

6-7 December 2023

09:00-17:30 / 09:00-15:30

MINUTES - Agreed on 20 December 2023

**Location:** Parma and webconference

**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, Romolo Nonno, Giuseppe Ru, Luisa Peixe, Marion Simmons, Panagiotis Skandamis (web), Elisabetta Suffredini (web)

o Hearing Experts<sup>1</sup>:

Not Applicable

o European Commission and/or Member States representatives:

None

o EFSA:

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

Montserrat Anguita, Rosella Brozzi (FEED Unit)

o Others:

Observers (see Annex I)

## 1. Welcome and apologies for absence

Apologies were received from Panel member Maarten Nauta.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>3</sup> 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.

<sup>1</sup> 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/en/keydocs/docs/expertselection.pdf>

<sup>2</sup> [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/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## 4. Brief introduction of Panel members to Observers

The BIOHAZ Panel members and EFSA staff briefly introduced themselves to the observers.

## 5. Presentation of the EFSA Guidelines for Observers

EFSA BIOHAZ Secretariat 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 165<sup>th</sup> Panel Plenary meeting held on 25-26 October 2023 by webconference

The minutes of the 165<sup>th</sup> Panel plenary meeting were agreed by written procedure on 9 November 2023.

## 7. Scientific output(s) submitted for adoption/endorsement

### 7.1 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)<sup>4</sup>

Last working group (WG) meeting took place on 7 November in Parma. Seventy-one notifications were received between April and September 2023 (inclusive): 30 as feed additives, 22 as food enzymes, food additives and flavourings, 7 as novel foods and 12 as PPPs. From these 71, 61 were not evaluated because they belong to taxonomic units excluded from the QPS evaluation (26 filamentous fungi, 1 *Enterococcus faecium*, 5 *E. coli* and 1 bacteriophage), and 28 belong to taxonomic units that already have a QPS status. The remaining 10 notifications, corresponding to 9 TUs, were evaluated for a possible QPS status: *Serratia marcescens* (2 notifications), *Weizmannia faecalis*, *Clostridium tyrobutyricum*, *Burkholderia ubonensis*, *Ensifer adhaerens*, *Candida oleophila*, *Pseudomonas putida*, *Chlamydomonas reinhardtii* and *Klebsiella pneumoniae*. The summaries of the extensive literature search (ELS) for potential safety concerns related to the QPS list TUs were finalised. The revised draft Panel statement was presented to the BIOHAZ Panel for possible adoption. The WG Chair went through the various comments received and the Panel statement was adopted by the BIOHAZ Panel.

One observer had submitted the following question in advance of the meeting: “*Since the latest revision of the QPS (EFSA BIOHAZ, 2023), we have observed additional relevant taxonomic changes at species level that have not been included as updates. Please advise us on the appropriate procedure or guidelines for submitting relevant information for the incorporation of these taxonomic changes into the QPS list*”. The Panel thanked for the relevant question concerning the improvement of the way EFSA revises the QPS microorganisms’ taxonomy. The BIOHAZ Panel/QPS WG are going to evaluate it in the near future, and then IPA Europe will be informed in due time of the outcome.

One observer made a question concerning the AI exercise for screening the potential safety concerns in relation to the QPS list microorganisms, asking whether EFSA is going to share the details of the AI methodology used. The BIOHAZ Panel and staff replied that the new AI procedure is still being evaluated but as soon as it is implemented, the procedure followed is going to be explained for the sake of the transparency of the process within the relevant QPS statements/opinions published.

<sup>4</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00771?search=EFSA-Q-2021-00771>



## **7.2 Scientific opinion on the persistence of microbiological hazards in food and feed production and processing environments (EFSA-Q-2022-00217)<sup>5</sup>**

The last WG meeting was held on 15 and 20 November by web-conference. The comments from the BIOHAZ Panel were discussed during this last WG meeting and the scientific opinion was finalised. The revised draft scientific opinion was shared with the BIOHAZ Panel for possible adoption. The WG Chair went through the various comments requiring a discussion with the BIOHAZ panel, and the presented answers to the terms of reference (ToRs), recommendations and abstract. The scientific opinion was adopted by the BIOHAZ Panel.

## **8. Scientific Output submitted for discussion**

### **8.1 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)<sup>6</sup>**

Last WG meeting took place 7 November in Parma. There was no further development since the last plenary. The next WG meeting will be at the end of January by web meeting. The QPS opinion document will be presented to the BIOHAZ Panel for possible adoption in December 2025.

### **8.2 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<sup>7</sup>, EFSA-Q-2023-00074<sup>8</sup>, EFSA-Q-2023-00075<sup>9</sup> and EFSA-Q-2023-00076<sup>10</sup>), including associated outsourcing activities (OC/EFSA/BIOCONTAM/2021/02)**

The last WG meeting took place on 29 November 2023 afternoon online. The WG Chair presented the progress of work made by the WASHTOP consortium in the context of the ongoing tender with EFSA. The Panel agreed with the new layout for recategorized and colour coded boxplots that WASHTOP will provide in their final deliverable. WASHTOP took more time to correct and complete the raw data Excel file than what was expected, and this had an impact on the progress of the modelling work as well as on the tasks allocated in the WG. The next WG meeting will be a web meeting on 10 and 11 January 2024 afternoon. The WG Chair also presented the progress made with the discussion with the WG about the contents of the three sector-specific scientific opinions (Fresh-whole, Fresh-cut and Frozen FVHs) and the Model scientific opinion. 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.

### **8.3 Scientific opinion on the public health aspects of *Vibrio* spp. related to the consumption of seafood in the EU (EFSA-Q-2022-00826)<sup>11</sup>**

The last WG meeting was held on 5 December 2023 in Parma. The WG chair presented some more advanced sections of the draft opinion with the BIOHAZ panel. The next WG meeting

<sup>5</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00217?search=EFSA-Q-2022-00217>

<sup>6</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00054?search=EFSA-Q-2023-00054>

<sup>7</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00073?search=EFSA-Q-2021-00771>

<sup>8</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00074?search=EFSA-Q-2023-00074>

<sup>9</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00075?search=EFSA-Q-2023-00075+>

<sup>10</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00076?search=EFSA-Q-2023-00076>

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



will be held on 10 January 2024 by web-conference. The deadline for adoption of this Scientific Opinion is 30 June 2024.

#### **8.4 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)<sup>12</sup>**

The last WG meetings were held on 8 and 20 November 2023. The WG chair updated the panel on the answers provided by the Australian's Authority to the WG questions, and also about the progress of the different simulation models for APC, *E. coli* and *Salmonella* to compare the current and proposed monitoring programs. In light of the answers provided by the Australian Authority on converting carcasses into bulk meat, primal and offal, the WG decided to carry out a complete analysis including the data from bulk meat, primal cuts and offal. An additional model will be developed to include these (bulk meat, primal and offal) in the estimation of the average annual number of alerts. All models are still under preparation and the next WG meeting will be the occasion to validate the model which will be used for the assessment of the proposed program. The next WG meeting is scheduled on 29<sup>th</sup> January 2024. The deadline for this mandate is extended to 30 June 2024.

#### **8.5 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 (EFSA-Q-2023-00090)<sup>13</sup>**

The last WG meeting of took place on 14 November (web conference). The draft scientific opinion was presented for first reading. The Chair of the WG presented the developments since the last plenary with regards to ToR1: main EU/EFTA aquaculture finfish species, parasites of public health importance, and data on the occurrence of those parasites in the finfish species considered; ToR2: update on the diagnostic/detection methods since 2010; and ToR3: update on the methods/treatments available or under development for the inactivation or removal of those parasites. Comments received from the Panel members were discussed. Data on production and consumption of the fish species were considered to be part of the ToR1-assessment instead of the introduction. Conclusions, uncertainties and recommendations will be further developed at the next WG meeting that will take place on 13-14 December in EFSA premises, and the WG meeting on 12 January. The draft opinion will be presented for thorough reading at the next BIOHAZ Panel Plenary meeting. 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.

#### **8.6 Scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins (EFSA-Q-2023-00105)<sup>14</sup>**

The Chair of the WG presented the draft protocol for the first time. Comments by Panel members made before the plenary had already been addressed except one about the implementation of the uncertainty guidance in the last assessment question. There were no major comments during the plenary. The WG Chair informed of the discussions on the possible submission for adoption in June 2024, three months before the agreed deadline. The decision will be made in the next WG meeting that will take place on Monday 11 December 2023. The protocol will be submitted for approval to the BIOHAZ Panel at the January 2024 plenary. The possibility of conducting an informal/semi-formal EKE to produce final conclusions has not been discussed. The fifth meeting is scheduled for Monday 15 January 2024.

<sup>12</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00058?search=EFSA-Q-2023-00058>

<sup>13</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00090?search=EFSA-Q-2023-00090>

<sup>14</sup> <https://open.efsa.europa.eu/questions?search=EFSA-Q-2023-00105>



### **8.7 Application alternative method ECN tunnel composting (EFSA-Q-2023-00448)<sup>15</sup>**

This agenda item was dealt within the closed session of the plenary meeting (no participation of observers).

The WG Chair presented the draft opinion for the first time. He informed of the support provided by the contractor in the production of the draft opinion, following the framework contract signed with EFSA. The WG Chair highlighted the main difference between the application submitted in 2019 and this one, i.e., the demonstration of inactivation at the required level of thermoresistant virus identified as potential hazards in the material to be treated. For the sections similar to the previous opinion, they will be replicated without changes. The second WG meeting will take place on Friday 12 January 2024, in which a more updated version of the draft opinion will be discussed, and then presented to the BIOHAZ Panel for thorough reading.

### **8.8 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 (EFSA-Q-2022-00626)<sup>16</sup>**

This agenda item was dealt with within the closed session of the plenary meeting (no participation of observers).

EFSA staff from the BIOHAW Unit informed that a request for additional information was sent to the applicant on 17 November 2023 and the scientific evaluation suspended. The initial deadline to deliver the Scientific Opinion of 11 September 2024 will be extended accordingly. The BIOHAZ panel was informed that the CEP Panel identified the need to update the Guidance on the Evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption, to specify in more details the data and information to be provided by the applicants, according to the latest EFSA guidance documents, especially in relation to the toxicological and ecotoxicological risk assessment. The BIOHAZ panel agreed it is a good opportunity to revise certain aspects based on the lessons learned and experience obtained by the dossiers assessed so far. A request for a self-task mandate is being initiated. The WG on the evaluation of substances used to remove microbial contamination from products of animal origin will deal with this mandate.

## **9. New mandates**

No new mandates were received since the previous Plenary meetings.

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

### **10.1 Scientific Committee**

The BIOHAZ Panel Chair briefly reported the outcome of the last meeting of the Scientific Committee<sup>17</sup>. In particular, he reported the discussions held during one agenda item about “the future of risk assessment: holistic approaches, challenges and possibilities”, where both

<sup>15</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00448?search=EFSA-Q-2023-00448%29+>

<sup>16</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00626?search=EFSA-Q-2022-00626>

<sup>17</sup> <https://www.efsa.europa.eu/en/events/116th-plenary-meeting-scientific-committee>



BIOHAZ chair and BIOHAZ staff delivered some presentations. The discussion on such topic is expected to continue in future meetings of the Scientific Committee.

## **10.2 European Commission**

No new feedback or information has been received from the European Commission about upcoming mandates or other relevant topics for discussion in addition to what indicated at the previous Plenary meeting.

## **10.3 Update on Rapid Outbreak Assessments and related activities**

EFSA staff Eleonora Sarno presented the latest published report on the assessment of a multi-country outbreak of three clusters of *Salmonella* Enteritidis ST11 infections linked to chicken meat and chicken meat products. The event background was followed by the description of the food investigation and the joint EFSA-ECDC assessment<sup>18</sup>.

## **10.4 Update of the Guidance on the characterisation of microorganisms used as feed additives or as production organisms**

This agenda item was dealt with within the closed session of the plenary meeting (no participation of observers).

The BIOHAZ Panel was informed by EFSA staff from the FEED Unit about the following EFSA activity. EFSA conducts the risk assessment of microorganisms that are used in the food chain for different purposes. The assessments are linked to requests for authorisation of the products under the applicable Regulation/s; the products evaluated may contain the microorganism, be prepared from, or obtained with the microorganism, and the microorganisms can be genetically modified or not. EFSA considers it necessary to have one scientific guidance document detailing the requirements for the risk assessment of microorganisms that could be applied across sectors. As the Scientific Committee plays a major role in harmonising practices across areas, it was proposed to the Scientific Committee to prepare a guidance document on the risk assessment of microorganisms used in the food chain to be applied across sectors. The Scientific Committee agreed on the proposal and a self-task will be prepared. At this regard, it is intended that the WG on microbiology from the FEEDAP Panel with experts from other Panels will prepare the draft guidance for the consideration of the relevant EFSA Panels and finally for the endorsement and adoption by the Scientific Committee.

# **11. Other topics for information and/or discussion**

## **11.1 Implementation of the guidance on uncertainty analysis in scientific assessments**

Following up from the agreement taken at the September plenary meeting about the development 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 BIOHAZ Panel Chair and Secretariat presented to the Panel the plan for developing such internal document in the first half of 2024.

One observer asked to the Panel whether such decision tree/guidance is expected to be published when completed. EFSA Secretariat indicated that so far this is only expected to be an internal repository and reflection on the practices used within the BIOHAZ Panel to

---

<sup>18</sup> <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2023.EN-8388>





address uncertainty analysis in its assessments, and therefore is not expected to generate any published document or addition to the current EFSA guidance on uncertainty analysis in scientific assessments.

### **11.2 Topics of scientific concern in the area of biological hazards and preparedness**

Following from the discussions at the previous Plenary meeting, EFSA staff from BIOHAW Unit informed the Panel about the progress in drafting a self-task from the BIOHAZ Panel to address the topic of emerging resistance to carbapenems in *E. coli* isolated from food-producing animals and food in various EU countries. A draft self-task mandate prepared in collaboration with a Panel member was presented in detail to the Panel. The mandate would aim at collecting information from European countries on recent and planned scientific investigations on the topic, at designing and carrying out a number of additional studies to produce relevant data in addition to the ones already being collected through the EU Summary Report on Antimicrobial Resistance (AMR), and at drawing conclusions from such new data and from any other source in the scientific literature that would update the information reported in a previous EFSA BIOHAZ Scientific Opinion on Carbapenem resistance in food animal ecosystems, published in 2013. The work is expected to be carried out in close collaboration with the European and National Reference Laboratories for AMR, and with ECDC. The European Commission and ECDC will be consulted on the draft self-task mandate. Comments on the draft mandate were gathered from the BIOHAZ Panel. The draft mandate will be revised accordingly and presented for possible agreement by the BIOHAZ Panel in January 2024.

## **12. Answers to questions from observers**

No additional questions were posed by Observers in addition to the ones reported above under agenda items 7.1 and 11.1. Observers were reminded that further questions can be also submitted, at any time, through the “Ask EFSA a question” service, on EFSA website<sup>19</sup>. The Observers were informed that after the meeting they will receive a survey to gather feedback about their participation in the BIOHAZ open plenary.

## **13. Any other business**

As a follow-up of information provided at the previous plenary meeting, EFSA Staff from the BIOHAW Unit informed the Panel about an upcoming Panel feedback survey, used by EFSA to gather comments from experts on their experience as Panel members during years 2018-2024. EFSA Secretariat Panel was informed that in 2024 the January and April plenary meetings will be held as webconferences, while the March and June plenary meetings will be held as physical meetings in Parma.

---

<sup>19</sup> <https://connect.efsa.europa.eu/RM/s/askefsa>



### Annex I List of Observers

15 observers registered, 10 observers attended.

<b>Observer</b>	<b>Organization</b>
Anja Buschulte	German Federal Institute for Risk Assessment
Aarieke De Jong	Netherlands Food and Consumer Product Safety Authority (NVWA)
Stefanie Geiser	EAS Strategies
Pauline Kooh	ANSES
Yeonkyu Lee	CJ CheilJedang Corporation
Rosanna Pecere	IPA Europe - Probiotic Association Europe
Giovanna Soviero	Self-employed
Mélanie Terro	ANSES
Giulia Ventura	ASSOCARNI
Marc Vermeulen	Cefic