



SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 132nd PLENARY MEETING

**Held on 11-12 December 2019, Parma
(Agreed on 8 January 2020)**

Participants

■ **Panel Members:**

Ana Allende, Avelino Alvarez-Ordóñez (web-conference), 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:**

Halvard Kvamsdal (EC, DG Health and Food Safety, Unit E1; for item 6.7)

■ **EFSA:**

■ **BIOCONTAM Unit:**

Sean Ashe, Katrin Bote, Sandra Correia, Maria Teresa da Silva Felício, Beatriz Guerra, Michaela Hempten, Winy Messens, Angel Ortiz-Pelaez, Valentina Rizzi, Mirko Rossi, Eleonora Sarno, Pietro Stella

■ **ALPHA Unit:**

Francesca Baldinelli

■ **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

Apologies were received from Panel member Giuseppe Ru (12 December).

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 131st Plenary meeting held on 23-24 October 2019, Parma (Italy)

The minutes of the 131st Plenary meeting were agreed by written procedure on 7 November 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. 11: Suitability of taxonomic units notified to EFSA until September 2019⁴

The last WG meeting was held on 21/22 October in Parma. The 5th ELS exercise (articles published between January and June 2019) was finalised during this meeting. Summary of this 5th ELS exercise was incorporated in the Panel Statement part 11. Between April and September 2019, the list of microorganisms notified to EFSA from applications for market authorisation was updated with 54 biological agents. Of these, 23 already had QPS status, 14 were excluded from the QPS exercise by the previous QPS mandate (7 filamentous fungi) or from further evaluations within the current mandate (6 notifications of *Escherichia coli*) and *Sphingomonas paucimobilis* which was already evaluated in the previous Panel Statement. *Aurantiochytrium limacinum*, *Bacillus velezensis*, *Corynebacterium stationis*, *Cupriavidus necator*, *Hamamotoa singularis*, *Kodamaea ohmeri*, *Lactobacillus parafarraginis*, *Paenibacillus illinoisensis*, *Pantoea ananatis*, *Parageobacillus thermoglucosidasius*, *Rhodococcus aetherivorans*, *Rhodococcus ruber*, *Tetraselmis chuii*, and *Zygosaccharomyces rouxii* 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>



5.2. Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA⁵

The last WG meeting was held on 21/22 October in Parma. The 5th ELS exercise (articles published between January and June 2019) was finalised during this meeting. Summary of this 5th ELS exercise was incorporated in the Panel Statement part 11. A draft summary of all 5 ELS exercises run within this three-year mandate was included in the document. The scientific opinion was adopted by the BIOHAZ Panel.

5.3. 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. The Panel discussed the draft opinion and provided some comments to finalise the answer to terms of reference and recommendations. The scientific opinion was adopted by the BIOHAZ Panel.

6. Scientific outputs submitted for discussion

6.1. Scientific opinion providing an update and review of control options for *Campylobacter* in broilers at primary production⁷

The WG chair informed the panel on the progress of the draft opinion and the results from the expert knowledge elicitation (EKE) that was carried out on 19/20 November. The chair informed the panel about the experiences with the implementation of the Uncertainty Guidance. Including uncertainty in the risk assessment adds workload and complexity but also provides more precision in the assessment. The Panel suggested to add an introductory chapter before the ranking of control options that provides a justification for the use of EKE. The conclusions should be refined and presented in five sub-sets: review, identify and rank control options, advantages and disadvantages and combination of control options. The next WG meeting is scheduled on 9 January 2020. The original deadline for adoption of the opinion was January 2020, however EFSA requested to the European Commission the extension of the deadline 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 processing⁸

The WG Chair updated the Panel on the outcome of the last WG meeting which took as place on 18 November by web-conference. The draft opinion was presented to the Panel for first reading and a discussion was held. For term of reference 1, the results of the ranking of the mean probability of illness (for elderly females and males in the EU) per serving of blanched frozen vegetables was compared with seven RTE food subcategories categorized by the type of packaging (i.e. normal atmosphere packaging or reduced oxygen packaging). The blanched frozen vegetables were categorized in relation to the mode of use/consumption (i.e. those cooked or uncooked). Also, the ranking based on the predicted number of cases was shown

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-2018-00676>

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01006>



considering different proportions of consumption as either cooked or uncooked. Minor comments were discussed in the assessment of term of reference 2 and term of reference 3. The WG Chair informed that the uncertainty assessment with EKE will take place at the WG meeting in Parma on 13 December 2019. The deadline for adoption is March 2020.

6.3. Scientific opinion on the use of the so called "tubs" for transporting and storing fresh fishery products⁹

The last WG meetings were held on 4 November and 7 November 2019 by web-conference and on 10 December in Parma. The WG Chair presented the draft scientific opinion to the Panel for the first reading and a discussion was held. The two processes ("cooling after a temperature peak" and "keeping the chill temperature") and the scenarios of the assessment together with the conceptual map were presented in detail. The hazard identification has been concluded considering the association of the hazards to human illnesses and potential for growth and survival. The increase of the water content of the fish meat of fresh fishery products transferred to fresh water/ice ("tubs") was concluded alongside the decrease of the water phase salt associated with this potential water content increase. The preliminary heat transfer modelling results were presented and the panel agreed with the approach. The predictive modelling will focus on *Listeria monocytogenes* and *Morganella psychrotolerans* as it was agreed that the difference in growth would be smaller for the other hazards. The next WG meetings will be held on 27-28 January 2020 in Parma and on 24 February 2020 by web-conference. The deadline for adoption is March 2020.

6.4. Scientific opinion on the use of the so-called "superchilling" technique for the transport of fresh fishery products¹⁰

There was no update to be provided for this opinion as this assessment will start in 2020 when the work on the scientific opinion on the use of the so called "tubs" for transporting and storing fresh fishery products is further developed. 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 ungulates¹¹

The WG Chair updated the Panel on the outcome of the last WG meeting which took as place as sub-WG on 18 November 2019. The draft opinion will describe for each disease/condition the following information: description of the pathogen/agent, pathology, testing requirements and protocols by animal species. Where possible, reference to previous EFSA opinions is made. Throughout the document, any differences between domestic and game animals will be specified. The sub-WGs on animal health and contaminants are working in parallel and a meeting of the entire WG is planned for 18th December 2019. The deadline for adoption is December 2020.

6.6. 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 very briefly the Panel on the progress made during the fourth WG meeting (subWG-AMR, web 8 November). The fifth WG meeting would take place linked to the Plenary (12-13 December, Parma). She presented briefly the on-going discussions on available data (minimal inhibitory concentrations of the most susceptible bacteria included in EUCAST or other reports on antimicrobial resistance, minimal selective concentrations and PNECs), the

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00053>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00437>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00124>

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



main pharmacokinetics aspects to be considered and the possible approach to be followed (e.g. adaptation of the Acceptable Daily Intake equation (mADI) used by EMA/JEFCA). During the first months of 2020, only meetings of the SubWG-AMR will take place. The deadline for adoption of the opinion(s) is 30 September 2021.

6.7. Scientific opinions providing guidance on date marking and related food information¹³

The WG Chair reminded to the Panel the terms of reference of the mandate and updated the Panel on the progress made during the second WG meeting (30-31 October 2019, Parma). During the meeting the WG discussed and clarified several aspects of the terms of reference with the European Commission and related wording. In the present opinion, and from a microbiological perspective, “unfit for human consumption” is considered to be related only to food quality not affecting health and is taken as the relevant end point for decisions concerning best-before date marked food. The decision on which type of date-marking to apply is interpreted as being related only to whether the risk will increase with time or not, i.e. growth of pathogenic microorganisms and/or toxin production can take place during transport and storage. To answer terms of reference 1 and 2, tool(s) will be developed in the opinion to guide food business operators on the appropriate date marking, on factors needed to be taken into account when setting the shelf life and on the appropriate storage conditions. A review of the literature, existing guidances and advice will be provided to answer terms of reference 2, 3 and 4. Uncertainties related to the data, assumptions and methods used in the opinion will be discussed, as well as their impact on decisions possibly taken through the tool(s) proposed. The deadline for adoption of the first opinion (ToRs 1 and 2) is September 2020 and of the second opinion (ToRs 3 and 4) is March 2021.

6.8. Scientific opinion on potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminants farmed animals¹⁴

The Panel chair informed the Panel of the recent nomination, by written procedure, of Marion Simmons as Vice-Chair of the ad hoc WG.

The WG Chair reminded the terms of reference of the mandate, and the outcome of the first WG meeting. It took place on 21 October 2019. During such meeting the terms of reference were discussed, the possible methodological approaches and the data needed. The request to the EC for clarification of the terms of reference were received and the assessment will be conducted accordingly: the risk should be assessed only for cattle and the risk should be only assessed with respect to C-, L- and H-BSE. The decision on the possibility to take a quantitative or semi-quantitative approach to approach the terms of reference will be taken during the second WG meeting, which has been fixed for Wednesday, 8 January 2020.

6.9. 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 chain¹⁵

The Chair informed the Panel on the outcome of the first (24-25 October, Parma) and second (web 5 December) meeting of the WG. The WG had agreed on the interpretation of the ToRs and discussed on the different topics and contributions received for the three food production systems identified: terrestrial animals, agriculture regarding foods of non-animal origin, and aquaculture. System maps in which the sources and pathways for contamination of the food

¹³ <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>

¹⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00436>

¹⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00343>



via “food-producing environment” (e.g. farms, fields, slaughter, processing plants) are being developed and will be discussed in the next meeting (24 January, web-conference). The deadline for the adoption of the opinion is December 2020.

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-products¹⁶

The Panel chair informed the Panel of the recent nomination, by written procedure, of Avelino Alvarez-Ordóñez as Chair of the ad hoc WG and of Marion Simmons as Vice-Chair of the ad hoc WG.

The chair reminded the main aspects of the application for an alternative method for the production of biodiesel from processed fats derived from category 1,2 and 3 animal by-products. The application under discussion in this agenda item, submitted by an Irish company and channelled to EFSA through the Irish competent authority, was validated by EFSA on 8 October hence the opinion will have to be delivered on 8 April 2020, as per legal requirement, unless additional information is deemed needed by the working group to conduct the evaluation. The chair presented the working group composition and the work plan. At the time of reporting, no meetings had taken place. The first working group meeting will take place on Monday 16 December 2019, as a web-conference, followed by the second meeting as a one-day physical meeting in Parma on Thursday 9 January 2020. The chair informed that one member of the WG has taken a special role to review the dossier in advance and drafting the scientific opinion.

6.11. Application for the evaluation of the alternative method ECN tunnel composting¹⁷

The application under discussion in this agenda item, channelled to EFSA through the Belgian competent authority, was validated by EFSA on 12 December. EFSA will have six months to conduct the assessment, unless additional information would be needed by the applicants during the process. 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).

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

The 96th Plenary meeting of the Scientific Committee (SC) took place on 4-5 December 2019. The BIOHAZ Chair briefly reported to the Panel about the main topics discussed at the SC meeting. In particular, he briefly reported about the discussions on uncertainty, and indicated that in one of the next SC meetings, he will report back to the SC the experience of the BIOHAZ Panel in the implementation of the uncertainty guidance. He also informed the Panel that the

¹⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00432>

¹⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00583>



endorsement of the draft framework for protocol development for EFSA's non-application scientific assessments was postponed. For further details refer to the minutes of the SC Plenary meeting¹⁸.

8.2. Update on Rapid Outbreak Assessments and related activities

EFSA Secretariat presented to the Panel the latest published EFSA/ECDC Outbreak Assessments (ROA) on multi-country outbreak of *Listeria monocytogenes* sequence type 6 infections linked to ready-to-eat meat products. A brief overview on the ongoing activities of monitoring and of evaluation of food incidents/outbreaks was also provided.

8.3. European Commission

The European Commission representative indicated that planning on possible future mandates on the BIOHAZ area were shared with EFSA, as preliminary indicated in previous plenary meetings.

8.4. Scientific Networks on BSE-TSE and MRA

No new Network meetings have taken place. Next meetings will take place in 2020.

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.

9.2. 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.

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

No update on this agenda item.

10. Any other business

Two additional items were discussed within this agenda item.

EFSA Secretariat (ALPHA Unit) presented to the BIOHAZ Panel a recent mandate received for a scientific opinion on listing and categorisation of transmissible animal diseases caused by bacteria resistant to antimicrobials, in the framework of the Animal Health Law. The mandate

¹⁸ <http://www.efsa.europa.eu/en/events/event/96th-plenary-meeting-scientific-committee>



is assigned to the EFSA AHAW Panel, who is now setting up an ad hoc WG to draft the scientific opinion. Given the expertise on AMR in the BIOHAZ Panel, the Panel was requested, if possible, that one expert from the Panel would join the ad hoc WG. The BIOHAZ Panel would also be updated regularly on the progress of the mandate and requested to provide comments on the AMR aspects of the draft opinion under development.

EFSA Secretariat (BIOCONTAM Unit) informed the Panel on an ongoing EMA public consultation on a draft EMA CVMP reflection paper on promoting the authorisation of alternatives to antimicrobials in the EU. This reflection paper follows up a past EMA-EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU (RONAFA Opinion), which was adopted by the BIOHAZ Panel in December 2016.