



SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 128TH PLENARY MEETING

**Held on 5-6 June 2019, Parma
(Agreed on 21 June 2019)**

Participants

■ **Panel Members:**

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

■ **Hearing Experts¹:**

Not applicable

■ **European Commission and/or Member States representatives:**

Pamina Suzuki (European Commission, DG Health and Food Safety, Unit G4; for items 6.2, 6.3, 6.4)

Petros Angelopoulos (European Commission, DG Health and Food Safety, Unit G4; for item 6.6)

Paolo Caricato (European Commission, DG Health and Food Safety, Unit G4; for item 7.2)

Athanasios Raikos, Halvard Kvamsdal (European Commission, DG Health and Food Safety, Unit G4; for item 6.6)

■ **EFSA:**

■ **BIOCONTAM Unit:**

Sandra Correia, Maria Teresa da Silva Felício, Michaela Hempten, Maria Francesca Iulietto, Ernesto Liebana, Winy Messens, Angel Ortiz Pelaez, Mirko Rossi, Eleonora Sarno, Pietro Stella

■ **TS Unit:**

Samantha Carapezzi, Claudia Paoletti

■ **Observers:**

Not applicable

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/en/keydocs/docs/expertselection.pdf>.



1. Welcome and apologies for absence

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, 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 127th Plenary meeting held on 9-7 March 2019, Parma (Italy)

The minutes of the 127th Plenary meeting were agreed by written procedure on 25 April 2019.

5. Scientific outputs submitted for possible adoption or endorsement

5.1. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 10: Suitability of taxonomic units notified to EFSA until March 2019⁴

Last meeting was held on 21 (afternoon) and 22 May in Valencia. The article evaluation ELS exercise (articles published between July and December 2018) was finalised and its summary included in this Panel Statement. Between October 2018 and March 2019, the QPS notification list was updated with 45 microorganisms from applications for market authorisation. Of these, 19 biological agents already had QPS status, 18 were excluded from the QPS exercise by the previous QPS mandate (11 filamentous fungi) or from further evaluations within the current mandate (7 notifications of *Escherichia coli*). *Sphingomonas elodea*, *Gluconobacter frateurii*, *Corynebacterium ammoniagenes*, *Corynebacterium casei*, *Burkholderia ubonensis*, *Phaeodactylum tricornutum*, *Microbacterium foliorum* and *Euglena gracilis* were evaluated for the first time. The Panel Statement was adopted by the BIOHAZ Panel.

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00831>



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 feed as notified to EFSA⁵

Last meeting was held on 21 (afternoon) and 22 May in Valencia. The article evaluation ELS exercise (articles published between July and December 2018) was finalised and its summary included in the Panel Statement. The overall summary of all ELS exercises run the three-years length of this mandate will be included in this opinion. The next working group (WG) meeting will be held on 9 September by web meeting. The deadline for adoption of this scientific opinion is December 2019.

6.2. Scientific opinion on the pathogenicity assessment of Shiga toxin-producing *Escherichia coli* (STEC) and the public health risk posed by contamination of food with STEC⁶

The WG Chair updated the Panel on the progress of work made. Some Panel members found the introductory section 1.3. Additional information too complex and long and suggested to move it into an Appendix. A request was also made to clarify better the remit of this draft opinion and ensure consistency on that across the complete document, i.e. if it only applies to pathogenic STEC or also includes hybrid STEC strains. The European Commission also requested for the answer to term of reference 4 to establish relevant links to any potential future Part 2 STEC mandate. The next WG meeting will take place on 21 June 2019 as a physical meeting in Brussels, the European Commission will participate. The deadline for the adoption of this scientific opinion is at the plenary meeting on 11-12 December 2019.

6.3. Scientific opinion on the application and use of next generation sequencing (including whole genome sequencing) for risk assessment for foodborne microorganisms⁷

The WG Chair updated the Panel on the progress of work made. The Panel requested to: (i) include a broader perspective into the structure of the draft opinion, i.e. covering all general steps of the MRA and not only specific applications of NGs in foodborne outbreak investigation, source attribution, hazard identification and characterisation; (ii) incorporate uncertainty better into the conclusions. The next WG meeting will take place in Parma from 4 to 5 July 2019. The deadline for adoption of this opinion is the October 2019 plenary meeting.

6.4. Scientific opinion providing an update and review of control options for *Campylobacter* in broilers at primary production⁸

The WG chair updated the panel on the progress made and the upcoming WG meetings. In particular, the approach using population-attributable fractions and first results of estimating the impact of interventions aiming at a reduction of *Campylobacter* prevalence in broilers was presented. The approach for interventions aiming at reducing *Campylobacter* concentrations was also presented. The panel agreed with both approaches and with the use of the 2008 baseline survey data on *Campylobacter* prevalence and concentrations. The next meeting is on 1-2 July 2019, which is a two days meeting with one day focussing on the development of

⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00293>

⁷<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00397>

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00676>



the draft opinion and the second day on the uncertainty analysis. The deadline for adoption is January 2020.

6.5. Scientific opinion on an update of the scientific opinion on Chronic Wasting Disease (CWD) in cervids⁹

The Chair of the WG presented the draft of the scientific opinion for first reading by describing the layout and rationale of the approach applied as well as some relevant extracts from the body of the assessment. Although provisional, some concluding remarks, the answers to the terms of reference and the table of uncertainty analysis were explained in more detail. The current content of the opinion was well received and there were no major concerns or reservations to the approach and initial conclusions. The comments received by Panel members during the plenary concern to: the excessive background information on strains at the beginning of section 3, the inadequate use of risk/probability terms in the exposure assessment, the criteria to select and appraise studies included in some tables, need for some clarifications on terms applied throughout the opinion and some layout issues. The chair informed of some additional changes to be made between now and the thorough reading related to the revamp the Data and methodology section, the completion of the uncertainty table and the finalization of the appraisal of the studies included in the table of risk factors for term of reference 3. The next meeting will be a physical in Parma on Wednesday 19 and Thursday 20 June 2019.

6.6. Request for a scientific opinion on the public health risk posed by *Listeria monocytogenes* in frozen fruit and vegetables including herbs, blanched during processing¹⁰

The WG Chair updated the panel on the progress made during the second WG meeting (web-conference on 7 May). Based on the information kindly provided by the European Association of Fruit and Vegetable Processing Industries (PROFEL), not any fruit groups and typically any herbs are blanched while some or all groups of vegetables may be blanched. Therefore, the panel agreed with the WG proposal that fruit and herbs are out of scope of the assessment. The European Commission also agreed with this proposal. The panel also agreed that *Listeria monocytogenes* is the most relevant pathogen in this assessment based on the epidemiological data and considering its potential for recontamination and growth. It was clarified that, as mostly hot water blanching and steam blanching are applied in freezing plants in the EU, these technologies will be addressed. The draft assessment questions (AQs) were presented together with some hypothetical answers to illustrate their formulation. For term of reference 1, it was suggested to keep vegetables as one group considering the lack of data and considering that the products are not having too dissimilar growth potentials. Its splitting into subgroups was proposed if data would allow. The methods to compare the public health risk posed by *L. monocytogenes* in blanched frozen vegetables (or subgroups) in comparison with other known pathogen-food combinations were discussed. For term of reference 2, it was clarified that the risk factors of contamination will be interpreted as sources of contamination (introducing or increasing contamination) and those of growth as the parameters that impact on growth (increasing growth). The panel was informed about the data request to the Microbiological Risk Assessment (MRA) network mtg on 21-22 May 2019 with a deadline of end of June 2019. The next WG meeting will take place in Parma on 3-4 July. The deadline for adoption is March 2020.

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00763>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01006>



6.7. Request for a scientific opinion on the use of the so called "tubs" for transporting and storing fresh fishery products

The WG Chair presented the outcome of the second WG meeting held on 7-8 May 2019 in Parma. The interpretation of "impact" was discussed; the panel agreed that it is not feasible to quantitatively assess the risk for public health but considered that the potential risk could be described. The draft assessment questions (AQs) and their hypothetical answers were welcomed. The conceptual map was presented so the various conditions to be assessed were clarified. The approaches to deal with the proposed six steps to answer the terms of reference was explained. The next meeting will take place on 27 June by web-conference. The deadline for adoption is March 2020.

6.8. Scientific opinion on the evaluation of public and animal health risks in case of a delayed post-mortem inspection in ungulates

The WG chair updated the panel about the composition of the WG. The first WG meeting is planned for 11 June 2019 for the whole WG, subsequent meetings will be organised as sub-WG meetings focussing on specific issues related in the scope of the BIOHAZ, CONTAM and AHAW panels. Some sections will be endorsed by the CONTAM and AHAW panels before presenting the draft opinion to the BIOHAZ panel in December 2020.

6.9. Request for a scientific opinion on specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed

The WG Chair updated the panel on the composition of the WG and informed the Panel on the background and terms of reference of this mandate. The BIOHAZ Panel is the leading panel for this mandate and specific sections will be endorsed by AHAW and FEEDAP Panel. The assessment will be done in collaboration with EMA, which has nominated an expert as member of the WG. The first meeting of the whole WG is planned for 12 June 2019. The whole WG will be divided in two subgroups (Sub-AMR and Sub-GP) to initially address each ToR. Subsequent SubWG meetings focussing on specific issues related to the scope of the different panels and EMA will be planned. Deadline for the opinion is 30 September 2019.

7. New Mandates

7.1. Request for scientific opinions providing guidance on date marking and related food information

EFSA Secretariat presented to the Panel the background and terms of reference of this mandate, received on 21 May 2019. The Panel chair nominated Roland Lindqvist as Chair of the *ad hoc* WG which will be established for this mandate (conditional to screening and approval of his declaration of interests).

7.2. Request for a scientific opinion on the use of the so-called "superchilling" technique for the transport of fresh fishery products

EFSA Secretariat presented to the Panel the background and term of reference of this mandate, received on 28 May 2019. The Panel chair indicated that the mandate could be tackled by the existing *ad hoc* working group on the use of the so called "tubs" for transporting and storing fresh fishery products. The terms of reference were discussed by the Panel, who concluded that term of reference 2 of the mandate as formulated is not strictly connected to food safety and suggested that the EFSA Secretariat would discuss further this



term of reference with the European Commission and internally in EFSA to assess the link with food safety and whether it would fall under EFSA remit.

7.3. Request for a scientific opinion on potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminants farmed animals

EFSA Secretariat presented to the Panel the background and term of reference of this mandate, received on 28 May 2019. The Panel chair nominated Avelino Alvarez-Ordóñez as Chair of the *ad hoc* WG which will be established for this mandate (conditional to screening and approval of his declaration of interests).

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

8.1. Scientific Committee

The 93rd Plenary meeting of the Scientific Committee (SC) took place on 24 April 2019,¹¹. The BIOHAZ Panel Vice-chair Lieve Herman reported to the Panel about the SC meeting, that she attended, and in particular about the discussions on a proposal for a technical guidance on the use of Whole Genome Sequencing in risk assessment (see SC meeting minutes). The Panel Chair and EFSA Secretariat also reported the ongoing discussions in the SC about a guidance on the use of epidemiological studies in risk assessment. The next SC meeting will take place on 25-26 June 2019.

8.2. Scientific Networks on BSE-TSE and MRA

The panel was updated on the last MRA network meeting, which was held on 21-22 May 2019 in Parma. The next meeting will be in spring 2020. The next BSE-TSE Network meeting will be on 14-15 October 2019 in Parma.

8.3. Update on Rapid Outbreak Assessments and related activities

EFSA Secretariat presented to the Panel the last two Rapid Outbreak Assessment outputs published. The aim and the meaning of the documents were clarified and two specific outbreak events illustrated, namely the multi-country outbreak of *Salmonella* Poona infections linked to consumption of infant formula and of *Listeria monocytogenes* clonal complex 8 infections linked to consumption of cold-smoked fish products. The event backgrounds were provided followed by the microbiological investigation of the available isolates, traceability analyses of the implicated food products, control measures implemented and relative follow up, and by the overall assessments.

8.4. European Commission

EFSA Secretariat indicated that participation of the European Commission (DG SANTE) to the Plenary is scheduled for the next Plenary meeting (3-4 July 2019).

¹¹ <https://www.efsa.europa.eu/en/events/event/190424>



9. Other scientific topics for information and/or discussion

9.1. Follow-up of the training on the implementation of the guidance on uncertainty analysis in scientific assessments

EFSA Secretariat presented a draft document defining minimum requirements that should be applied in BIOHAZ assessments when implementing the guidance and related checklist. The Panel discussed such document and Panel members will provide comments by the next Plenary meeting (3-4 July 2019). EFSA Secretariat circulated the report on the March training prepared by the trainers and the updated case-studies used in the training, which will remain as examples of possible implementation of the guidance for some types of BIOHAZ assessments. Further progress has been made by the Panel and its working groups in the implementation of the guidance according to the checklist in the last mandates received (e.g. reviewing in detail the formulation of the terms of reference and assessment questions, discussing the need to quantify uncertainties, presenting the structure of draft conclusions at early stages etc.). This agenda item will be kept for further discussion in future plenaries.

9.2. Request to participate in the EMA expert group on the establishment of the criteria for the designation of antimicrobials to be reserved for humans

BIOHAZ Panel member Luisa Peixe, who is representing EFSA in the EMA expert group, briefly reported to the BIOHAZ Panel the progress made in the EMA expert group meetings and the plan for future meetings.

9.3. Topics of scientific concern in the area of biological hazards and BIOHAZ self-tasks

EFSA Secretariat indicated that the draft proposal for a self-task activity on the role played by the environment in the emergence and spread of antimicrobial resistance through the food chain has been approved by EFSA's Project Coordination Office.

9.4. Presentation of the EU Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2017

This agenda item was postponed to the next Plenary meeting (3-4 July 2019).

9.5. Presentation of the update of the General Food Law (Regulation (EC) No 178/2002)

EFSA Secretariat from Transformation Services Unit updated the Panel on the EFSA programme aimed at implementing the changes required by the legal amendments of the General Food Law.

9.6. Dates for 2020 BIOHAZ Plenary meetings

Preliminary dates for 2020 BIOHAZ Plenary meetings were circulated to the Panel and will be agreed at the next Plenary (3-4 July 2019).

10. Any other business

EFSA Secretariat indicated that no comments were gathered on the document summarising discussions related to the EFSA 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 intended for human consumption, discussed in previous Plenaries. The Panel agreed in keeping such summary for future reference.

EFSA Secretariat circulated to the BIOHAZ Panel a document summarising rules and best practices for publications and presentation related to BIOHAZ Panel opinions. Panel members were invited to consult the document.