

23-24 October 2024

09:00-18:00 / 09:00-15:00

MINUTES - Agreed on 7 November 2024

**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 Perez-Rodriguez, Panagiotis Skandamis, Elisabetta Suffredini

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

Declan Bolton (item 6.4), Romolo Nonno (item 6.8)

o European Commission and/or Member States representatives:  
Kris De Smet(EC DG SANTE)

## o EFSA:

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

Montserrat Anguita, Rosella Brozzi (FEED Unit)

Georgia Gkritzali (KNOW Unit)

Laura Martino (MESE Unit)

## o Others:

None

## 1. Welcome and apologies for absence

Apologies were received from Lapo Mughini-Gras for absence during part of the meeting on 24 October.

## 2. Adoption of agenda

The agenda was adopted without changes. However, it was clarified that since the draft scientific opinion related to parasites in fishery products (agenda item 6.4) was at a very advanced stage, it might be considered also for possible adoption at this plenary meeting.

## 3. Declarations of Interest

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

<sup>1</sup> 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>

<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)



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 172<sup>nd</sup> Panel Plenary meeting held on 18-19 September 2024

The minutes of the 172<sup>nd</sup> Panel plenary meeting were agreed by written procedure on 3 October 2024.

## 5. Scientific outputs submitted for adoption/endorsement

### 5.1 EFSA Guidance on the risk assessment of microorganisms used in the food chain ([EFSA-Q-2022-00249](#))

This question refers to a self-task of the Scientific Committee of EFSA to prepare a guidance on the characterisation of microorganisms used in the food chain. The Panel was informed that following the consultation of the relevant Scientific Panels, no major comments were received. An overview of the comments was given to the Panel and some discussion took place. The Panel endorsed the document which will be proposed for endorsement by the Scientific Committee, prior to public consultation.

## 6. Scientific outputs 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 ([EFSA-Q-2023-00054](#))

The last meeting of the WG dealing with QPS-related items was held on 22 October. The different sections of the draft opinion are being prepared and discussed by the QPS WG. The deadline for adoption of this opinion is 31 December 2025.

### 6.2 Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA. 21: Suitability of taxonomic units notified to EFSA until September 2024 ([EFSA-Q-2021-00773](#))

The last meeting was held on 22 October in Parma. An extra meeting was organised to work on the QPS status assessment of *Bacillus thuringiensis* on 8 October. 54 notifications were received between April and September 2024 (inclusive): 33 as feed additives, 17 as food enzymes, food additives and flavourings, 4 as novel foods and none as PPPs. From these 54, 21 were not evaluated because they belong to taxonomic units excluded from the QPS evaluation (12 filamentous fungi, 1 *Enterococcus faecium*, 8 *E. coli*), and 29 belong to taxonomic units that already have a QPS status. Two of the remaining 4 notifications were already assessed before: *Ensifer adhaerens* (assessed within PS 19), which will not be included now, and *Enterococcus lactis* (assessed within PS 15), which will be re-assessed for QPS status. The other 2, corresponding to 2 TUs, are being evaluated for a possible QPS status: *Serratia plymuthica* and *Lacticaseibacillus huelsenbergensis*. The ELS was finalised and its summaries were included in the text of the draft statement. An ELS concerning a possible QPS status for *B. thuringiensis* QPS status was developed, and the evaluation of the possible safety concerns found is being prepared by the experts. The document was presented for thorough reading. The deadline for adoption of the statement is 31 December 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 2-3 October 2024. The three 'sector-specific draft opinions for Fresh-whole, Fresh-cut and Frozen FVHs (Parts 3 to 5)' as well as the 'model draft opinion' were tabled for discussion. The most critical points raised by the Panel were listed in a presentation and discussed with all in order to reach the relevant agreements. The comments received on the Annex on the 'multivariable logistic regression model' used across all sector-specific opinions were also discussed with the Panel and Laura Martino from EFSA MESE Unit will implement a few comments that require some actions in the Annex. A brief summary of the feedback collected from the Panel members testing the prototype of the R Shiny app was presented and the deadline for collection of more feedback on the R Shiny app was extended until 30 October. The next WG meeting will take place on 30 October 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 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 – addressing term of reference 4 ([EFSA-Q-2023-00172](#))**

As clarified when adopting the agenda (see agenda item 2), this draft opinion was considered for possible adoption at this plenary meeting. The WG chair presented the draft opinion, addressing comments raised by panel member. There were only minor clarifications requested concerning the exact wording of the conclusions, recommendations and abstract. After short discussion, the draft opinion was adopted by the BIOHAZ panel.

**6.5 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](#))**

The BIOHAZ Panel was informed about a change of the Chair of the WG on the evaluation of substances used to reduce microbial contamination from products of animal origin. Cristina Croera (EFSA staff) has been nominated WG Chair by the head of the FIP Unit and Winy Messens (EFSA staff) has been nominated vice-Chair by the head of the BIOHAW Unit; both of them in consultation with the Chair of the respective Panels (FCM Panel and BIOHAW Panel). The last WG meeting was held on 15 October 2024. The WG vice-Chair presented the draft opinion to the BIOHAZ Panel for thorough reading. The Panel agreed that to date the only biological agents would be bacteriophages. The sections dealing with the safety assessment have been reorganized. For biological agents, it has been clarified what requirements are needed for a bacteriophage and/or its production strain. In the efficacy section, it was agreed that a proper control would be a treatment with water, unless the decontamination treatment would not replace a water treatment (e.g. treatment of RTE food) or when the treatment is not applied as a liquid with run-off. Most changes for clarification were requested in the section dealing with reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials. Amongst others, clarification of the interpretation of the absence of concerns and improved differentiation of pre- and post-application are requested. No comments were made in the section dealing with environmental risk assessment. The next WG meeting will be held on 26 November 2024. The current deadline for endorsement by the BIOHAZ and FCM Panels, followed by public consultation, is the end of December 2024.



**6.6 Scientific opinion(s) on the current status of the occurrence and spread of carbapenemase-producing Enterobacterales in the food chain in the EU/EFTA ([EFSA-Q-2024-00149](#))**

The WG Coordinator and EFSA staff updated the Panel on the developments since the last Plenary. The last WG meeting was held on 10 October, and the next meeting will be held on 11 November. The targeted EU-surveys to collect information from the MSs/EFTA countries on on-going studies, positive findings, detection methods in use and existing control measures/contingency plans are being finalized. The Monopole Framework Partnership Agreement (FPA) with EU and National Reference Laboratories on antimicrobial resistance for the production of data related to testing protocols, for the performance of epidemiological investigations, for in depth genetic analyses of relevant resistant isolates (2024-2026), and for genomic comparison of isolates from different sources, should enter into force soon. The Part 1 scientific opinion is being further developed by the WG and is expected to be presented for adoption by the Panel by March 2025. The duration of the whole mandate is up to the end of June 2027.

**6.7 Scientific opinion on the equivalence of an alternative heat treatment process of feathers and down ([EFSA-Q-2024-00169](#))**

The last WG mtg was held on 3 October 2024. The next WG meeting will be held on 18 November. The data extracted by the experts (DistillerSR and Excel) were split into data sets (different products/temperature/times/aw). The WG went through the data extracted and discussed the preliminary analysis already included in the text. It was decided not to carry out an expert knowledge elicitation (EKE) but to conclude on the uncertainty in conclusions based on expert consensus judgment. The deadline for the adoption of this opinion is 31 January 2025.

**6.8 Scientific opinion on the presence of biological and chemical hazards in ash from Category 1 material after incineration, co-incineration, and combustion ([EFSA-Q-2024-00278](#))**

The WG Chair presented the protocol for possible approval. There were minor comments on the wording of the amended assessment questions to harmonize the terminology used and improve their clarity. Eventually the Panel did not agree with the potential formulation of the outputs of the opinion nor with the integration of the evidence and the uncertainty analysis. For the former, it was questioned the usefulness of the potential formulation of the answer to this opinion to address the question on whether the second opinion should be produced. It was agreed to call a meeting with the EC to explain the approach described in the protocol and agree on the how the answer would be formulated. On the latter, the protocol proposed an EKE for the certainty on the level of infectivity reduction measured in log10, but the Panel proposed to use the EKE question to extract from the experts the minimum reduction with the associated quantitative estimation of the uncertainty. These two points will be taken back to the WG in the next meeting that will take place on 25 November. The protocol will be resubmitted for possible approval to the BIOHAZ Panel in December.

**6.9 Application for alternative processing method for animal by-products: alkaline hydrolysis under atmospheric pressure ([EFSA-Q-2024-00286](#))**

The WG Chair presented the draft opinion for first reading. He went through the comments provided by the Panel members, some of them already addressed before the plenary. The main point for discussion was the evidence to demonstrate the level of risk reduction. The WG Chair read the preliminary conclusions that were well received by the BIOHAZ Panel. In the next plenary, the draft opinion will contain summary and abstract and will be submitted for thorough reading or adoption, depending on the agenda of the meeting. The non-confidential



version of the dossier still needs to be subject for public consultation once the confidential claim assessment is finished. The deadline for delivery of the opinion is 20 February 2025.

#### **6.10 Application for fluidized catalytic cracking co-processing for the production of renewable fuels ([EFSA-Q-2024-00539](#))**

There were no major points to report. The WG Chair informed that the first WG meeting will take place on 25 November and the first draft of the opinion will be delivered by the contractor on 11 November. The first draft of the opinion will be submitted to the next plenary in December 2024 for the first time.

#### **6.11 Update of the scientific opinion 'Evaluation of the safety and efficacy of ListexTM P100 for reduction of pathogens on different ready-to-eat (RTE) food products' ([EFSA-Q-2024-00551](#))**

EFSA staff from the BIOHAW Unit informed the Panel that a request for information was sent to the applicant on 25 October 2024. The deadline to respond is 24 November 2024. Hence, the dossier has not been yet considered valid.

### **7. New mandates**

#### **7.1 Request for a scientific opinion on the microbiological safety of ungulates meat intended to be frozen**

EFSA staff from the BIOHAW Unit informed the Panel that a new request for a scientific opinion on the microbiological safety of ungulates meat intended to be frozen was received in EFSA from the European Commission on 18 October 2024. The background to the mandate and the terms of reference were presented and discussed with the Panel and with SANTE representative.

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

#### **8.1 Scientific Committee**

The Panel Chair briefly reported to the BIOHAZ Panel the main topics discussed within the 121<sup>st</sup> Plenary meeting of the Scientific Committee (SC), taking place on 18 October 2024<sup>4</sup>. The Panel briefly discussed few possible ideas to be transmitted to the SC in preparation of their upcoming discussion on the SC work programme 2026-2027. EFSA BIOHAZ Secretariat will further assess the proposed ideas and if relevant finalise them with selected Panel members and transmit them to the SC.

#### **8.2 European Commission**

The Panel coordinator updated the Panel on the possible future attendance by EC DG SANTE to BIOHAZ Plenary meetings.

<sup>4</sup> <https://www.efsa.europa.eu/en/events/121st-plenary-meeting-scientific-committee>



### **8.3 Update on the activities of the EFSA Scientific Network on Microbiological Risk Assessment**

The Panel was briefly updated about the last meeting of the EFSA Scientific Network on Microbiological Risk Assessment, which took place on 8 and 9 October 2024<sup>5</sup>.

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

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

Relevant issues related to uncertainty analysis in specific mandates were tackled during the respective discussions in previous agenda items. No additional discussion took place.

### **9.2 Topics of scientific concern in the area of biological hazards, including an update from EFSA on the activities of the Networks dealing with emerging risks**

EFSA Staff from the KNOW Unit introduced to the Panel the activities of the EFSA Emerging Risks Exchange (EREN) Network and of the EFSA Stakeholder Discussion Group on Emerging Risks (StaDG-ER), and the process and criteria used to identify emerging risks. A number of topics in the area of biological hazards discussed during recent Network meetings were presented (*Providencia* spp. in food, *Arcobacter* risk to the food industry and human health, colistin resistance, global spread of *Angiostronglus cantonensis*, Aichivirus, vertical transmission of *Salmonella* Reading, public health risk associated to raw meat-based diets (RMBD) for cats and dogs, Q fever).

## **10. Any other business**

EFSA BIOHAW Staff reminded the Panel that the next BIOHAZ Plenary meeting (4-5 December 2024) will be open to observers and explained how participation and interaction with observers is expected to take place.

<sup>5</sup> <https://www.efsa.europa.eu/en/events/25th-meeting-efsa-network-microbiological-risk-assessment>