

18-19 September 2024

09:00-17:00 / 09:00-17:00

MINUTES - Agreed on 3 October 2024

**Location:** Web-Conference**Attendees:**

## o Panel Members:

Ana Allende, Avelino Alvarez-Ordóñez, 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, Gunilla Eklund (EC DG SANTE)

## o EFSA:

Angela Botteon, Sandra Correia, Maria Teresa Da Silva Felicio, Elisabeth Dottolo, 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)

Alexandros Georganas, Georgia Gkrintzali (KNOW Unit)

## o Others:

None

**1. Welcome and apologies for absence**

Apologies were received from Valeria Bortolaia.

**2. Adoption of agenda**

The agenda was adopted without changes.

**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 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 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)



## 4. Agreement of the minutes of the 171<sup>st</sup> Panel Plenary meeting held on 2-3 July 2024

The minutes of the 171<sup>st</sup> Panel plenary meeting were agreed by written procedure on 17 July 2024.

## 5. Scientific outputs submitted for adoption/endorsement

No scientific outputs were submitted for adoption/endorsement.

## 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 2 September 2024 and the next one is scheduled for 25 September 2024. The different sections of the draft opinion are being prepared and discussed by the QPS experts. The draft opinion will cover different aspects dealt by the experts within this QPS 3-years cycle (e.g. the revision of the Taxonomic unit nomenclature and on the publication of a Panel Statement on the "Interpretation of the QPS qualification on 'acquired antimicrobial resistance genes'"). Other aspects dealt by this document will be: "QPS and the new genetic techniques and synthetic microbiology" and the "Safety of strains in relation to the gut environment and its application in the QPS concept". The deadline for 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 of the WG dealing with QPS-related items was held on 2 September 2024 and the next one is scheduled for 25 September 2024. The work for the new QPS Panel statement (part 21) was launched last July. 49 notifications were received between April and September 2024 (inclusive): 31 as feed additives, 15 as food enzymes, food additives and flavourings, 3 as novel foods and none as PPPs. From these 49, 21 were not evaluated because belong to taxonomic units excluded from the QPS evaluation (12 filamentous fungi, 1 *Enterococcus faecium*, 8 *E. coli*), and 24 belong to taxonomic units that already have a QPS status. The other 4 notifications belong to 4 TUs that have no QPS status. Two of them were already evaluated for a possible QPS status in previous Panel Statements: *Ensifer adhaerens* (Panel statement part 19), and there is no need to assess them again in the current statement, and *Enterococcus lactis* (Panel statement part 15), to be assessed within this Panel Statement as the previous assessment was done within the previous 3-years QPS cycle. The other 2 TUs were notified for the first time and therefore will be assessed for a possible QPS status in this Panel Statement: *Serratia plymuthica* and *Lacticaseibacillus huelsenbergensis*. *Bacillus thuringiensis* will be re-assessed for a possible QPS status in response to an internal request. The current QPS ELS is now at the full text phase. A specific ELS concerning a possible *B. thuringiensis* QPS status is being developed by the experts. A dedicated WG meeting will be organised on 9 October. The document was presented for first reading. The deadline for this Panel 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 September 2024. Three 'sector-specific draft opinions for Fresh-whole, Fresh-cut and Frozen FVHs (Parts 3 to 5)', the 'model draft opinion', as well as annex A, 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 Panel endorsed the layout and content of all figures and tables included across the four draft opinions tabled for discussion. The Panel also provided some comments on the annex describing the multivariable logistic regression model used across all sector-specific opinions and this feedback will be shared with Laura Martino from MESE who developed this model. The EC also participated at the discussion and provided relevant comments which will be presented and discussed with the WG members during their next meeting.

The Panel was informed that two Individual Scientific Advisor (ISA) contractors are currently developing a R Shiny app based on the R code of the model provided by WASHTOP. At the end of September, the ISA experts will submit to EFSA the prototype of the R Shiny app and four Panel members volunteered to test this app in October. The aim is to collect any relevant feedback that can be used by the contractors to improve the app when used by not experts and non-expert users.

The next WG meeting will take place on 2-3 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](#))**

The WG chair presented the draft opinion. The background information provides an overview of zoonotic parasites finfish, wild finfish species consumed in the EU and the areas where they are caught. The assessment itself provides a table with studies that found zoonotic parasites in wild caught fish. For marine waters, anisakids are found in all FAO fishing areas. Various zoonotic parasites are reported in all inland water fishing areas except Antarctica for which no data was found. It was suggested to present the draft opinion for possible adoption at the next Panel Plenary meeting in October. The deadline for the adoption is 31 December 2024.

**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 last WG meeting was held on 6 September 2024. The WG Chair presented the draft opinion to the current Panel for the first time. The Panel was informed that microbial food cultures are out of scope. The safety assessment of biological agents was revised considering the draft EFSA Guidance on the risk assessment of microorganisms used in the food chain (see point 7.3); an exposure assessment would not be needed for such agents, but the fate of phages is of relevance. In the efficacy section, it was agreed keeping "consistent", "relevant" and "significant" in the definition; the achieved reduction is expected to provide protection to public health, while the satisfactory level of public health risk reduction is a risk management decision. Further, the efficacy to reduce background flora is not to be requested, but instead the reduction of target pathogens (or indicators of those) until the end of shelf-life is relevant. Minor changes were requested, especially for biological agents, in the section dealing with reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials and the one dealing with environmental risk assessment. The next WG meeting will be held on 15 October



2024. The current deadline for endorsement by the BIOHAZ and FCM Panels is 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 within the WG dealing with this mandate and other activities since the last Plenary. The protocol for the first scientific opinion, presenting the state of the art on the topic (Part 1, addressing ToR 1 and part of ToR 3), was discussed and approved by the Panel. The developed 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 were shared with the Panel for information. A 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 be in place soon. The Part 1 scientific opinion is expected to be adopted by March 2025. One or more additional scientific opinions reviewing and analysing the results of the FPA studies performed and the new literature developments are expected by 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 meeting was held on 3 September 2024. Next meeting will be on 3 October. The WG discussed the criteria (including years range and type of study) for including/excluding an article for the data extraction phase. Experts went through the articles, discussed divergences in the approach to tackle and agreed on common strategies. Before the next meeting, experts will finalise this exercise and will prepare the preliminary analysis of the data found through the extensive literature search (ELS). The deadline for the adoption of this opinion is 31 January 2025.

**6.8 Request for a 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 reminded the background of this mandate, the ToR, the composition of the working group and the work plan. After that, he presented the draft protocol for the first time and reviewed the comments by Panel members, including the use infectivity or seeding activity as a measure for the level of inactivation and the distinction between assessment question 3 (AQ3) and AQ4, which are not clear to the reader. They will be taken into account in the next draft, which will be submitted to the BIOHAZ Panel for approval to the next Plenary meeting in October 2024.

**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 information. He informed that the application has been offered to the contractor that will provide support to produce the scientific opinion. Many of the comments added by Panel members had already identified by WG and sent to the contractor for them to take time on board for the second draft. For example, the clarification on the material to be treated, the deficiencies of the HACCP plan, the comparability of the methods proposed to measure the reduction/inactivation of prions. The draft opinion will be submitted for first reading to the next Plenary meeting in October. The WG coordinator informed that the second WG meeting will take place on 21 October, only two days before the



October plenary so it will not be possible to share the opinion one week in advance as customary. Only after the WG meeting the draft will be ready for submission. He also informed that the non-confidential version of the dossier will be subject for public consultation when 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](#))**

The WG Chair presented the main aspects of the application (applicant, material to be treated, steps of process, time/temperature regime), the working group composition and work plan. The application has been offered to the contractor that will provide support to produce the scientific opinion. The WG coordinator informed that the non-confidential version of the dossier will be subject for public consultation when the confidential claim assessment will be finished. The deadline for delivery of the opinion is 5 March 2025. Since the March plenary in 2025 will take place on 12-13 March, an extension of one week will be requested to the EC, as it was done in a previous application. The first WG meeting will take place on 19 November 2024.

### **7. New mandates**

#### **7.1 Request for an update of the scientific opinion 'Evaluation of the safety and efficacy of Listex™ P100 for reduction of pathogens on different ready-to-eat (RTE) food products' ([EFSA-Q-2024-00551](#))**

EFSA staff from the BIOHAZ Unit informed the Panel that a new request for an update of the scientific opinion 'Evaluation of the safety and efficacy of Listex™ P100 for reduction of pathogens on different ready-to-eat (RTE) food products' was received in EFSA from the European Commission on 4 September 2024. The request is based on the receipt of an application dossier from Mircros Food Safety B.V. / Phageguard under Article 3(2) of Regulation (EC) No 853/2004. The dossier was not yet considered valid at the moment of the BIOHAZ plenary meeting.

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

#### **8.1 Scientific Committee**

The Panel Chair and the Panel coordinator reported to the BIOHAZ Panel the main topics discussed within the 120<sup>th</sup> Plenary meeting of the Scientific Committee (SC), taking place on 11 and 12 September 2024<sup>4</sup>, focusing in particular on the ongoing discussions on the SC work programme 2025-2026 and on the structure of EFSA opinions.

#### **8.2 European Commission**

The Panel coordinator reported briefly to the Panel about recent discussions with the European Commission (EC) on the possible upcoming mandates from EC to EFSA on BIOHAZ topics and on the future attendance by EC DG SANTE to BIOHAZ Plenary meetings.

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

<sup>4</sup> <https://www.efsa.europa.eu/en/events/120th-plenary-meeting-scientific-committee>



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. This document is currently being presented to all the relevant Scientific Panels for endorsement before it will be discussed for endorsement by the Scientific Committee. The draft guidance was presented to the Panel and the Panel experts were invited to submit comments, by 6 October, to the draft document, which will be tabled in one of the next Plenary meetings for endorsement.

#### **8.4 Rapid Outbreak Assessments and related activities**

EFSA staff from the BIOHAW Unit explained to the Panel the joint EFSA-ECDC process to perform Rapid Outbreak Assessments (ROAs) and presented the latest published report on the assessment of a prolonged multi-country outbreak of *Listeria monocytogenes* ST173 linked to consumption of fish products. The event background was followed by the description of the food investigation and the joint EFSA-ECDC assessment<sup>5</sup>.

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

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

Panel expert Maarten Nauta introduced to the Panel background information on the EFSA Guidances related to uncertainty analysis in scientific assessments and the key concepts gathered in a working document developed and agreed by the former Panel, providing some background and tools that aim to support the 2024-2029 BIOHAZ Panel in the implementation of EFSA's uncertainty guidances. EFSA staff from the BIOHAW Unit reminded the Panel about the need of carrying out fit-for-purpose uncertainty analyses within EFSA scientific assessments, about the challenges in implementing the EFSA guidance in the framework of One Health interagency mandates and about the need for all Panel members to get familiar with carrying out uncertainty analyses within BIOHAZ assessments.

#### **9.2 Topics of scientific concern in the area of biological hazards**

EFSA BIOHAW Staff indicated that at the next Plenary meeting EFSA Staff from the KNOW Unit will join to report to the Panel on the topics discussed by the EFSA Emerging Risks Exchange (EREN) Network and by the EFSA Stakeholder Discussion Group on Emerging Risks (StaDG-ER), and to gather related-comments by the Panel. Panel member Elisabetta Suffredini informed the Panel that an ISO standard related to "Microbiology of the food chain – Determination and use of cardinal values" is currently under revision, and therefore the new standard might be available in the coming years.

### **10. Any other business**

Within this agenda item, as well as through the previous agenda items dedicated to the ongoing mandates, EFSA BIOHAW Staff and the Panel Chair asked Panel members to volunteer for acting as main reviewers for the different mandates in preparation of the next Plenary meetings. Some Panel members volunteered during and after the meeting.

EFSA BIOHAW Staff also informed the Panel of the upcoming consultation period on the draft EU One Health Zoonoses Report 2023: Panel members will be given the possibility to provide comments, similarly to EU Member States, during the course of October 2024.

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<sup>5</sup> <https://www.efsa.europa.eu/en/supporting/pub/en-8885>