

SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 145th PLENARY MEETING

**Held on 29 April and 6 May 2021, web-conference
(Agreed on 20 May 2021)**

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, Giuseppe Ru, Luisa Peixe, Marion Simmons, Panagiotis Skandamis, Elisabetta Suffredini

■ Hearing Experts¹:

Not applicable

■ European Commission (EC) and/or Member States representatives:

Luis Vivas-Alegre (EC, DG Health and Food Safety, Unit D1)

Jean-Baptiste Perrin (EC, DG Health and Food Safety, Unit G4; for items 6.5 and 8.3)

Kris De Smet (EC, DG Health and Food Safety, Unit G4; for item 9.2)

■ EFSA:

■ BIOCONTAM Unit:

Pierre-Alexandre Beloeil, Frank Boelaert, Katrin Bote, Maria Teresa Da Silva Felicio, Beatriz Guerra, Michaela Hempen, Maria Francesca Iulietto, Ernesto Liébana, Winy Messens, Karoline Noerstrud, Angel Ortiz-Peláez, Valentina Rizzi, Eleonora Sarno, Pietro Stella

■ FEED Unit:

Gloria Lopez-Galvez (for item 6.3)

■ Observers:

Not applicable

1. Welcome and apologies for absence

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

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>.

3. Declarations of Interest

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 144th Plenary meeting held on 10-11 March 2021, web-conference

The minutes of the 143rd Plenary meeting were agreed by written procedure on 25 March 2021.

5. Scientific outputs submitted for possible adoption or endorsement

5.1. Scientific opinion on the role played by the environment in the emergence and spread of antimicrobial resistance through the food chain

The last meeting of the WG took place on 7 April by Web-conference. The WG Chair presented the draft opinion for adoption, in particular the changes implemented since the last Panel meeting. The comments received from the Panel experts before the Plenary, the updated concluding remarks for each section, the answers to the ToRs and the uncertainties' analysis were discussed. Following discussions, some changes were implemented. An alternative to the uncertainties wording used to support the conclusions and the Table indicating the impact of the uncertainties, giving the numeric probability, followed by the ordinal scale in brackets, was discussed. However, it was finally decided that the previous qualitative wording agreed with the WG members to express the impact of the uncertainties should be used. Minor changes were done in the abstract, summary and answers to the ToRs during the plenary. The opinion was finally adopted pending the alignment throughout the text of changes proposed during the plenary, amendment of the uncertainty wording used in the Table and conclusions, and revision for consistency of some references included in Tables supporting Section 3.2.

6. Scientific outputs submitted for discussion⁴

6.1. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 1: Suitability of taxonomic units notified to EFSA until March 2021

The WG Chair informed the Panel about the notifications received since October 2020: 78 microorganisms were notified, of which 71 were excluded. Seven TUs were newly evaluated: *Anoxybacillus caldiproteolyticus*, *Bacillus paralicheniformis*, *Enterobacter hormaechei*, *Eremothecium ashbyi*, and *Lactococcus garvieae* for the first time; *Corynebacterium stationis* and *Kodamaea ohmeri* were re-assessed because an update was requested for the current mandate. In the period covered by this statement, no new information was found that would change the status of previously recommended QPS TUs except for *B. licheniformis*, for which an additional qualification was introduced. The next WG meeting is 19 May 2021 and the deadline for adoption of this Panel Statement 14 is June 2021.

² https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ Please be aware that EFSA's Register of Questions is unavailable from 21 January until March. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available [here](#)

6.2. Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA

The WG Chair informed the Panel that there is no update on the draft opinion since the last plenary meeting. The deadline for adoption of this QPS opinion is December 2022.

6.3. Scientific opinion on specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed

The Chair of the WG informed the Panel that the WG is working on the assessment of the different substances included in the mandate, both for ToR1-AMR (to assess the specific concentrations of antimicrobials, resulting from cross-contamination in non-target feed for food-producing animals, below which there would not be an effect on the emergence of and/or selection for resistance to microbial agents relevant for human and animal health; SubWG-AMR) and ToR2 (to assess which levels of the antimicrobials have a growth promotion/increase yield effect; SubWG-GP). EFSA staff from the FEED Unit updated the Panel on the activities of the SubWG-GP: the draft assessment of 9 substances (florfenicol, lincomycin, sulfonamides, tetracycline, thiamphenicol, tiamulin, tilmicosin, tylvalosin and valnemulin), prepared by the SubWG-GP, were presented to the FEEDAP Panel on 6 May and endorsed by it. From the SubWG-AMR, no meetings had taken place since the last BIOHAZ Panel meeting. The next WG meetings will be on 12 May (SubWG-GP) and on 26-27 May (SubWG-AMR). The deadline for adoption/delivery of the scientific opinion(s) is 30 September 2021.

6.4. Scientific opinion on the capacity of certain specific processing transformation methods of animal by-products used in the production of organic fertilisers and soil improvers in view of determining the endpoints in the manufacturing chain of certain derived products

The WG Chair reminded the Panel of the final wording of the ToR and new list of materials. The Chair informed of the latest developments following the discussion during the 5th WG meeting that took place on 25 March 2021. He reported the results of the extensive literature search conducted in order to extract viral hazards that can be found intrinsically in the Category 2 and 3 materials and derived products, and the approach followed in the extraction of data for thermal and chemical inactivation of the indicator pathogens. In relation to viruses, extraction would focus on the most heat-resistant viruses (non-enveloped viruses). Preliminary information on the approach being developed by the WG for the uncertainty analysis was presented to the Panel; this is to be further finalised during the next WG meetings. The 6th WG meeting will take place on 27 May 2021. The deadline for adoption of the scientific opinion is 31 October 2021.

6.5. Scientific opinion on the efficacy and safety of high pressure processing of food

The last WG meeting was held on 14-15 April 2021 (related to BIOHAZ issues). The WG Chair informed that a new expert has joined the WG. Some sections of the draft scientific opinion were shared with the BIOHAZ Panel for review. This concerns the introduction and interpretation of the ToRs, and the data and methodologies, assessment and conclusions related to (i) the foods to which high pressure processing (HPP) could be applied along with the processing conditions (it was concluded that most frequently, pressures between 400 and 600 MPa are applied for 1.5 to 8 min), (ii) the other relevant hazards in milk/colostrum (i.e. *Mycobacterium bovis*, *Brucella melitensis*, *Listeria monocytogenes*, *Salmonella* spp., STEC, *Campylobacter* spp., Tick-borne encephalitis virus and *Staphylococcus aureus*), (iii) the most relevant foods associated with human listeriosis in the EU and that are relevant to be treated with HPP (i.e. ready-to-eat cooked meat products, soft and semi-soft cheese, fresh cheese, smoked or gravad fish) and (iv) the other relevant pathogens in these foods (i.e. *Salmonella* spp. and pathogenic *Escherichia coli*). The Panel was also updated on the approach used for modelling for equivalence in ToR2 (requirements as regards time and pressure of the for the control of the hazards to achieve an equivalent efficacy to that of thermal pasteurisation of raw milk and raw colostrum) and ToR3 (requirements to reduce significantly *L. monocytogenes*

levels in foods associated with human listeriosis). The next WG meeting related to BIOHAZ issues will be held on 28-29 June 2021. The deadline for adoption is 31 January 2022.

6.6. Scientific opinion on the microbiological safety of aged meat

The WG chair briefly presented the terms of reference and that the WG is being established. The first WG meeting is planned for 10 May 2021. The deadline for adoption of this opinion is 31 December 2022.

6.7. Scientific opinion on the evaluation of safety and efficacy of lactic acid to reduce microbiological contamination on carcasses from wild game and small stock

The Panel was informed that the deadline for the applicant to provide additional information was extended to 24 June 2021 and the scientific evaluation suspended. The initial deadline to deliver the Scientific Opinion of 10 December 2021 will be extended accordingly.

7. New Mandates

No new mandates for the BIOHAZ Panel received.

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

8.1. Scientific Committee

The 103rd Plenary meeting of the Scientific Committee (SC) took place on 14-15 April⁵. The Panel Chair reported that no topics of specific interest for the BIOHAZ Panel were discussed at such meeting.

8.2. European Commission

EFSA Secretariat briefly reminded the Panel about past information provided by EC colleagues in relation to possible topics for future mandates to EFSA in the BIOHAZ area.

8.3. Request for scientific and technical assistance to examine the data collected by the Member States in the framework of the 2-years compulsory intensified surveillance in case of atypical scrapie

The Chair of the WG presented the draft report. The final results of the descriptive, analytical, and modelling approaches for ToR1 were described in depth by the WG chair and WG members. A summary of the introduction section giving the background of the disease and the main features underpinning the ToRs was carried by the chair of the WG. The simulation model was described in more detail following questions by Panel members. The code of the model was shared with the Panel the day before. The chair encouraged Panel members to review it and send comments to the secretariat in the days following the plenary. The conclusions were not in its final wording because the WG will hold another meeting to finalise them. Some preliminary conclusions were presented triggering discussion about the limitations of the data, the intensified monitoring and how the results of the analyses would be interpreted in order to answer the ToRs. The fifth and last meeting of the WG will take place on Friday 21 May 2021. The final draft of the report will be submitted for endorsement by the BIOHAZ Panel in the next plenary on Thursday 6 June 2021.

⁵ <https://www.efsa.europa.eu/it/events/event/103rd-plenary-meeting-scientific-committee>

9. Other scientific topics for information and/or discussion

9.1. Implementation of the guidance on uncertainty analysis in scientific assessments

The Panel Chair suggested that in one of the next plenaries the Panel should discuss again the implementation of the uncertainty analysis in qualitative assessments, and in particular the wording to be possibly used when quantifying the impact of uncertainty on the overall conclusions. He stressed the need to ensure consistency between the approaches followed in the different opinions, to progress slowly and carefully with adaptations of the approaches agreed, and to fully involve WG members in the formulation of the impact of uncertainty in conclusions. EFSA Secretariat reminded the Panel of the previous agreements made in May 2020 (137th Plenary meeting) with regard to the qualitative and quantitative assessments and uncertainty tables in BIOHAZ opinions, and invited all Panel members to contribute to the discussions on uncertainty when scheduled in one of the next plenaries.

9.2. Topics of scientific concern in the area of biological hazards and BIOHAZ self-tasks (including draft selftask on microbiological risks linked to the use of water in processing of fruits and vegetables)

The revised draft self-task mandate on the microbiological hazards associated with the use of water in the handling and processing of fresh and frozen fruits, vegetables and herbs (ffFVHs) was presented to the Panel. The updated terms of reference were discussed and approved by the Panel members in order to be shared with DG SANTE for commenting. The EC also participated in the discussion and expressed its interest in following the activities of this self-task mandate which focuses on post-harvesting handling and processing of ffFVHs. The EC is currently coordinating Codex activities to develop guidelines for the safe use and reuse of water in food production including a specific Annex on the use and reuse of water in fresh produce production. The Panel also discussed the draft table listing questions for possible outsourcing integrated in this mandate. The deadline for this mandate still needs to be defined, as it will also depend on the proposed and approved associated outsourcing. Due to this outsourcing it is expected to last longer than the standard BIOHAZ mandates (at least 2 to 3 years, to be confirmed).

EFSA Secretariat provided a brief feedback on the BIOHAZ-related topics discussed at the last Emerging Risks Exchange Network (EREN) meeting, held on 15-16 April 2021.

9.3. Presentation of the European Union Summary Report on Antimicrobial Resistance in zoonotic and indicator bacteria from humans, animals and food in 2018/2019

EFSA Secretariat presented to the Panel the key findings reported in the 2019 EU Summary Report on AMR⁶, published in 12 April 2021, in particular with regard to the frequent resistance to the commonly used antimicrobials in animals and the low to very low levels of combined resistance to the critically important antibiotics for human medicine, in *Salmonella*, *Campylobacter*, and indicator *E. coli*. Trends in the Key Outcome Indicators of antimicrobial resistance in food-producing animals, the rate of complete susceptibility in indicator *E. coli* and the prevalence of ESBL-/AmpC-producing *E. coli*, have showed some encouraging progress in reducing AMR in a number of EU Member States over the last years.

9.4. Update on the EMA expert groups on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, and on the establishment of a list of antimicrobials which shall not be used or which may be used subject to certain conditions

BIOHAZ Panel member Luisa Peixe, who is representing EFSA in the EMA expert groups responsible for these topics, briefly reported the progress made in the EMA expert group

⁶ <https://www.efsa.europa.eu/it/efsajournal/pub/6490>

meetings. She indicated that these EMA activities were postponed compared to their original deadline, in agreement with the European Commission, and would be finalised later this year.

10. Any other business

The Panel discussed preliminary dates for 2022 Plenaries. Alternative proposals will be circulated to the Panel in relation to the Plenaries scheduled in May and December to check availability from Panel members, and a decision will be made based on this.

EFSA Secretariat informed the Panel of the opportunity for all Panel members to take part in an elicitation exercise dedicated to the prioritisation of the elements that will be used in the story maps and the dashboard of the future EU One Health Report, and asked them to express interest on this.

EFSA Secretariat informed the Panel on a recently published Topic page published on EFSA website in relation to EFSA and COVID-19.

EFSA Secretariat informed the Panel that during the Plenary meeting of 7-8 July a new election of the Panel Chair and Vice-Chairs will take place. Written information to all Panel members would follow in the next weeks. Despite all Panel members will be able to express their interest to run for the election until the day of the election, they were encouraged to inform the Unit in advance of the July plenary meeting.