eu/it/events/117th-plenary-meeting-scientific-committee

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EFSA staff from the BIOHAW Unit presented the latest published report on the assessment of a prolonged multi-country clusters of Listeria monocytogenes ST155 infections linked to ready-to-eat fish products. The event background was followed by the description of the food investigation and the joint EFSA-ECDC assessment⁶.

9. Other topics for information and/or discussion

9.1 Implementation of the guidance on uncertainty analysis in scientific assessments

BIOHAZ Panel member Maarten Nauta presented to the Panel the results of a questionnaire submitted to BIOHAZ Panel, WG and EFSA staff in order to gather views on the implementation of uncertainty analysis in BIOHAZ mandates. The Panel had a discussion on the results of the questionnaire, with specific focus on a number of topics, i.e. positive and negative experiences in implementing the uncertainty guidance, possible reasons for implementing it or not and on the extent of implementation, the feedback from and communication with risk managers on the implementation of uncertainty analysis and on how to make use of expression of uncertainty when translating risk assessments into risk management measures, use of quantitative expression of uncertainty and possible use of expert elicitation during the process. The presentation included a preliminary version of an internal decision tree/guidance for use by the Panel to guide the selection of the most appropriate option for carrying out uncertainty analysis in BIOHAZ assessments. The discussion will continue during the next Plenary meeting.

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

No specific topics were raised by BIOHAZ Panel members. EFSA staff from the BIOHAW Unit indicated that EFSA colleagues from KNOW Unit might be joining one of the next plenary meetings to update the Panel on possible emerging risks discussed during the last meetings of the Emerging Risks Exchange network (EREN) and of the Stakeholder Discussion Group on Emerging Risks (StaDG-ER).

9.3 Presentation on the EU Summary Report on surveillance for the presence of transmissible spongiform encephalopathies in 2022

EFSA Staff from the BIOHAW Unit presented the main findings of the EU Summary Report on TSE for year 2022⁷, published on 28 November 2023. It includes data 27 Member States (MS, EU27), the United Kingdom (in respect of Northern Ireland) and other eight non- EU reporting countries. A Dashboard⁸ is available, allowing to explore and visualise TSE surveillance data. A TSE story map⁹ was developed, explaining what TSE are and the main measures put in place in the EU to monitor and control these diseases. Both are available via links in the report.

10. Any other business

EFSA informed the Panel of a few topics:

- the recent signature of a direct contract under the call OC/EFSA/BIOHAW/2023/01 on the "Role of water used in the growing, handling and processing of fruits, vegetables and herbs

⁶ https://www.efsa.europa.eu/en/supporting/pub/en-8538

⁷ https://www.efsa.europa.eu/en/efsajournal/pub/8384

⁸ https://www.efsa.europa.eu/en/microstrategy/tse

https://storymaps.arcgis.com/stories/0b1c91eddf814f5993d72335b6be8f41

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on the spread of antimicrobial resistance (AMR)". The granted project, WATERRESIST, will take place over 36 months from the kick-off meeting (planned for mid-April 2024). The contractor is the Agencia Estatal Consejo Superior de Investigaciones Científicas (CSIC) in consortium with RIVM, UGent, University of León, DTU, and Universidade de Porto;

- the progress in the organisation of a scientific session at the conference FoodMicro2024, related to the topic of persistence of bacteria in food and feed processing environments;
- some ongoing public consultations on draft outputs of the Scientific Committee and the NDA Panel;
- the possibility for experts to receive a daily media review prepared by EFSA;
- the organisation of a meeting on 18 March 2024 by EFSA's Knowledge and Innovation Communities on Biotechnology and Environmental Risk Assessment, during which the outcomes of the outsourced Gut (human and animal) and Environmental Microbiome Project will be presented.