

SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

MINUTES OF THE 144th PLENARY MEETING

Held on 10-11 March 2021, web-conference

(Agreed on 25 March 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:

Andrew Hart (for item 9.1)

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

Luis Vivas-Alegre (EC, DG Health and Food Safety, Unit D1)

Olga Goulaki, Hannah Sievers (EC, DG Health and Food Safety, Unit E1; for item 5.1)

Jean-Baptiste Perrin (EC, DG Health and Food Safety, Unit G4; for item 6.6)

Fabien Schneegans (EC, DG Health and Food Safety, Unit G4; for item 8.4)

Kris De Smet (EC, DG Health and Food Safety, Unit G4; for item 9.2)

■ EFSA:

■ BIOCONTAM Unit:

Frank Boelaert, Katrin Bote, Maria Teresa Da Silva Felicio, Beatriz Guerra, Michaela Hempen, Maria Francesca Iulietto, Ernesto Liébana, Winy Messens, Angel Ortiz-Peláez, Valentina Rizzi, Mirko Rossi, Eleonora Sarno, 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 143rd Plenary meeting held on 25-26 January 2021, web-conference

The minutes of the 143rd Plenary meeting were agreed by written procedure on 25-26 January 2021.

5. Scientific outputs submitted for possible adoption or endorsement

5.1. Scientific opinions providing guidance on date marking and related food information – part II

The WG Chair presented the changes implemented since the last panel meeting. The decision tree was modified to address comments made during the last meeting and the panel agreed with the amendment. All comments on the document were addressed. The concluding remarks for each section were discussed in detail, as well as conclusions, recommendations and the abstract. The BIOHAZ Panel adopted the opinion.

5.2. Evaluation of the application for new alternative biodiesel process for rendered fat of Category 1 (BDI-RepCat Process, AT)

The WG chair updated the Panel on the activities of the WG since the last BIOHAZ Panel plenary meeting and presented the main conclusions from the last WG meeting, which took place on 22 February 2021. The WG Chair described how the comments received by the Panel were addressed and selected ones were further discussed with the Panel, during the meeting. The conclusions and the abstract were discussed in detail and it was agreed to not include any recommendations. The BIOHAZ Panel adopted the opinion.

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

6. Scientific outputs submitted for discussion⁴

6.1. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 1: Suitability of taxonomic units notified to EFSA until March 2021

The WG Chair informed the panel about the notifications received since October 2020: 54 taxonomic units (TUs) were notified, most of them already have QPS status or have been excluded from QPS assessment. The following TUs are included in Statement 14: *Bacillus paralicheniformis*, *Corynebacterium stationis*, *Dyella* sp, *Enterobacter hormoaechei*, *Eremothecium ashbyi*, *Kodamaea ohmeri* and *Lactococcus garvieae*. The WG is currently doing the extensive literature search for monitoring the TUs on the QPS list. The next WG meeting is 14 April 2021 and the deadline for adoption of this Panel Statement 14 is June 2021.

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

The WG Chair informed the panel that there is no update on the draft opinion since the last panel meeting. The deadline for adoption of this QPS opinion is December 2022.

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

The WG Chair updated the Panel about the outcome of the last WG meeting held on 12 February by web-conference. The draft scientific opinion had been shared with the experts of the BIOHAZ Panel. The draft opinion was presented for thorough reading, and major changes in the current version (mainly regarding Section 2 Bacteria and genes) were presented. The comments received from the Panel experts, the concluding remarks for each section and the draft conclusions were discussed during the Plenary. The WG Chair asked the BIOHAZ Panel to revise with particular attention the Sections related to knowledge gaps, recommendations for research needs and uncertainties, and provide feedback soon after the plenary. The scientific opinion will be presented for adoption at the next BIOHAZ Panel. The next meeting of the WG will take place on 12 April 2021. The deadline for the adoption of this scientific opinion is 30 April 2021.

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

The WG Chair updated the Panel briefly on the activities since the last BIOHAZ Plenary meeting. No WG has taken place since then. The technical report containing the comments received and the actions taken by EFSA, and the updated draft scientific opinion was shared with the EMA CVMP experts and presented at their meeting on 17 February 2021. The WG is working on the assessment of the different substances included in the mandate (both for ToR1-AMR and ToR2-Growth Promotion). The next WG meetings will be on 15 March-SubWG-AMR, and 30 March, SubWG-GP. The deadline for adoption of the scientific opinion(s) is 30 September 2021. The technical report will be published together with the opinion.

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 products

The WG Chair reminded the Panel of the final wording of the ToR and new list of materials, as agreed with the EC. The Chair informed of the latest developments following the discussion during the 4th WG meeting that took place on Wednesday 17 February 2021. The WG decided to use the extensive literature search conducted in the previous months in order to extract viral hazards that can be found intrinsically in the Category 2 and 3 materials and derived

⁴ Please be aware that EFSA's Register of Questions is unavailable from 21 January until March. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available [here](#)

products as defined in the clarification of the mandate. Data on thermal and chemical inactivation of the indicator pathogens was pursued using different combinations of search strings, with limited success. For bacteria and parasites, data on thermal inactivation will be extracted from review papers. Raw data have been identified for thermal inactivation of a selected group of viruses, but an additional literature search will be necessary for the chemical inactivation of bacteria, virus and parasites. Regarding the standard processing methods, the chair stressed to the Panel the difficulty for certain materials to ascertain the transformation methods given the generic description in the legislation, whereas for other materials, they are clearly described. The 5th WG meeting will take place on Thursday 25 March 2021, and the 6th WG meeting on Thursday 27 May 2021, both as full-day web meetings.

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

The last WG meeting was held on 17-18 February 2021 (related to BIOHAZ issues). The WG Chair informed that a table has been added in the draft protocol showing the integration of evidence across sub-questions and remaining overall uncertainty. The WG Chair informed that a new expert has accepted to join the WG (pending ADoI approval). For ToR1, feedback was given on the outcome of the last WG meeting using a presentation. An overview was given of the replies to the questionnaire on the commercial use of high pressure processing (HPP). For ToR2, it was clarified that the efficacy of the processing conditions is of relevance (not the post-processing contamination) using the minimum time/temperature requirements for pasteurisation and UHT treatment of milk from legislation. The Panel was informed about biphasic trends in the microbial inactivation using HPP, using as an example *Staphylococcus aureus* inactivation in milk. The way forward will be further discussed at the next WG and plenary meetings. For ToR3, the panel was informed that data are being collected on the inactivation of *Listeria monocytogenes* in the three selected categories (cooked RTE meat, smoked and gravid fish and soft and semi-soft cheese). The occurrence of resistant tails was discussed and the impact of various intrinsic factors on inactivation. The next WG meeting related to BIOHAZ issues will be held on 14-15 April 2021. The deadline for adoption is 31 January 2022.

6.7. Scientific opinion on the microbiological safety of aged meat

The WG chair briefly presented the terms of reference and that the WG is being established. The deadline for adoption of this opinion is 31 December 2022.

6.8. Scientific opinion on the evaluation of safety and efficacy of lactic acid to reduce microbiological contamination on carcasses from wild game and small stock

The vice-chair of the WG briefed the panel on the outcome of the first WG meeting held on 15 February 2021 of the WG from the CEP Panel on the evaluation of substances used to reduce microbial contamination from products of animal origin. He informed that a request for additional information was sent to the applicant on 24 February 2021 and the scientific evaluation suspended. The initial deadline to deliver the Scientific Opinion of 10 December 2021 will be extended accordingly.

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 102nd Plenary meeting of the Scientific Committee (SC) took place on 17-18 February 2021⁵. At that meeting, the BIOHAZ Panel chair updated the SC about BIOHAZ opinions adopted in 2020, the 2021 BIOHAZ workplan and the progress made in the implementation of the uncertainty guidance in BIOHAZ assessments. The Panel Chair informed the BIOHAZ Panel about the activities of the SCER Cross-cutting WG Uncertainty, including the possible future revision of the EFSA guidance on EKE and the development of a brief written procedure for carrying out a simplified EKE. A workshop will be organised in autumn 2021 with risk managers from DG SANTE on the application of the uncertainty guidance. EFSA Secretariat indicated that the WG Uncertainty has recently developed a new version of the uncertainty checklist, incorporating requirements related to protocol development.

8.2. European Commission

The Panel Chair thanked EC for attending the plenary, and highlighted the importance and benefits of EC's participation to plenary and working groups, as well as of receiving periodic updates from the EC at plenaries in relation to follow-up risk management decisions based on adopted BIOHAZ scientific opinion, and anticipating medium-term priorities for future mandates to the Panel. Luis Vivas-Alegre (EC, DG SANTE) thanked the Panel Chair and noted the challenge to anticipate a calendar of requests to EFSA due to the policy/regulatory-making nature in the area where agenda is mainly set up with MSs. He also informed the Panel that a candidate R&I Partnership on One Health Antimicrobial Resistance has been proposed under the future Horizon Europe 2023-2024 work programme. This Partnership could provide a framework for coordinating EU research activities addressing AMR, with the EU One Health Action plan against AMR as a point of reference. EFSA Secretariat reminded the Panel about areas of possible future mandates to be received by the BIOHAZ Panel.

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 comments received through the first review were discussed during the WG meeting held on 11 February 2021. The revised draft scientific report of EFSA, addressing the comments by the reviewers, has been shared for information with the Panel members and for a second review until 10 March 2021. It will be presented for approval to EFSA before the deadline of end of April 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 presented the draft report for the first time and the work progress. The descriptive, analytical, and modelling approaches for ToR1 were described in depth by the chair and working group members. Preliminary results for ToR1 were also presented. The approach to ToR2 was also briefly presented even though it is less elaborated. Members of the Panel requested additional information about the simulation model. The third meeting of the WG will take place on Friday 23 April 2021.

8.5. Update on Rapid Outbreak Assessments and related activities

EFSA Secretariat presented to the Panel the Joint ECD-CD-EFSA Rapid Outbreak Assessment on a multi-country outbreak of *Salmonella* Enteritidis ST11 infections linked to poultry products,

⁵ <https://www.efsa.europa.eu/it/events/event/102nd-plenary-meeting-scientific-committee>

published in February 2021⁶. Between May 2018 and December 2020, 193 cases of infections have been reported: Denmark (2), Finland (4), France (33), Germany (6), Ireland (12), the Netherlands (3), Poland (5), Sweden (6), and the United Kingdom (122). Five batches of non-ready-to-eat poultry products (breaded products) tested positive for *S. Enteritidis* matching the outbreak strain. Control measures were implemented for the products involved (withdrawals, recalls).

9. Other scientific topics for information and/or discussion

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

Hearing expert Andrew Hart delivered a presentation to the Panel in relation to uncertainty analysis in qualitative assessments. He explained possible reasons indicated in the uncertainty guidance to always try to quantify the overall uncertainty. He suggested for which type of ToRs quantification of uncertainty might be appropriate or not. He presented examples from qualitative conclusions of past BIOHAZ opinions, highlighting which ones might have benefited from quantification of uncertainty. He indicated that formal EKE is not always needed when quantifying uncertainty and he mentioned possible alternatives to formal EKE as proposed by the BIOHAZ Panel in the past and recently discussed in the SCER cross-cutting WG on uncertainty. Luis Vivas-Alegre (EC, DG SANTE) indicated that presentation of uncertainty in EFSA assessments is important for EC and indicated that in general the feedback from EC on the implementation in BIOHAZ assessments is positive. This will be further discussed in the upcoming workshop on uncertainty for risk managers (see agenda item 8.1). The presentation was discussed by the BIOHAZ Panel, that acknowledged added values of quantifying uncertainties but also discussed some related concerns and limitations, such as: resources available, feasibility of quantifying uncertainty for all ToRs/conclusions, need to receive detailed feedback from risk managers on the added value of the quantification of uncertainty in conclusions. The Panel chair thanked Andrew Hart for the presentation and the Panel for the discussion, acknowledged the progresses made in the last years in the implementation of uncertainty analysis in BIOHAZ assessments. He indicated that further developments and improvements are expected to be gradual, therefore this item will continue being included as a standing item in BIOHAZ plenary meetings. Past agreements by the BIOHAZ Panel on the implementation of the uncertainty analysis were also reminded (see minutes 137th meeting of the BIOHAZ Panel⁷).

9.2. Topics of scientific concern in the area of biological hazards and BIOHAZ self-tasks (including draft selftask on microbiological risks linked to the use of water in processing of fruits and vegetables)

The revised draft self-task mandate on the microbiological hazards associated with the use of water in the handling and processing of fresh and frozen fruits, vegetables and herbs was presented to the Panel. The terms of reference were discussed and will be reviewed by a subgroup of Panel members and by the Secretariat in order to produce a more consolidated version that will be also shared with DG SANTE. Thereafter the draft background and ToRs will be agreed by the Panel by written procedure. The Panel was also requested to review carefully after the plenary meeting the file including a table listing questions for possible outsourcing integrated in this mandate. The purpose of reviewing and completing this table is to identify the best questions for possible outsourcing, i.e. those for which: (i) there is currently low level of evidence available, (ii) the tender could contribute a lot to the answer and (iii) we expect the tenderer to be able to achieve useful results with less limitations.

9.3. Presentation of the EU One Health 2019 Zoonoses Report

⁶ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2021.EN-6486>

⁷ <https://www.efsa.europa.eu/en/events/event/137th-plenary-meeting-biohaz-panel>

EFSA Secretariat presented to the Panel the findings reported in the EU One Health 2019 Report, published in February 2021⁸, in particular with regard to the overall numbers and notification rates of zoonoses in humans, results from the monitoring of the main food-borne zoonoses, reported food-borne outbreaks including agents and foods implicated.

10. Any other business

The Panel agreed to modify the dates of the next plenary, which is now confirmed for 29 April and 6 May.

⁸ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6406>