

SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 142th PLENARY MEETING

Held on 9-10 December 2020, web-conference

(Agreed on 8 January 2021)

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:

Athanasios Raikos (EC, DG Health and Food Safety, Unit E1; for item 6.2)

Matjaz Klemencic (EC, DG Health and Food Safety, Unit G2; for items 6.5 and 8.2)

Eric Thévenard, Martial Plantady (EC, DG Health and Food Safety, Unit G4; for item 8.2)

■ EFSA:

■ BIOCONTAM Unit:

Frank Boelaert, Katrin Bote, Beatriz Guerra, Michaela Hempen, Maria Francesca Iulietto, Ernesto Liébana, Winy Messens, Karoline Noerstrud, Angel Ortiz-Peláez, Denise Pezzutto, Eleonora Sarno, Valentina Rizzi, Mirko Rossi, Pietro Stella

■ Observers:

Not applicable

1. Welcome and apologies for absence

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

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>.

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 141th Plenary meeting held on 21-22 October 2020, web-conference

The minutes of the 141th Plenary meeting were agreed by written procedure on 9 November 2020.

5. Scientific outputs submitted for possible adoption or endorsement

5.1. Scientific opinion on the use of the so-called "superchilling" technique for the transport of fresh fishery products⁴

The last WG meeting took place on 9 November 2020. The WG Chair presented the draft scientific opinion, in particular the changes implemented since the last Panel meeting, and the conclusions and recommendations. Following discussions, some changes were implemented in the formulation of the expression of uncertainty when the degree of superchilling is estimated using the fish temperature after superchilling and its initial freezing point, after which the BIOHAZ Panel adopted the scientific opinion.

5.2. 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 2020⁵

The WG Chair summarised the results of the QPS Assessment 13. No new information was found that would change the status of previously recommended QPS TUs. Of the 36 microorganisms notified to EFSA between April and September 2020, three TUs were evaluated: *Methylobacterium extorquens* and *Mycobacterium aurum* for the first time and *Bacillus circulans* was re-assessed because an update was requested in relation to a new mandate. *M. extorquens* and *M. aurum* are not recommended for QPS status due to the lack of a body of knowledge in relation to use in the food or feed chain and *M. aurum*, due to uncertainty concerning its pathogenicity potential. *B. circulans* was recommended for QPS status with the qualifications for 'production purposes only' and 'absence of cytotoxic activity'. The BIOHAZ Panel adopted the statement.

6. Scientific outputs submitted for discussion

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

The WG Chair presented a revised structure of the draft opinion. The main change suggested is that the assessments already published in the Panel statements will not be repeated in the draft opinion to avoid duplication. The Panel agreed that reference to the statements is

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-2019-00437>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00078>

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

sufficient and will improve readability. Instead the draft opinion is focussing on specific topics in more detail, which are not discussed in the statements. The deadline for the next QPS opinion is December 2022.

6.2. Scientific opinions providing guidance on date marking and related food information – part II⁷

The WG Chair presented the draft opinion for discussion to the BIOHAZ Panel and gave an update of the outcome of the WG meeting that took place on 17 November 2020. The decision tree was presented in detail and changes were suggested. The EC noted that labelling instruction is a risk management decision and the Panel agreed to adjust the decision tree accordingly. The deadline for adoption of this part II opinion (ToRs 3 and 4) is March 2021. The next WG meeting will take place on 17 December 2020.

6.3. Scientific opinion on the role played by the environment in the emergence and spread of antimicrobial resistance through the food chain⁸

The WG Chair updated the Panel about the outcome of the last WG meeting held on 30 November by web-conference. The draft scientific opinion had been shared with the experts of the BIOHAZ Panel. Only the sections addressing the Introduction and Methodology, as well as Sources were presented for first reading and comments from the Panel were discussed. Major changes done in the section Resistant bacteria and genes, and the approach to determine their public health importance was also presented. This section, together with Mitigation options and Data gaps/research needs will be presented for first reading at the next BIOHAZ Panel. The next meeting of the WG will take place on 12 January 2020. The deadline for the adoption of this scientific opinion was extended to 30 April 2021.

6.4. Scientific opinion on specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed⁹

The WG Chair shortly updated the Panel on the comments received after the public consultation of the methodology proposed to address the ToR1 of the mandate (antimicrobial resistance development). The consultation closed on 18 November. Comments were received from eleven organizations. Several comments addressed issues out of the scope of the mandate (e.g. risk management options). Those comments related to the scientific aspects under consultation were discussed by the WG experts on 27 November and will be further discussed during the next WG meeting on 17 December. The Technical report on the public consultation is under preparation and will be shared for discussion with the BIOHAZ Panel and the EMA CVMP. The deadline for adoption of the opinion(s) is 30 September 2021.

6.5. 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 products¹⁰

The WG Chair reminded the Panel the background and terms of reference of this mandate and the deadline for adoption (31 October 2021). The second WG meeting took place on 5-6 November. The EC attended part of the meeting where the ToR and the list of materials were discussed. The Chair informed that EFSA sent a letter to the EC on 18 November asking confirmation of the decisions agreed with the EC during the meeting, which were presented to the plenary, as follows: a) to consider only the transformation processes included in the Commission Regulation (EU) 142/2011 for the declaration of the end points in the manufacturing chain (for raw materials, i.e. groups 4 to 9) and the standard or alternative methods approved to produce derived materials (compost, glycerine and other products of materials derived from the production of biodiesel and renewable fuels, ash) or residues (biogas digestion residues), disregarding the further transformation processes the fertiliser industry

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00439>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00343>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00221>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00401>

might apply to produce the final OF/SI, and disregarding the use or applications of the final OF/SI product. b) only consider materials produced in the EU since all imported materials from third countries will have to comply with the EU legislation. c) the revised list of materials including certain other derived products authorized to be included in petfood as in Annex XIII of Regulation (EC) 142/2011, and derived materials of animal by-products authorised to be included in feed for farmed animals (including aquaculture) except fur animals, and the in Annex X of Regulation (EC) 142/2011. The Chair clarified that if the interpretation of the above was correct, the output of the scientific opinion will not be a full risk assessment but will consist in the identification of the biological hazards potentially present in the different groups and the description or estimation of the level of inactivation / reduction of concentration of the identified hazards after the standard processing for end points or for production of the residues or derived materials is applied. In this case, the output of the assessment will not conclude on any relationship between the presence of hazards and the risks to human and animal health of the OF/SI containing them. The Chair also informed that letter included a proposed new wording of the ToR, as follows: "In particular, the scientific opinion should comprise an assessment of the efficacy of the transformation processes for the declaration of the end points in the manufacturing chain, and the standard or alternative methods approved to produce derived materials or residues of the following Category 2 and 3 materials and derived products that can be further processed and used as OF/SI, processed in accordance to..., to reduce/eliminate the presence of biological hazards to human and animal health". The EC commented that the mandate as presented by the Chair represents a huge amount of work and the focus should be on what can be achieved during the time left of the mandate. The Chairs of the WG and of the Panel exhorted the EC to provide official feedback to the letter before the next WG meeting that will take place on Thursday 17 December 2020, so that the WG can proceed with the work according of the needs of the EC. The Chair also informed of the ongoing activities between meetings, which consist of the pilot study of the extensive literature search for the hazard identification, the draft of background sections of the opinion and the development of the draft protocol, which are all subject to the final decision on the scope of the mandate.

6.6. Scientific opinion on the efficacy and safety of high pressure processing of food¹¹

The last WG meetings were held on 10 November 2020 (related to BIOHAZ issues), 17 November 2020 (on ToR1c - chemical food safety risks through formation of process contaminants) and 8-9 December 2020 (on ToR1c - chemical food safety risks through food contact materials). The WG Chair gave feedback on the outcome of the last WG meeting using a presentation. The Panel agreed with the WG proposal to consider for ToR2 the following additional hazards to be reduced by thermal pasteurization of raw milk/raw colostrum from ruminants: *Campylobacter* spp., Tick-borne encephalitis virus and *Staphylococcus aureus*. For ToR3, a discussion was held on the foods to consider (the most relevant foods known to cause human listeriosis in the EU) but further discussion will be needed. The draft protocol, that includes the problem formulation (step 1) and the planning of the methods to conduct the assessment (step 2), was shared with the BIOHAZ Panel. The next WG meetings will be held on 14-15 December 2020 (on all ToRs apart from ToR1c – chemical food safety risks), on 3 February 2021 (ToR1c - chemical food safety risks due to contaminants) and on 3-4 February 2021 (on ToR1c - chemical food safety risks through food contact materials). The deadline for adoption is 31 January 2022.

6.7. Scientific opinion on the microbiological safety of aged meat¹²

Work on this mandate has not started yet. The deadline for adoption of this opinion is 31 December 2022.

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00380>

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00380>

6.8. New alternative biodiesel process for rendered fat of Category 1 (BDI-RepCat Process, AT)¹³

The WG Chair gave an update on the outcome of the first WG meeting (9 November 2020, web-conference) and the draft opinion was presented for first reading to the BIOHAZ Panel. The WG Chair reminded the Panel of the background of the mandate and the content of the application; subsequently the WG Chair provided an overview on the sections on the assessment performed and the comparison with the approved method by the current regulation. The approach proposed by the WG was presented and discussed: because of the lack of risk reduction standards for proposed alternative methods for biodiesel production using animal by-products (ABPs), the WG considered that a reduction of 6 log₁₀ in prion infectivity by the alternative method is required to consider it at least equivalent, for Category 1 ABPs, to the approved standard method. This approach was followed in previous EFSA opinions and the Panel agreed with it. Selected comments from the BIOHAZ Panel were further discussed with the Panel members; in particular concerning the use of units of measurement (referring to Directive 2009/3/EC) and the terminology used in the text (in particular, the name of the sections). The Panel considered that these aspects should be included and clarified in a future update of the EFSA opinion (2010) *Statement on technical assistance on the format for applications for new alternative methods for animal by-products*. The WG will address the comments raised by the Panel during the next WG meetings (14 December 2020 and 12 January 2021, both web-conferences) and present the updated draft opinion for thorough reading at the next BIOHAZ Panel meeting in January.

7. New Mandates

No new mandates for the BIOHAZ Panel received.

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

8.1. Scientific Committee

The 101st Plenary meeting of the Scientific Committee (SC) took place on 11-12 November 2020. The BIOHAZ Chair briefly reported the main points discussed at the meeting, in particular with reference to the activities of the SCER Cross-cutting WG Uncertainty. During the SC plenary meeting it was indicated that a workshop will be held in autumn 2021 with risk managers from DG SANTE on the application of the uncertainty guidance. The SC also discussed the need to provide a simplified EKE procedure and will discuss a possible review of the EKE guidance document. For further details refer to the minutes of the SC Plenary meeting¹⁴.

8.2. European Commission

EC representative Eric Thévenard updated the Panel on the ongoing EC 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. Some upcoming requests to EFSA in this area include e.g. possible applications for substances for the removal of surface decontamination of products of animal origin, and Chronic Wasting Disease surveillance. EC representative Matjaz Klemencic updated the Panel on the ongoing EC activities in the area of animal by-products (ABP). Some upcoming requests to EFSA in this area include e.g. possible applications for alternative processing methods for ABP, including for products to be used in the production of fertilisers, and a possible revision of the statement on technical assistance

¹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00450>

¹⁴ <http://www.efsa.europa.eu/en/events/event/101st-plenary-meeting-scientific-committee>

on the format for applications for new alternative methods for animal by-products (EFSA, 2010). EC representatives thanked the BIOHAZ Panel for the quality of the scientific opinions delivered.

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 last WG meeting took place on 8 December 2020. As mentioned at last plenary meeting, the deadline for approval of the scientific report is likely to be extended to end of April 2021. Based on this a planning has been made in which the draft report will be shared with the reviewers and panel members before the end of January 2021. The next WG meetings have been scheduled for 8 January 2021 and 11 February 2021.

8.4. Request for scientific and technical assistance to examine the data collected by the Member States in the framework of the 2-years compulsory intensified surveillance in case of atypical scrapie

The Chair of the WG reminded the ToRs and deadline for delivery of the scientific report. The only update from the last plenary was the establishment of the WG, whose members were presented to the Panel. The first meeting of the WG will take place on Friday 11 December.

8.5. Update on Rapid Outbreak Assessments and related activities

EFSA Secretariat presented to the Panel the Joint ECDCD-EFSA Rapid outbreak assessment on a multi-country outbreak of *Salmonella* Typhimurium and *S. Anatum* infections linked to Brazilian nuts, published in October 2020¹⁵. Since 1 August 2019, and as of 20 October 2020 123 cases of *S. Typhimurium* ST19 and one case of *S. Anatum* have been reported, of which 105 were in the UK (including the *S. Anatum* case), 14 in France, three in Luxembourg, one each in the Netherlands and Canada.

8.6. Scientific Networks on MRA and on BSE-TSE

The 20th annual meeting of the MRA network was held on 29-30 October 2020 as a web meeting. Currently, 24 European Union Member States and two observer countries (Switzerland and Norway) are members of the MRA Network. A wide range of activities related to microbial risk assessment were presented including risk ranking of pathogens in food, *Listeria monocytogenes*, *Staphylococcus aureus* and *Escherichia coli* in cheeses, STEC in flour, *Campylobacter* in broilers flocks, an overview on food safety reports, as well as EFSA activities.

9. Other scientific topics for information and/or discussion

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

Related discussions were covered under item 8.1.

9.2. Protocol development

EFSA Secretariat presented to the Panel an internal draft document with a template to be used as basis for protocols related to BIOHAZ mandates. The Panel agreed on the use of such template and on the minimum information to be included in BIOHAZ protocols.

¹⁵ <https://www.ecdc.europa.eu/sites/default/files/documents/salmonella-typhimurium-rapid-outbreak-assessment-october-2020.pdf>

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

A draft self-task mandate on the microbiological risks related to the use of water in processing and handling of fruits and vegetables and related control options was presented to the panel and the terms of reference were discussed. The Panel agreed to develop the document further with the aim of finalising the draft mandate by March 2021.

9.4. Presentation on the EU Summary Report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2019

EFSA staff (BIOCONTAM Unit) presented the main findings of the EU Summary Report on TSE for the year 2019. The report presents the results of surveillance of TSE in animals and was published on 17 November 2020. It includes data from 28 Member States (MS), Iceland, North Macedonia, Montenegro, Norway, Serbia and Switzerland. In total, 1,150,388 cattle were tested by Member States, a 2.7% decrease from 2018. Seven atypical BSE cases were reported in 2019: 1 L-type reported by Poland and 6 H-type, reported by Spain (2) and France (4). Over the year, a total of 338,098 sheep and 143,529 goats were tested in the EU, an increase of 3.9% in both species, compared with 2018. In sheep, 997 cases of scrapie were reported: 911 classical by seven MS and 86 atypical by 11 MS. Random genotyping was only reported by eight MS and after excluding Cyprus showed that 15.7% of the genotyped sheep carried genotypes of the susceptible groups. In goats, 390 cases of scrapie were reported: 379 classical by six MS and 11 atypical by six MS. The six MS implementing mandatory surveillance for CWD reported 7,980 tested cervids with three cases of CWD reported by Sweden in moose. In addition, other six MS reported 2,732 tested cervids with negative results. Norway tested 30,147 cervids with 2 moose cases in 2019 and Iceland reported 114 negative cervids.

9.5. 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. She indicated that this EMA activity might be delayed compared to its original deadline.

10. Any other business

The BIOHAZ Panel was informed that, following to a request from the applicant, a post-adoption clarification teleconference was held with the applicant on 20 November 2020 to clarify some scientific aspects of the scientific opinion adopted on the "evaluation of alternative methods of tunnel composting (submitted by the European Composting Network)", adopted by the BIOHAZ Panel in July 2020.

EFSA Secretariat updated the Panel in relation to the draft European Union 2019 One Health Zoonoses Summary Report (EUOHZ) and indicated that comments by Panel members are welcome.

The BIOHAZ Panel was informed that on 30 July 2020, EFSA received from the European Commission the application referring to the request for a scientific opinion on the evaluation of the safety and efficacy of lactic acid to reduce microbiological surface contamination on carcasses from wild game and small stock, submitted by Australian Government Department of Agriculture and Water Resources. On 9 October 2020, EFSA requested the applicant to provide missing information, which was made available on 19 November 2020. EFSA considered the application valid on 10 December 2020. The deadline to deliver the scientific opinion is 12 months since the validity. However, during the risk assessment, EFSA may request the applicant for additional information if necessary. In such case, the time limit of 12 months shall be extended. The standing WG on the evaluation of substances used to reduce microbial contamination from products of animal origin (CEP Panel) will be re-activated.