



SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 133rd PLENARY MEETING

**Held on 29-30 January 2020, Parma
(Agreed on 13 February 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:

Marina Marini (EC, DG Health and Food Safety, Unit D1)

Paolo Caricato, Kris De Smet (EC, DG Health and Food Safety, Unit G4; for items 6.2, 6.3)

■ EFSA:

■ BIOCONTAM Unit:

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

■ COM Unit:

Anthony Smith

■ 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 132nd Plenary meeting held on 11-12 December 2019, Parma (Italy)

The minutes of the 132nd Plenary meeting were agreed by written procedure on 8 January 2020. EFSA Secretariat informed the Panel about editorial amendments brought to the minutes.

5. Scientific outputs submitted for possible adoption or endorsement

No outputs submitted for possible adoption or endorsement.

6. Scientific outputs submitted for discussion

6.1. Scientific opinion providing an update and review of control options for *Campylobacter* in broilers at primary production⁴

The WG chair presented the draft opinion in detail, in particular, the concluding remarks for each section and the ranking of control options which was carried out using expert knowledge elicitation (EKE) were discussed. The methodology used was a two-step process whereby the WG first prioritised a set of control options for the EKE process that were judged to have a high probability of an effect above 10% risk reduction and then judged their expected effect on human campylobacteriosis. The panel suggested to clarify the methodology further to make it clear for the reader which decisions were taken and provide justification. The WG will address the comments raised by the panel and present an updated draft opinion for possible adoption

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00676>



at the next meeting. The deadline for this mandate was extended by two months, i.e. end of March 2020.

6.2. Scientific opinion on the public health risk posed by *Listeria monocytogenes* in frozen fruit and vegetables including herbs, blanched during processing⁵

The WG Chair gave an update on the outcome of the last WG meeting which took place on 13 December 2019 in Parma. She briefed that the discussion of the potential sources of uncertainty identified in the assessment using the mgQMRA model took a considerably amount of time. The objective was to assess the impact that these uncertainties could have on the outcome, i.e. the probability of illness per serving of non-cooked or cooked blanched frozen vegetables and the number of cases due to blanched frozen vegetables. This is the first step of the uncertainty assessment; the second one foreseen was to conduct an EKE using the Sheffield protocol. The first step was finalized resulting in an elaborated uncertainty table. The draft opinion was presented to the Panel for thorough reading and in particular the concluding remarks for each section and the conclusions were carefully reviewed. The comments received were discussed. For term of reference 1, the panel agreed to conduct the uncertainty assessment without EKE. Minor comments were discussed in the assessment of term of reference 2 and term of reference 3. The panel was informed that the EC requested to also conduct the evaluation of the impact of setting microbiological targets for *Listeria monocytogenes* in frozen vegetables. It was explained and agreed how this would be carried out. There is no additional WG scheduled and the deadline for adoption of the opinion is March 2020.

6.3. Scientific opinion on the use of the so called "tubs" for transporting and storing fresh fishery products⁶

The last WG meeting was held on 27-28 January 2020 in Parma. The WG Chair presented the draft scientific opinion for thorough reading and a discussion was held. The conditions of the assessment were better presented using revised conceptual maps. The panel proposed to clarify that the "cooling after a temperature peak" process also consists of further keeping the temperature. The WG Chair presented the final outcome of the heat transfer modelling and assessment of growth/survival of hazards and histamine levels. The panel informed to stress that the assessment basically relies on temperature differences between the two containers and agreed to focus on the maximum duration being 3 days as 5 days is an exceptional situation. The predictive modelling considered *L. monocytogenes* and *Morganella psychrotolerans* growth, as previously agreed. In addition, *Aeromonas hydrophila* growth will be simulated using a calibrated *Aeromonas* model as well as *Clostridium botulinum* growth and *Vibrio* survival. Related to public health risks, the panel suggested to reply in a "theoretical way" as it depends on various factors (such as mode of consumption) and therefore cannot be answered. The panel confirmed that for the public health concern growth is more important and deserves more attention compared to survival of hazards. The next WG meeting will be held on 24 February 2020 by web-conference. The deadline for adoption is March 2020.

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01006>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00053>



6.4. Scientific opinion on the use of the so-called “superchilling” technique for the transport of fresh fishery products⁷

The first meeting to discuss this mandate has been scheduled on 24 February 2020 by web-conference. The deadline for adoption is December 2020.

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

The WG chair presented a list of assessment questions for the interpretation of TORs that ask for each disease/condition if the sensitivity of timely detection of that disease/condition is decreased if *post-mortem* inspection is delayed by 24/72 hours after slaughter or arrival at the game handling establishment? A probability range will be given for each answer based on expert judgement. The panel requested the WG to provide a description of the methodology suggested to provide that probability range for the next plenary in March. The next sub-WG meeting is planned for 12 February 2020. The deadline for adoption is December 2020.

6.6. Scientific opinion on potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminants farmed animals⁹

The WG Chair reminded the terms of reference of the mandate, and presented the approaches agreed in the second meeting on Wednesday 8 January 2020. The current practices gathered via contact with EU industry associations have led to the WG to consider the quantitative estimation of the risk posed by the possible contamination of ruminant feed with BSE (TSE)-infected collagen/gelatine used in feed intended for non-ruminant animals including aquaculture by cross-contamination of feed and by the use food waste containing infected C&G to feed non-ruminants unfeasible. The chair briefed the activities implemented so far in terms of data collection and development of the conceptual framework for a QRA. An individual model of the BSE residual risk in the gelatine produced with bones and hide of one adult bovine animal infected with BSE at clinical stage has been considered instead. The structure of the model was presented and well received by the Panel. A possible extension of the individual model to a population model was also discussed but discarded by the WG due to the lack of data on the two risk pathways that would need to be considered. The date of the third meeting has been fixed for Thursday 19 and Friday 20 March 2020, linked to the next BIOHAZ Panel plenary meeting.

6.7. Scientific opinions providing guidance on date marking and related food information¹⁰

The WG Chair updated the Panel on the progress made during the third WG meeting (19 December 2019, webconference). During this webconference tasks were allocated to the WG members and EFSA. A sub-WG meeting took place on 14 January, and on 20 January an informal meeting took place to discuss the draft decision tree proposals. The next WG meeting will be on 17/18 February in Parma. The deadline for adoption of the first opinion (ToRs 1 and 2) is October 2020 (after one month extension agreement with EC) and of the second opinion (ToRs 3 and 4) is March 2021.

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00437>

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

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00436>

¹⁰ <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>



6.8. Self-tasking mandate for a 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 third meeting of the WG (web-conference on 24 January). The WG had discussed the contributions received for the three food production sectors identified: terrestrial animals, agriculture regarding foods of non-animal origin (plants production), and aquaculture. The WG members had developed sector maps in which the different production workflows, and AMR sources and transfer pathways for contamination of the food via “food-producing environment” associated to each sector had been indicated. This information, gathered in order to address ToR1, was discussed. Next meeting of the WG will be 19-20 March in Parma. The deadline for the adoption of the opinion is December 2020.

6.9. Request for a scientific opinion on specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed¹²

The WG Chair updated the Panel on the progress made during the fifth meeting of the WG (sub-WG-AMR, 12-13 December). She presented the on-going discussions on the possible approach to infer concentrations of antimicrobials in the feed that would not develop resistance (e.g. adaptation of the Acceptable Daily Intake equation (mADI) used by EMA/JEFCA considering minimal selective concentrations of the antimicrobials, as well as bioavailability and activity of the drugs in the gut and the daily feed intake for different animal species. The WG experts continue with the assessment of trimethoprim and tetracycline as a pilot. The next meeting of the sub-WG-AMR will be web-conference on 26 February. The deadline for adoption of the opinion(s) is 30 September 2021.

6.10. Application for the evaluation of an alternative method for the production of biodiesel from processed fats derived from category 1,2 and 3 animal by-products¹³

The WG chair presented the draft opinion for thorough review although it was the first time it had been circulated to the BIOHAZ Panel due to the delay in the establishment of the working group and the mismatch between the meetings of the working group and of the Panel. The standard sections of the scientific opinions on the evaluation of methods for the processing of ABP were reviewed with special emphasis on the section on the level of risk reduction. The Panel discussed the evidence provided by the applicant and the suitability of the methods applied to demonstrate the efficacy of the method at experimental level. It was recognised that there are new methods that would allow the quantification of the level of reduction of the TSE infectivity in a more accurate way and with higher sensitivity and should be promoted among applicants for future applications. It was also acknowledged the lack of standards required for the treatment of Category 1 material in the legislation or EFSA guidelines. The chair of the Panel encouraged to take forward this issue and several forms were suggested: in the recommendations of the opinion, direct communications between EFSA and the EC, self-task, mandate to review the guidelines, etc. the chair of the WG informed that the decision of the WG has been to apply the approach followed by previous EFSA opinions whereby a 6 log₁₀ reduction is required by the alternative method to be considered equivalent of the approved standard method. The chair of the WG read the conclusions and recommendations where all

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

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221>

¹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00432>



these points were captured. The Panel received well these two sections and no major changes were requested in the final draft to be submitted for adoption in the next plenary.

6.11. Application for the evaluation of the alternative method ECN tunnel composting¹⁴

The WG chair indicated that the composition of the WG dealing with the assessment of this application is being finalised, with a view of having a first WG meeting in early February. Unless additional information would be needed by the applicants during the process, which would imply stopping the clock on the timetable for the assessment, the deadline for adoption of the scientific opinion is 12 June 2020. The Panel chair informed the Panel of the recent nomination, by written procedure, of Alessandra De Cesare as Vice-Chair of the ad hoc WG.

6.12. 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 2020¹⁵

The Panel Statement 11 adopted by the BIOHAZ Panel in December 2019 has been published.¹⁶ Ten taxonomic units have so far been notified in the reporting period of the QPS statement part 12. The deadline for the panel statement part 12 is June 2020.

6.13. Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA¹⁷

The scientific opinion (2016-2019) adopted by the BIOHAZ Panel in December 2019 has been published.¹⁸ The Extensive Literature Search for the QPS opinion 2020-2022 is in preparation and will start soon. The deadline for the next QPS opinion is December 2022.

7. New Mandates

No new mandates have been received since the previous plenary meeting.

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

8.1. Scientific Committee

No new Plenary meeting of the Scientific Committee (SC) has taken place since the previous BIOHAZ Plenary, therefore there were no updates on this agenda item.

8.2. Update on Rapid Outbreak Assessments and related activities

There were no new updates on this agenda item.

¹⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00583>

¹⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00077>

¹⁶ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.5965>

¹⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00083>

¹⁸ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.5966>



8.3. European Commission

There were no new updates on this agenda item.

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 indicated that in one of the next plenaries a thorough discussion on the experience gained by the BIOHAZ Panel in the implementation of the Guidance will take place, with the aim of analysing advantages and disadvantages, and the impact on Panel and WG activities. In particular, the Panel should reflect in detail on the lessons learnt from the implementation of the uncertainty guidance in the mandates discussed under agenda items 6.1, 6.2, 6.3.

9.2. Presentation of the EFSA Guidance on Communication of Uncertainty in Scientific Assessments

Anthony Smith (EFSA COM Unit) provided a presentation to the Panel on the EFSA Guidance on Communication of Uncertainty in Scientific Assessment. He explained the structure of the guidance, key points in the communication of uncertainty, and provided examples on communication by risk assessors of different types of uncertainty expressions as tackled by the guidance.

9.3. Update on 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 the progress made in the EMA expert group meetings and the plan for future meetings. She reminded the Panel about the publication of the EMA advice on criteria for designation of antimicrobials to be reserved for treatment of human infections. She also informed the Panel of the recent publication of the EMA/AMEG advice on categorisation of antibiotics in the EU. EFSA Secretariat will circulate the link to these documents to the Panel.

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

There were no new updates on this agenda item.

9.5. Presentation on the EU One Health 2018 Zoonoses Report

Due to lack of time this presentation was postponed to a future plenary meeting.

9.6. Presentation on the EU Summary Report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2018

Due to lack of time this presentation was postponed to a future plenary meeting.



9.7. Presentation on new EFSA expert compensation scheme, extension of current Panel mandate and mutual assessment of EFSA staff and experts

The Head of the RASA department attended the Plenary meeting to inform the Panel about the changes introduced by the New Transparency Regulation and the implication to the Scientific Committee and Panels, in particular in relation to the Panel mandate extension, the increase in expert indemnity, expert mutual assessment and timeline.

10. Any other business

Given that during the next plenary (18-19 March 2020) four opinions will be tabled for adoption, the Panel discussed the possibility to preliminary block the date for one three-hour-web-plenary towards the end of March. EFSA Secretariat will circulate possible dates for a meeting. If not needed, the meeting would be then cancelled.