



SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 140th PLENARY MEETING

**Held on 22-23 September 2020, web-conference
(Agreed on 8 October 2020)**

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:

Kris De Smet (EC, DG Health and Food Safety, Unit G4; for item 6.2)

Athanasios Raikos (EC, DG Health and Food Safety, Unit E1; for item 6.1)

Fabien Schneegans (EC, DG Health and Food Safety, Unit G4; for item 5.1)

■ EFSA:

■ BIOCONTAM Unit:

Katrin Bote, Maria Teresa da Silva Felício, Beatriz Guerra, Michaela Hempen, Maria Francesca Iulietto, Ernesto Liébana, Winy Messens, Karoline Noerstrud, Angel Ortiz-Peláez, Denise Pezzutto, Eleonora Sarno, Valentina Rizzi, Pietro Stella

■ ALPHA Unit:

Francesca Baldinelli (for item 8.4), Sean Ashe (for item 10.2)

■ 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

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.

EFSA Secretariat reminded BIOHAZ Panel members to promptly update their DoIs whenever a new interest arises and in any case as soon as the annual request for updating the DoI is sent out by EFSA.

4. Agreement of the minutes of the 139th Plenary meeting held on 8-9 July 2020, web-conference

The minutes of the 139th Plenary meeting were agreed by written procedure on 23 July 2020.

5. Scientific outputs submitted for possible adoption or endorsement

5.1. Scientific opinion on potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminants farmed animals⁴

The WG Chair presented the draft opinion for adoption. Firstly, the chair thanked the Panel for all the comments received from Panel members before the plenary. Most of the comments had already been addressed in the version presented and discussed during the plenary. Secondly, the chair highlighted the main changes from the version reviewed during the thorough reading: new order of subsections in the Assessment section, the rationalization of the concluding remarks in blocks, the elimination of assessment question 5 (AQ5) (included in AQ4), and the new draft of the answers to the AQ, the summary and the abstract. The chair read the answers to the terms of reference (ToRs). The Panel discussed the wording of expressing uncertainties and it was agreed to express first the numeric probability, followed by the ordinal scale in brackets, as defined in the table in the uncertainty checklist. It was agreed to add a paragraph in the methodology section pointing out this decision, that would become a standard paragraph in future scientific opinions. These changes would be done after the plenary. The chair of the Panel welcomed the approach followed by the WG to address the uncertainty analysis in the opinion, by adding tables describing types, sources and impact in a qualitative way of the

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 <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00436>



uncertainties, both accounted and not accounted for by the probabilistic model. He also supported the approach of agreeing final probabilities associated to uncertainties within the WG by consensus. Minor changes were done in the abstract, answers to the ToRs and recommendations during the plenary. The opinion was finally adopted pending the revision of the summary to align with the changes made in abstract, answers to the ToRs and recommendations.

5.2. Scientific opinion on specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed⁵

The WG chair presented the revised version of the draft scientific opinion to the BIOHAZ Panel for endorsement of specific sections that should be submitted to public consultation, namely the methodological approach proposed to address the ToR 1, *"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 in microbial agents relevant for human and animal health"* and the associated uncertainties. The Opinion had been updated addressing comments received from the EMA CVMP (opinion presented and discussed in their meeting on 14-16 July) and discussed with the WG at the meeting held on 25 August. Also, comments received from FEEDAP and AHAW panels experts had been considered. Additional comments from the BIOHAZ Panel experts, especially those related to the Table of uncertainties, were discussed during the Plenary. The BIOHAZ Panel agreed to include the section "Data gaps and other considerations" among those to be submitted to public consultation. The Panel endorsed the sections including the description of the methodology proposed to answer ToR1, the uncertainties associated with it, the data gaps/other considerations identified. As previously agreed by the Panel, additional sections of the draft opinion will be shared during the public consultation to provide the background, contextualize the methodology, and to provide the tetracyclines assessment as an example if the methodology would be applied. These additional sections will be provided only for information and will not be submitted to consultation. The next meeting of the sub-WG-AMR will be web-conference on 27 November. The deadline for adoption of the opinion(s) is 30 September 2021.

6. Scientific outputs submitted for discussion

6.1. Scientific opinions providing guidance on date marking and related food information⁶

The WG Chair presented the draft opinion for thorough reading to the BIOHAZ panel. The most important comments received on the Part 1 Date Marking draft opinion were discussed and the approach that will be used by the WG to address these was agreed. The panel had no major comments on the revised decision tree to assist the choice between 'use by' and 'best before' dates; few suggestions for consideration by the WG were made. As agreed in the previous plenary, the justification for the exclusion of mycotoxins, produced following to the growth of moulds during shelf-life, as main hazards was explained in more detail within the section of the draft opinion discussing relevant microbiological hazards. The deadline for adoption of Part 1 opinion (ToRs 1 and 2) is October 2020. The Food Information Part 2 draft opinion wasn't discussed during this plenary meeting, as the working group is still working on the tasks

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00438> and <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00439>



allocated to them in this opinion and the deadline for adoption of this second opinion (ToRs 3 and 4) is March 2021. The next WG meeting will take place on 28-29 September 2020.

6.2. Scientific opinion on the evaluation of public and animal health risks in case of a delayed *post-mortem* inspection in ungulates⁷

During the last WG meeting on 25 August 2020, the results of the assessments of both panels, AHAW and BIOHAZ, were discussed as well as the conclusions to ensure that the overall approach for answering the terms of reference is consistent. The main focus of this presentation to the BIOHAZ panel was on the model results estimating the effect of a delayed meat inspection on the detection of *Salmonella* as a Process Hygiene Criterion and the related uncertainty assessment. The BIOHAZ panel agreed with the description of the model results and made some suggestions for the conclusion which the WG will discuss during their next meeting on 1 October 2020. The CONTAM sections were already endorsed by the CONTAM panel and the AHAW panel endorsed the sections on animal health during their September plenary which coincided with that of the BIOHAZ panel. The deadline for adoption of the opinion by the BIOHAZ panel is December 2020.

6.3. Scientific opinion on the use of the so-called “superchilling” technique for the transport of fresh fishery products⁸

The WG chair presented the draft scientific opinion to the panel and gave an update about the outcome of the last WG meeting on 9 September 2020 by web-conference. For ToR 1, the results of the heat balance model were presented, using two representative cases of lean and fat sea fish species as examples in the assessment, i.e. cod and salmon, and a species from temperate freshwater (e.g. Nile perch). Experimental data supplementing the heat balance model was presented. For ToR 2, the panel approved the classification of the markers [into biochemical methods (incl. the Hydroxyacyl-coenzyme A dehydrogenase (HADH) enzymatic test) and physicochemical methods] and the method to assess their suitability to detect whether a fish frozen before is commercially presented as “superchilled”. Simplification of the answers to ToR was proposed by the panel. The answers to ToR 2 and the uncertainty analysis of the assessment of ToR 1 and 2 were not yet finalised and have not been discussed with the panel. The next WG meeting will take place on 12 October 2020. The deadline for adoption is December 2020.

6.4. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 13: Suitability of taxonomic units notified to EFSA until September 2020⁹

The WG chair informed the panel that the Extensive Literature Search (ELS) is under way and results will be presented during the October plenary. Since April, new taxonomic units were notified and the following three are included for QPS assessment: *Aureobasidium pullulans*, *Bacillus circulans* and *Methylobacterium extorquens*. The next WG meeting will take place on 7 October 2020. The Statement Part 13 will be presented to the BIOHAZ Panel for possible adoption in December 2020.

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00124>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00437>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00078>



6.5. Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA¹⁰

The WG chair informed the panel that an algae expert joined the WG. The draft opinion will include a description on the differentiation between yeasts and filamentous fungi and a brief discussion on microbiological safety in relation to opportunistic infections. The deadline for the next QPS opinion is December 2022.

6.6. Scientific opinion on the role played by the environment in the emergence and spread of antimicrobial resistance through the food chain¹¹

The WG chair updated briefly the Panel about the outcome of the last WG meeting held on 19 August by web-conference. The more advanced sections of the scientific opinion (those addressing the Introduction, Sources and Resistant bacteria and genes) had been shared with the experts of the BIOHAZ Panel and the two first sections were discussed at the Plenary. The general feedback of the Panel members was the need to shorten the current text, summarize and group information in order to avoid repetitions, especially when regarding the different terrestrial animals (poultry, cattle and swine). The next meeting of the WG, dedicated to revise the contributions done for the section mitigation options, would take place on 24 September 2020. Due to the COVID situation and other unexpected reasons that hampered the progress of the scientific opinion as initially planned, the deadline for the adoption of this scientific opinion was extended from 31 December 2020 to 30 April 2021.

6.7. 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 products¹²

The WG Chair reminded the Panel the terms of reference of this mandate and the deadline for adoption (31 October 2021), and informed on the composition of the working group, established at the end of August. The first WG meeting took place on 8 September 2020, as a half-day webmeeting. Since there are experts collaborating with EFSA for the first time, the first meeting focused on the administrative, logistics and general information about EFSA and how EFSA operates. The time left was devoted to the discussion of the background and terms of reference. It was agreed to seek clarification from the EC on the scope of the risk assessment. It was also agreed to conduct a literature review on the identification of biological hazards in the nine groups of materials. It was also agreed to have the second meeting on the first week of November as a full-day webmeeting, and the third in mid-December as a half-day webmeeting.

6.8. Scientific opinion on the efficacy and safety of high pressure processing of food¹³

The *ad hoc* WG has fully been established for this mandate and the first WG meeting was held on 15-16 September 2020. The WG chair gave feedback of the progress at that meeting. She reminded about pilot phase to implement in the scientific assessment the draft framework for protocol development. Recommendations from the guidance document were used. Following clarifications of the terms of reference of the mandate were agreed with the EC: (a) high pressure homogenisation is out of scope, (b) the aim of the high pressure processing (HPP) is to increase the microbiological food safety, (c) HPP can be applied at different points in the

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00083>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00343>

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00401>

¹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00380>



processing of food and (d) nutritional aspects are out of scope. In ToR1, HPP could be applied to any food, with few exceptions (low moisture foods). The focus can be on those foods that are currently subjected commercially to HPP (for processing conditions). To broaden the range, evidence for experimental studies could complement. The panel proposed to change microbiological food safety “risk” to “concerns” (e.g. spores). The shelf-life of the foods is to be considered. For ToR2, it was clarified that the end point in the assessment is the raw milk or colostrum for direct consumption. Its further use in cheese or yoghurt production is out of scope. The minimum time/temperature requirements for thermal treatments of milk and colostrum from ruminants from legislation are applicable. The translation of each ToR into assessment questions (AQs) and sub-questions (SQs) was presented. The next WG meetings will be held on 14-15 October 2020 (related to food contact material), on 10 November 2020 (related to BIOHAZ issues) and on 17 November 2020 (related to process contaminants). The deadline for adoption is 31 January 2022.

6.9. Scientific opinion on the microbiological safety of aged meat¹⁴

As indicated at the previous Plenary meeting, the WG chair will be nominated at one of the next plenary meetings, work on this mandate has not started yet. The deadline for adoption of this opinion is 31 December 2022.

7. New Mandates

7.1. New alternative biodiesel process for rendered fat of Category 1 (BDI-RepCat Process, AT)¹⁵

EFSA Secretariat presented to the Panel the general information of the application: timetable, applicant, main description of the method and expertise required to produce the evaluation. The application under discussion in this agenda item, channelled to EFSA through Austria, is not validated yet. Additional information/clarifications have been submitted by the applicant, following the request by EFSA. EFSA Secretariat proposed the Panel to set up in the future a working group that would take care of the assessment of all ABP applications, rather than setting up a dedicated WG for each one of the future ABP applications submitted for assessment. The proposal was supported by the Panel. The Chair of the Panel nominated Avelino Alvarez-Ordóñez as Chair of the *ad hoc* WG which will be established (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 100th Plenary meeting of the Scientific Committee (SC) took place on 16-17 September 2020. The BIOHAZ Chair briefly reported the main points discussed at the meeting. No issues of specific relevance for the BIOHAZ Panel were discussed. For further details refer to the minutes of the SC Plenary meeting¹⁶.

¹⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00380>

¹⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00450>

¹⁶ <http://www.efsa.europa.eu/en/events/event/100th-plenary-meeting-scientific-committee>



8.2. European Commission

No update on this agenda item.

8.3. Update on Scientific and technical assistance on the use of alkaline phosphatase and possible alternative testing to verify pasteurisation of raw milk, colostrum, dairy and colostrum-based products

The EFSA secretariat reminded the panel about the terms of reference of the Article 31 request asking for scientific and technical assistance on the use of alkaline phosphatase and possible alternative testing to verify pasteurisation of raw milk, colostrum, dairy and colostrum-based products. The composition of the ad hoc WG and the workplan was shown. The panel was explained that there will not be an endorsement of the scientific report but that it will be peer-reviewed by two panel members. The deadline for approval of the scientific report is 31 January 2020.

8.4. Update on Scientific opinion for the listing and categorisation of transmissible animal diseases caused by bacteria resistant to antimicrobials, in the framework of the Animal Health Law

Panel member Friederike Hilbert, member of the AHAW WG tackling this mandate and EFSA ALPHA staff Francesca Baldinelli updated the WG on the progress of the WG, including the methodology used to select relevant AMR bacterial pathogens causing diseases in animals and the review questions to be used in the data collection via extensive literature review. The general timelines for addressing the mandate were presented.

8.5. Scientific Networks on MRA and on BSE-TSE

The next BSE-TSE Network meeting is scheduled for 7-8 October 2020 (online meeting). The EFSA Secretariat presented the draft agenda that will include: standard updates of the latest activities carried out by the TSE EURL, EC, OIE and EFSA; presentation of the preliminary results of the 2019 TSE EUSR; presentations of the TSE activities by three new attending countries: Albania, Bosnia and Herzegovina and Turkey; scientific presentations on scrapie in goats, zoonotic potential of atypical strains and presence of multiple strains in TSE isolates.

The next MRA Network meeting is scheduled for 29-30 October 2020 (online meeting).

9. Other scientific topics for information and/or discussion

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

The BIOHAZ Panel Chair thanked the Panel for the efforts and good progress in the implementation of the uncertainty guidance in BIOHAZ assessments. He briefly reported feedback from the last EFSA SC cross cutting Working Group on Uncertainty¹⁷, where examples of uncertainty analysis carried out in BIOHAZ Opinions were presented, in particular on the opinion on the BSE risk in gelatine and collagen. EFSA Secretariat indicated, after internal discussions with colleagues from the SCER Unit, that when working groups need support to

¹⁷ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-uncertainty.pdf>



carry out uncertainty analyses, after agreement with the Panel, a request should be made directly to the cross-cutting WG during their meetings or through EFSA SCER secretariat.

9.2. Update on the EMA expert group on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans

BIOHAZ Panel member Luisa Peixe, who is representing EFSA in the EMA expert group, briefly reported 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 in the next months, the Panel may decide to start working on a self-task on the microbiological risks related to the use of water in processing and handling of fruits and vegetables and related control options, which was discussed by the BIOHAZ Panel in the past. This would also depend on the upcoming external mandates.

10. Any other business

The BIOHAZ Panel was informed that after the recent publication of the Scientific Opinion on the "*evaluation of alternative methods of tunnel composting (submitted by the European Composting Network)*", the applicants requested a post-adoption teleconference to clarify the scientific rationale of the final EFSA output as foreseen by the EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products). EFSA Secretariat informed the Panel of the requested clarifications and discussed them.

The BIOHAZ Panel was informed of the endorsement by the CEP Panel (CEP September Plenary meeting) of the revised version of the scientific opinion on a "*Revision of the joint AFC/BIOHAZ guidance document 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*"¹⁸, adopted in 2010. The same document had been endorsed by the BIOHAZ Panel in the BIOHAZ July Plenary meeting.

EFSA Secretariat explained to the Panel recent EFSA decisions with regards to chairing WG meetings. In particular, it was explained that the expert appointed as WG chair may be invited to participate in the role of chair or member in a given WG meeting, based on EFSA's decision whether the agenda topics are sensitive and/or complex.

EFSA Secretariat reminded the Panel that the next Plenary meeting will be open to observers. Further information about this will follow in due time. EFSA Secretariat and the Panel Chair will prepare the draft agenda for the next Plenary meeting and will assess whether one additional half-day meeting should be preliminarily blocked to ensure sufficient time is available for discussing agenda items.

¹⁸ <https://www.efsa.europa.eu/en/efsajournal/pub/1544>