



SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 129TH PLENARY MEETING

**Held on 3-4 July 2019, Parma
(Agreed on 18 July 2019)**

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

■ **Hearing Experts¹:**

Not applicable

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

Marini Marina (EC, DG Health and Food Safety, Unit D1; for 3 July)
Eric Thévenard (EC, DG Health and Food Safety, Unit G4; for item 6.6 and 8.3)
Petros Angelopoulos (EC, DG Health and Food Safety, Unit G4; for item 6.6)
Athanasios Raikos, Halvard Kvamsdal (EC, DG Health and Food Safety, Unit G4; for item 6.6)
Luisa Antunes (EC, DG Health and Food Safety, Unit G4; for item 6.4 and 6.10)

■ **EFSA:**

■ **BIOCONTAM Unit:**

Pierre-Alexandre Beloeil, Sandra Correia, Maria Teresa da Silva Felício, Beatriz Guerra, Michaela Hempten, Maria Francesca Iulietto, Ernesto Liebana, Winy Messens, Angel Ortiz Pelaez, Valentina Rizzi, Mirko Rossi, Eleonora Sarno, Pietro Stella

■ **LEGAL AND ASSURANCE SERVICES Unit:**

Simone Gabbi (for item 9.5)

■ **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 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 127th Plenary meeting held on 9-7 March 2019, Parma (Italy)

The minutes of the 127th Plenary meeting were agreed by written procedure on 25 April 2019.

5. Scientific outputs submitted for possible adoption or endorsement

None

6. Scientific outputs submitted for discussion

6.1. 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 article evaluation ELS exercise (articles published between January and June 2019) will be launched soon and its summary included in this Panel Statement. Between April and June 2019, the QPS notification list was updated with 16 microorganisms from applications for market authorisation. Of these, 8 biological agents already had QPS status, 4 were excluded from the QPS exercise by the previous QPS mandate (3 filamentous fungi) or from further evaluations within the current mandate (1 notification of *Escherichia coli*). *Pantoea ananatis*, *Schizochytrium* sp. and *Protaminobacter rubrum* will be evaluated for the first time. The next working group (WG) meeting will be held on 9 September by web meeting. The Panel Statement will be presented for possible adoption in December 2019.

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00831>



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

Last meeting was held on 21 (afternoon) and 22 May in Valencia. The article evaluation ELS exercise (articles published between January and June 2019) will be launched soon and its summary included in the Panel Statement part 11. The overall summary of all ELS exercises run the three-years length of this mandate will be included in this opinion. The next working group (WG) meeting will be held on 9 September by web meeting. The deadline for adoption of this scientific opinion is December 2019.

6.3. 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 introductory section 1.3. Additional information as well as section 3.1. have been shortened, simplified and partially moved into an Appendix. An explanation of how hybrid STEC strains are understood in this opinion has been added to the draft opinion. EC representatives participated at the last meeting on 21 June in Brussels and the WG Chair summarised the distinct way in which EC risk managers currently look at the public health risk posed by STEC or *Salmonella* spp. in food. EFSA will reconfirm with EC if "tap water (including well water)" should also be considered as a relevant source in the ranking model developed to answer terms of reference (ToRs). The next WG meeting will take place on 2 October 2019 as a web conference and the EC will be available to clarify/discuss questions. The deadline for the adoption of this scientific opinion is at the plenary meeting on 11-12 December 2019.

6.4. Scientific opinion on the application and use of next generation sequencing (including whole genome sequencing) for risk assessment for foodborne microorganisms⁷

The WG Chair updated the Panel on the progress of work made. The draft opinion includes now a broader perspective on the use of next generation sequencing (NGS) for all general steps of microbiological risk assessment (MRA). The Panel was asked to provide comments on the summarising figure that addresses the added value of NGS use in MRA. The first sections of the draft opinion answering ToR 1 will be restructured removing the specific analysis of benefits, challenges and opportunities and focusing instead on concise, summarising key messages. The next WG meeting will take place in Parma from 4 to 5 July 2019 followed by a web conference on 26 September. The deadline for adoption of this opinion is the October 2019 plenary meeting.

6.5. Scientific opinion providing an update and review of control options for *Campylobacter* in broilers at primary production⁸

The WG Chair updated the panel on the progress made during the last WG meeting. A revised structure of the draft opinion was suggested, moving some sub-chapters of the main text to the background, i.e. update on broiler production and risk factors. The assessment itself will focus on the control options, divided into those that reduce flock prevalence and those that reduce *Campylobacter* concentrations. First results of the population-attributable fractions

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-2017-00397>

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00676>



were presented which are used to assess effects on flock prevalence. The second day of the last WG meeting focussed on the preparation of an expert knowledge elicitation (EKE) on uncertainty which will take place on 19 November 2019. An approach was chosen to document the uncertainty for each control option in preparation to the EKE. The next meeting is on 1 October 2019. The deadline for adoption is January 2020.

6.6. Scientific opinion on an update of the scientific opinion on Chronic Wasting Disease (CWD) in cervids⁹

The Chair of the WG presented the draft of the scientific opinion for thorough reading by highlighting the changes made in the draft following the comments by the panel during the first reading and by the panel internal reviewers, focusing on the concluding remarks and the answers to the ToRs. The WG Chair mentioned that section Data and Methodologies had been revamped, the uncertainty table completed, and the appraisal of the studies included in the table of risk factors had all been completed, as it had been announced in the previous plenary. The Panel received well the changes, in particular the new concluding remarks added to almost all sections. The descriptive uncertainty analysis was accepted without assessing the direction of the impact but listing the ToRs affected by each source of uncertainty. The draft of the answers to the ToRs were commented by the panel and a number of changes were proposed for the final draft, including the transfer of some bullet points to concluding remarks, more targeted answers to the questions posed by ToR 1, the inclusion of the recommendations of measures to prevent risk, and the removal of the scenarios of disease in the answers to ToR 3, among other of minor relevance. The WG Chair explained that the intention of the WG was to include short answers to the ToRs and move to the concluding remarks explanations that do not actually address the ToRs. There were different opinions in the Panel and the Panel Chair insisted that the answers to the ToRs should be “fit for purpose”, as short as possible and as long as necessary. Overall the conclusions of the opinion were not contested by the Panel. The last meeting will be a web-conference on Thursday 18 July 2019.

6.7. Request for a scientific opinion on the public health risk posed by *Listeria monocytogenes* in frozen fruit and vegetables including herbs, blanched during processing¹⁰

The WG Chair updated the panel on the progress made during the third WG meeting held in Parma on 1-2 July. She reminded that the assessment would be restricted to blanched frozen vegetables. The draft assessment questions (AQs) to be addressed by the assessment when addressing the different ToRs were presented together with some hypothetical answers to illustrate their formulation. With regard to ToR 1 it was agreed that *L. monocytogenes* is the most important pathogen in blanched frozen vegetables based on current evidence and that the vegetables would be treated as one group when comparing risk with the one posed by other pathogen-food combinations. The tool Risk Ranger was selected for the semi-quantitative approach. For the quantitative approach, the generic QMRA developed in the previous *Listeria* opinion would be adapted and scenario analysis would be used. The approach taken to answer to ToR 2 was to prepare first the flowcharts for the production and consumption of blanched frozen vegetables followed by the identification of the main factors affecting contamination and growth of *L. monocytogenes* during the various steps. The potential control options to be considered by ToR 3 would be divided in prerequisite programme (PRP), control points (CP) and critical control points (CCP). The focus will be on practical control options. Available

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00763>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01006>



guidelines for the industry will be critically appraised and general recommendations will be summarized for routine monitoring for *L. monocytogenes*. The WG Chair also gave an update on the steps in the uncertainty assessment. The panel was informed that data has been received following the request to the Microbiological Risk Assessment (MRA) Network and that the deadline to provide data has been extended until end of July 2019. The draft industry guide of the European Association of Fruit and Vegetable Processing Industries (PROFEL) on good practices/HACCP to control *Listeria* in the frozen fruit and vegetables sector is expected to be presented at the next WG meeting on 1 October by webconference. The deadline for adoption is March 2020.

6.8. Request for a scientific opinion on the use of the so called "tubs" for transporting and storing fresh fishery products

The WG Chair presented the outcome of the third WG meeting held on 27 June 2019 by web-conference. The conceptual map with the various conditions to be assessed were reminded. The slightly revised draft AQs and their hypothetical answers were presented. The AQ 1 currently reads as "*What is the inactivation extent (i.e. log decrease) or growth potential (i.e. log increase) of relevant biological hazards when fresh fishery products, first stored in fresh or sea water/ice ("tubs") on board and then transferred to fresh water/ice ("tubs") compared to being transferred to ice (boxes) for transporting and storing in on land establishments?*". The AQ 2 is: "*What is the magnitude of the histamine accumulation in fish species associated with a high amount of histidine when (as before)?*" while the AQ 3 is "*What is the contribution of the change of the water content of the fish meat when (as before) on previous AQs outcomes?*". An update was given on the six steps to answer those AQs. The WG Chair also gave an update on the steps in the uncertainty assessment. She informed that the WG members were asked to identify and list the uncertainty sources encountered during the assessment and evaluate in which direction the uncertainty may affect the outcome of the assessment. A template was proposed. The next meeting will take place on 26-27 September in Parma. The deadline for adoption is March 2020.

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

The WG Chair updated the panel on the outcome of the first WG meeting which took place on 11 June 2019. The approach to answering the terms of reference is mainly based on literature review; for *Salmonella*, predictive modelling will be used to assess the effect on extended storage. The list of diseases/conditions was divided among three sub-WGs on animal health, biological hazards in food, and chemical hazards. For the uncertainty analysis, it was suggested to use an expert knowledge elicitation in order to describe the uncertainty about the estimated effect of delayed *post-mortem* meat inspection on the detection of the listed conditions. The next meetings will be organised in sub-WG meetings and the whole WG will meet again in early December 2019. The deadline for adoption is December 2020.

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

The WG Chair updated the panel on the progress made during the first WG meeting (web-conference on 12 June). The preliminary table of contents for the draft scientific opinion was presented. Different approaches (e.g. PNECs, SCMs, ADIs/NOAECs/NOAELs) could be suitable to address 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 (ToR1). The suitability of the different approaches will be explored by the Sub-WG AMR. To assess which levels of the antimicrobials have a growth promotion/increase yield effect (ToR2), an extensive literature review will be done, and results will be analysed by the SubWG-GP. Answers to both ToRs will be given per substance or antimicrobial classes in one or several opinions. This will be decided in a later stage. Deadline for adoption of the opinion(s) is 30 September 2021.

6.11. Scientific opinions providing guidance on date marking and related food information

EFSA Secretariat presented the workplan proposal for this mandate, received on 21 May 2019. An *ad hoc* WG dealing with this mandate is going to be set up.

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

EFSA Secretariat informed that the existing *ad hoc* working group on the use of the so called "tubs" for transporting and storing fresh fishery products would be available to address the mandate. Sara Bover-Cid would continue as Chair of this WG (conditional to screening and approval of her declaration of interests). The EFSA Secretariat discussed the term of reference 2 with the EC and internally in EFSA to assess the link with food safety and whether it would fall under EFSA remit. It was agreed that this ToR would be addressed as it is formulated but that the link to public health would be clarified in the Scientific Opinion by inclusion of a sentence in the interpretation of the ToR. The deadline for adoption is December 2020.

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

No updates on this mandate; an *ad hoc* WG dealing with this mandate is going to be set up.

7. New Mandates

7.1. 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 chain

EFSA Secretariat reminded the Panel the background and term of reference of this self-task mandate, accepted by EFSA on 24 June 2019. The Panel Chair nominated Luisa Peixe as Chair of the *ad hoc* WG which will be established for this mandate (conditional to screening and approval of her declaration of interests). ECDC will propose an expert as member of the WG. EMA, ECDC and EEA staff will participate as observers in the WG. The deadline for the opinion is one year after the start of the activity, the latest 31 December 2020.



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

8.1. Scientific Committee

The 94th Plenary meeting of the Scientific Committee (SC) took place on 25-26 June 2019¹¹. The BIOHAZ Chair briefly reported to the Panel about the main topics discussed at the SC meeting. The next SC meeting will take place on 11-13 September 2019.

8.2. Update on Rapid Outbreak Assessments and related activities

EFSA Secretariat presented to the Panel the last activities on the monitoring and evaluation of the ongoing food incidents/outbreaks and microbiological clusters.

8.3. European Commission

Eric Thévenard and Marina Marini from the European Commission (DG SANTE), attending the meeting through video-conference, updated the Panel on the ongoing European Commission activities related to BIOHAZ topics, current mandates requested to EFSA in this area and legislative initiatives taken as a follow-up of past opinions of the BIOHAZ Panel, the latter especially on meat inspection and *Campylobacter*-related process hygiene criteria.

9. Other scientific topics for information and/or discussion

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

The BIOHAZ Panel discussed the state of play with regards to the implementation of the uncertainty guidance in BIOHAZ assessments. Further discussion of the draft document defining minimum requirements that should be applied in BIOHAZ assessments when implementing the guidance and related checklist was postponed to the next Plenary meeting. In the meanwhile, in the mandates received recently, working groups have progressed further in the implementation of the guidance according to the checklist and the abovementioned list of minimum requirements. Feedback was collected on the uncertainty analysis being carried out within the ongoing mandate on *Campylobacter* (see item 6.5), which includes the organisation of an expert knowledge elicitation to quantify uncertainties. The WG chair highlighted the additional time and resources devoted to this exercise. BIOHAZ Panel members requested support from EFSA in carrying out informal expert elicitation to assess uncertainty in conclusions for the ongoing working groups on listeria in frozen fruits, vegetable and herbs and on tubs (see items 6.7 and 6.8). The BIOHAZ Panel also suggested considering the possibility of providing training on this topic for the whole Panel. During the Plenary meeting, the European Commission indicated that while uncertainty analysis should be reported within the text of the opinions, it is important for the risk manager that conclusions of scientific opinions are clear and precise when answering the terms of reference.

¹¹ <https://www.efsa.europa.eu/en/events/event/190625>



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 to the BIOHAZ Panel 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

None

9.4. Presentation of the EU Summary Report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2017

EFSA Secretariat addressed the Panel with a presentation on findings reported in the EU summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2017. The report was published on 26 February 2019¹².

9.5. Information session on independence progress in 2018

EFSA Secretariat from Legal and Assurance Services Unit addressed the Panel with a presentation, reminding the basic principles of the EFSA Independence Policy and rules on Competing Interest Management and updating the Panel on 2018 independence-related activities.

9.6. Dates for 2020 BIOHAZ Plenary meetings

Preliminary dates for 2020 BIOHAZ Plenary meetings were discussed with the Panel.

10. Any other business

None

¹² <https://www.efsa.europa.eu/en/efsajournal/pub/5598>