



UNIT ON BIOLOGICAL HAZARDS AND CONTAMINANTS

Parma, 15 May 2020

SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 136th PLENARY MEETING

**Held on 29-30 April 2020, web-conference
(Agreed on 15 May 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:**

Fabien Schneegans (EC, DG Health and Food Safety, Unit G4; for item 6.4)

Halvard Kvamsdal, Athanasios Raikos (EC, DG Health and Food Safety, Unit E1; for item 6.6)

Paolo Caricato (EC, DG Health and Food Safety, Unit G4; for item 6.9)

■ **EFSA:**

▪ **BIOCONTAM Unit:**

Sean Ashe, Katrin Bote, Maria Teresa da Silva Felício, Beatriz Guerra, Michaela Hempen, Ernesto Liébana, Winy Messens, Karoline Noerstrud, Angel Ortiz-Peláez, Valentina Rizzi, Mirko Rossi, Pietro Stella

■ **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.

4. Agreement of the minutes of the 134th and 135th Plenary meetings held on 18-19 March and on 25 March 2020, web-conference

The minutes of the 134th and 135th Plenary meeting were agreed by written procedure on 6 April 2020.

5. Scientific outputs submitted for possible adoption or endorsement

See agenda item 10.1 (Any other business) in relation to re-adoption of the BIOHAZ Panel Statement on QPS part 11 and of the QPS Opinion 2019, adopted by the BIOHAZ Panel in December 2019.

6. Scientific outputs submitted for discussion

6.1. Application for the evaluation of the alternative method ECN tunnel composting⁴

The relevant WG has held three meetings to date on the application for two proposed methods for composting Category 3 Animal By-Products. These were held on the 6th of February, the 17th of March and the 14th of April. A request for additional information was made by the WG to the applicant on the 15th of April thus stopping the clock on the process. The deadline for the provision of this additional information is the 15th of May.

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00583>



6.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 12: Suitability of taxonomic units notified to EFSA until March 2020⁵

38 notifications were received since October 2019, 19 were related to TUs that already had QPS status and did not require further evaluation. Two notifications included a TU previously recommended for QPS but only for enzyme production or production purposes. The recent notifications intended a different use, therefore the TUs were re-evaluated. Of the remaining 17 notifications, 14 were related to TUs not evaluated for a QPS status for the following reasons: 5 notifications related to filamentous fungi, which were excluded from QPS evaluations; 2 notifications related to *Enterococcus faecium*, which were excluded from QPS evaluations; 5 notifications related to *E. coli*, which were excluded from the QPS evaluations; 2 notifications of *Streptomyces* spp. (1 *Streptomyces aureofaciens* and 1 *Streptomyces lasaliensis*), which were also excluded from the QPS evaluations. The remaining 3 notifications, corresponding to 3 TUs, as well as the 2 notifications that already have a QPS status with qualification and were decided to be included again, were evaluated for a possible QPS recommendation: *Clostridium butyricum*, *Corynebacterium ammoniagenes* and *Pichia pastoris*, already evaluated during previous QPS mandates; and *Gardieria sulphuraria* and *Akkermansia muciniphila*, which are evaluated for the first time. The deadline for the panel statement part 12 is June 2020.

6.3. Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁶

The Extensive Literature Search for the QPS opinion 2020-2022 has started and completed for the first reporting period in the statement part 12. The deadline for the next QPS opinion is December 2022.

6.4. Scientific opinion on potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminants farmed animals⁷

The WG Chair presented the draft opinion for the first time, even it was a session for information only. The draft opinion contained the main sections of the assessment including background information, approaches based on the description of two main risk pathways and the description of an under-development probabilistic model to estimate the BSE infectivity load, measured in cattle oral ID50 (CoID50), contained in the gelatine produced with the bones and hide of one infected adult bovine animal older than 30 months of age with any of the three BSE strains (C, H, L) (hereinafter referred to as 'BSE' or 'BSE infectivity') at the clinical stage of the disease. The chair also presented a preliminary uncertainty table including sources and causes of uncertainty and impact on the conclusions. The panel did not express disagreement with the approach to address the terms of reference (ToRs) following explanations of the knowledge gained about current industry practices. The panel questioned the treatment of the uncertainty and variability in the model and the chair considered the model unclear with many parameters and requested the revision of the model by addressing either variability or uncertainty. It was agreed that, when the model is finalised and this issue has been addressed, it will be shared with some members of the panel the model for revision. The fourth meeting has been fixed for Wednesday 6 May pm and Thursday 7 May am and the feedback of the panel will be discussed.

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00077>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00083>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00436>



6.5. Scientific opinion on the evaluation of public and animal health risks in case of a delayed *post-mortem* inspection in ungulates⁸

The last WG meeting was held on 24 March 2020. The WG chair presented the outcome of that meeting and gave an update of the draft opinion. A detailed suggestion for the *Salmonella* model was presented that includes variability and uncertainty. The model will quantitatively estimate the decrease of sensitivity in the detection of *Salmonella* 24 and 72h after slaughter compared to testing immediately after slaughter. The factors that influence this detection are initial distribution, survival during chilled storage, transfer of cells from carcass to enrichment media and competition with background flora. The input variables are informed by scientific literature. The panel agreed with the modelling approach. The next sub-WG meeting is planned for 6 May 2020. The endorsement of their respective sections by AHAW, CONTAM and BIOHAZ panel is foreseen for September/October and adoption of the opinion by the BIOHAZ panel in December 2020 at the latest.

6.6. Scientific opinions providing guidance on date marking and related food information⁹

The WG Chair updated the Panel on the progress made during the last WG meeting (8 April 2020, web conference). The next WG meeting will take place on 8-9 June as a web conference. The WG Chair presented the ToRs as well as the approaches proposed by the WG to answer these. The Panel agreed with these approaches as well as with the possibility to aggregate some of the subToRs in the final answers to the ToRs (Conclusions). In principle the EC also agrees with this approach. A few comments were received on the decision tree proposed to assist the choice between 'use by' and 'best before' dates and it will be revised considering these. Comments on the Part 1 DM draft opinion were received in written from some Panel members and will be integrated in the version that is being used by the WG members. The Panel gave important suggestions to improve the preliminary decision tree developed to answer the ToR3 on durability/shelf life of opened packages of the Part 2 opinion. The Panel suggested to develop a few examples of the implementation of these decision trees for specific foods and include these in an appendix to facilitate its understanding. The deadline for adoption of the first opinion (ToRs 1 and 2) is October 2020 and of the second opinion (ToRs 3 and 4) is March 2021.

6.7. Scientific opinion on specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed¹⁰

The WG Chair informed the panel about the update of the WG composition, given resignation of a WG member. The Chair updated on the outcome of the 7-8th WG meetings (held on 31 March and 23 April, respectively). She also did an extensive presentation to update the Panel on the different methodologies evaluated by the WG to address ToR1 (concentrations of antimicrobials in the feed that would not develop resistance), and the reasons to go ahead with the selected approach: adaptation of the Acceptable Daily Intake equation (mADI) used by EMA/JEFCA considering a predicted minimal selective concentration (PMSC), as well as PK-based factors (bioavailability, activity) of the drugs in the gut, and the daily feed intake for different animal species (following the guidelines of the FEEDAP Panel). She also presented the results of the on-going pilots conducted with tetracycline and trimethoprim and the uncertainties and challenges associated. The BIOHAZ panel agreed with the approach presented for those antimicrobials and animal species for which data are available. A public

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00124>

⁹ <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>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221>



consultation on the methodology, including one example of its application, will be organised by EFSA in the next months. The next meeting of the sub-WG-AMR will be web-conference on 29 May. The deadline for adoption of the opinion(s) is 30 September 2021.

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

The Chair updated very briefly the Panel on the outcome of the fifth meeting of the WG (web-conference held on 27 April). The WG discussed the contributions received for the three food production sectors identified: terrestrial animals, plants (vegetables, fruits, etc.) and aquaculture, regarding source and pathways for contamination, resistant bacteria and genetic determinants. The deadline for the adoption of the opinion is December 2020.

6.9. Scientific opinion on the use of the so-called “superchilling” technique for the transport of fresh fishery products¹²

The WG chair reminded the terms of reference of the mandate and the previous agreements. She informed the panel about the update of the WG composition, given resignation of a WG member. She then updated the panel about the outcome of the WG meeting that took place on 2 April 2020 by web-conference. This was mainly related to the clarifications of the terms of reference; pointing out that the starting point of the assessment is after the superchilling process. The following groups are of interest (to be confirmed) for ToR1: the alternative group being superchilled fresh fishery products (SFFP) wrapped in plastic bag and placed in polystyrene box and reference group being conventional fresh fishery products (CFFP) wrapped in plastic bag and covered with flake ice made of fresh water and placed in polystyrene box. The purpose is to know if the SFFP stored/transported in boxes without ice is at least as safe as CFFP stored/transported in boxes with ice. The biological hazards would include relevant bacterial pathogens and histamine and the focus would be on the growth/increase of these biological hazards (not survival nor assessment of the public health impact). For ToR 2, it was agreed to focus the assessment on strategies that may be comprised of analytical methods, including the Hydroxyacyl-coenzyme A dehydrogenase (HADH) enzymatic test, and/or other tools (e.g., smart labels that reflect the time/temperature history of frozen foods), allowing an effective detection of the fraudulent use of previously frozen fish to commercialize it in the superchilling status. Further clarification from the requestor (European Commission) would be provided. The translation of the ToR into draft assessment questions and the steps in the assessment were presented. The next WG meeting will take place on 28 May 2020. The deadline for adoption is December 2020.

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

The Panel Chair nominated Ana Allende as Chair of the *ad hoc* WG which will be established for this mandate (conditional to screening and approval of his declaration of interests). The deadline for adoption is 31 January 2022.

7. New Mandates

No new mandates were allocated to the BIOHAZ Panel since the previous plenary meeting.

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

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00437>



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

8.1. Scientific Committee

The 98th Plenary meeting of the Scientific Committee (SC) took place on 22-23 April 2020. The BIOHAZ Chair briefly reported to the Panel about the main topics discussed at the SC meeting. The presentation to the SC of the BIOHAZ work programme was postponed to a future SC Plenary meeting. For further details refer to the minutes of the SC Plenary meeting¹³.

8.2. Update on Rapid Outbreak Assessments and related activities

EFSA Secretariat presented to the Panel the results of the Joint ECDC-EFSA rapid outbreak assessment (ROA) on the multi-country outbreak of *Salmonella Enteritidis* infection linked to eggs, published in February 2020, and an update on current monitoring activities related to food-borne outbreaks.

8.3. European Commission

EFSA Secretariat informed the Panel about future possible mandates in preparation by the European Commission (EC) in the BIOHAZ area, and indicated to the Panel that an update by the EC on BIOHAZ-related activities and on the follow-up of BIOHAZ opinions is expected later this year at a Plenary meeting.

9. Other scientific topics for information and/or discussion

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

Discussion on this agenda item was postponed to the next plenary meeting (4 May 2020, see also agenda item 10).

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

Discussion on this agenda item was postponed to the 2020 June plenary meeting.

9.3. Sharing and co-editing of Plenary documents

The Panel discussed digital collaboration within the Panel, structure and organisation of the folders for sharing and co-editing of documents and related technical problems and solutions.

10. Any other business

The Panel was informed about the inconsistent wording used in the conclusion of the QPS status of *Bacillus velezensis* in the BIOHAZ Panel Statement on QPS part 11, in the QPS Opinion 2019, and in the Annex with the updated QPS list published on the Zenodo community (all adopted by the BIOHAZ Panel in December 2019). Two versions of the conclusion for *B. velezensis* were used in these three documents: 'absence of toxigenic potential and absence of aminoglycoside

¹³ <http://www.efsa.europa.eu/en/events/event/98th-plenary-meeting-scientific-committee>



production or the genes encoding it' versus 'absence of toxigenic potential and absence of aminoglycoside production including the genes encoding it'. The corrected documents were presented and the BIOHAZ panel adopted the following qualification of *B. velezensis*: 'absence of toxigenic potential and absence of aminoglycoside production ability'.

As anticipated at the previous plenary meeting, the Panel confirmed the need to add one extra plenary meeting (4 May 2020, web-conference) to discuss item 9.1, not covered during the present meeting.