

# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

## MINUTES OF THE 146<sup>th</sup> PLENARY MEETING

**Held on 3 and 4 June 2021, web-conference**

**(Agreed on 18 June 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 Experts<sup>1</sup>:

Not applicable

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

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

Fabien Schneegans (EC, DG Health and Food Safety, Unit G4; for item 5.2)

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

#### ■ EFSA:

##### ■ BIOCONTAM Unit:

Anna Christodoulidou (for item 6.4), Maria Teresa Da Silva Felicio, Beatriz Guerra, Michaela Hempen, Maria Francesca Iulietto, Ernesto Liébana, Winy Messens, Angel Ortiz-Peláez, Denise Pezzutto, Eleonora Sarno, Pietro Stella

##### ■ ALPHA Unit:

Francesca Baldinelli (for item 8.3)

##### ■ FIP Unit:

Eric Barthélémy (for item 6.4)

#### ■ Observers:

Not applicable

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<sup>1</sup> 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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. Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

## 4. Agreement of the minutes of the 145<sup>th</sup> Plenary meeting held on 29 April and 6 May 2021, web-conference

The minutes of the 145<sup>th</sup> Plenary meeting were agreed by written procedure on 20 May 2021.

## 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. 1: Suitability of taxonomic units notified to EFSA until March 2021

The WG Chair presented the changes implemented since the last Panel meeting addressing the comments of the Panel members. In this Panel Statement seven taxonomic units (TUs) were evaluated: *Anoxybacillus caldiproteolyticus*, *Bacillus paralicheniformis*, *Enterobacter hormaechei*, *Eremothecium ashbyi*, *Lactococcus garvieae*, *Corynebacterium stationis* and *Kodamaea ohmeri*. No new information was found that would change the status of previously recommended TUs except for *B. licheniformis*, for which an additional qualification was introduced. The Panel discussed and agreed on the conclusions and proceeded with the adoption of this Panel Statement.

### 5.2. 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 final report. He thanked Panel members of the revision of the draft, the comments received and the review of the model by one member of the Panel. Most of the comments in the body of the text had been addressed before the meeting. The chair then read the conclusions, answers to the ToRs. There were some modifications made to those, changing the order of the bullet points and minor editorial changes. The sentence about certainty in the answer to ToR1 was discussed. The proposed wording by the WG was not as prescribed in the EFSA's uncertainty guidance. After an exchange of points of view, the chair and members of the WG present agreed on the second option proposed by the working group

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<sup>2</sup> [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

for the wording of the level of uncertainty associated with the possibility of atypical scrapie being non-contagious. The Panel agreed on expressing the uncertainty in words followed by numeric subjective probability, as opposed to the standard recommendation of the EFSA's uncertainty guidance. The chair of the Panel asked the working group to harmonize summary and abstract with the agreed wording of the answer to ToR1, after which the BIOHAZ Panel endorsed the scientific report.

## 6. Scientific outputs submitted for discussion<sup>4</sup>

### 6.1. 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 about the suggestions of the WG to include in the draft opinion a description of the change in type of notifications received during the ongoing and previous two mandates. The Panel was also informed that the WG discussed the introduction of qualifications for yeasts during the last WG meeting but concluded that there is not enough information available at this stage to justify such qualifications. The deadline for adoption of this QPS opinion is December 2022. The BIOHAZ secretariat presented a tool that is being developed in EFSA to visualise the QPS approach on the EFSA website.

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

The WG Chair informed the Panel about the developments of the ToR1-AMR (to assess 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 to microbial agents relevant for human and animal health; SubWG-AMR) assessments. The draft assessments for i) aminoglycosides: apramycin, neomycin, spectinomycin and paromomycin; ii) beta-lactams: amoxicillin and penicillin V; iii) lincosamides: lincomycin; iv), macrolides: tilmicosin, tylosin, and tylvalosin; v) phenicols: florfenicol and thiamphenicol; vi) sulfonamides; vii), amprolium; viii) pleuromutilins: tiamulin and valnemulin, had been shared with the Panel experts for comments. The draft conclusions of the assessments were discussed. Comments received from the EMA CVMP on the main body of the draft opinion (interpretation of ToRs and uncertainties) were also discussed. Those parts of the draft opinion(s) under the remit of the AHAW Panel will be presented for discussion and possible endorsement at the AHAW Panel's plenary meeting of 23-24 June. The assessments of ToR2 (growth promotion/increase of yield) for 13 substances (amoxicillin, amprolin, apramycin, colistin, doxycycline, flumequine, neomycin, paromomycin, penicillin V, spectinomycin, trimethoprim, tylosin and oxolinic acid) will be presented at the FEEDAP Panel's plenary meeting of 23-24 June for possible endorsement. The EMA CVMP will be updated on the current developments of the draft opinion at their meeting on 15-17 June. During the plenary it was agreed that the assessments for the substances belonging to the same antimicrobial class will be published as single scientific opinions, and together with the draft scientific opinion containing the methodology, uncertainties and data gaps, will be published in a virtual issue of the EFSA Journal. The deadline for adoption delivery of the scientific opinion(s) is 30 September 2021.

### 6.3. 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

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<sup>4</sup> 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](#)

The WG Chair informed that for the first time the draft opinion had been shared with the BIOHAZ Panel, despite being presented only for information. The Chair thanked Panel members for the comments already made to the document, that will help improve the draft as well as trigger new discussion points in the working group. Panel members were asked about the suitability of the approach for the viral hazard identification and thermal and chemical inactivation data. The Panel agreed with the approach followed by the working group on this point and also on the way proposed for the integration of the evidence. It was acknowledged by the Chair the uncertainty on the transformation processes of some of the materials, which will have to be dealt with in the final steps of the assessment. The Panel and working group member in charge of the elicitation of the final answer to the ToR and the uncertainty analysis informed that he will provide a short training to WG members in the next meeting in June on how to carry out the EKE, to be followed by the discussion of the individual subjective probabilities in the meeting in August. The 7<sup>th</sup> WG meeting will take place on 21 June 2021, and the 8<sup>th</sup> on 20 August 2021. The deadline for adoption of the scientific opinion is 31 October 2021.

#### **6.4. Scientific opinion on the efficacy and safety of high pressure processing of food**

No WG meeting related to BIOHAZ issues was held since the last BIOHAZ plenary meeting. The sections dealing with food processing contaminants and food contact materials were presented to the BIOHAZ panel by the respective EFSA coordinators and discussed. It concerns the sections answering assessment question 4 (AQ4) *"What are the potential chemical food safety concerns through formation of process contaminants in HPP-treated food compared to untreated food or food submitted to treatments, routinely applied to these foods with the purpose to increase microbiological food safety?"* and AQ5 *"What are the potential chemical food safety concerns through food contact materials (FCM) in HPP-treated food compared to untreated food or food submitted to treatments, routinely applied to these foods with the purpose to increase microbiological food safety?"*. These sections are scheduled for endorsement by the CEP and CONTAM Panels, respectively, at their July plenary meetings. More specifically, the BIOHAZ Panel commented to align and harmonise the wording of the conclusions throughout the opinion and suggested to use a subjective probability term in the final conclusions. Also, the BIOHAZ Panel commented to pay attention not to endorse responses from answers to the questionnaires from the establishments and equipment providers. The next WG meeting related to BIOHAZ issues will be held on 28-29 June 2021. The deadline for adoption is 31 January 2022.

#### **6.5. Scientific opinion on the microbiological safety of aged meat**

The WG chair presented the composition of the WG, the terms of reference and some clarifications to be discussed with EC. A general approach on how to address the TORs was presented to the Panel. The first WG meeting was on 10 May 2021, the next is planned on 17 June 2021. The deadline for adoption of this opinion is 31 December 2022.

#### **6.6. 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 Panel was informed that the additional information was not yet received (the current deadline is 24 June 2021) and thus the scientific evaluation is still 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**

No new meeting of the Scientific Committee (SC) took place after the last BIOHAZ plenary meeting.

### **8.2. European Commission**

No specific items were raised under this agenda item. The Chair thanked EC colleagues for their active participation to the plenary meeting.

### **8.3. European Commission Update on Scientific opinion for the listing and categorisation of transmissible animal diseases caused by bacteria resistant to antimicrobials, in the framework of the Animal Health Law**

BIOHAZ Panel member Friederike Hilbert, who is member of the AHAW Working Group addressing this mandate, reminded the BIOHAZ Panel about the background and terms of reference of the mandate, the first scientific opinions published, that describes the methodology adopted to conduct the assessments, and the plan for completion of the species-specific opinions.

## **9. Other scientific topics for information and/or discussion**

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

No specific discussion took place at this plenary meeting. The Panel Chair suggested that further discussion on uncertainty analysis could take place after gaining some more experience on implementation of the guidance, including on upcoming EKE exercises.

### **9.2. Topics of scientific concern in the area of biological hazards and BIOHAZ self-tasks (including draft selftask on microbiological hazards associated with the use of water in post-harvest handling and processing operations of fresh and frozen fruits, vegetables and herbs)**

With regard to the draft self-task mandate on the microbiological hazards associated with the use of water in the post-harvest handling and processing operations of fresh and frozen fruits, vegetables and herbs (ffFVHs), the revised draft self-task was presented to the Panel. DG SANTE has been consulted since the last plenary meeting welcoming this self-task mandate suggestion and providing some suggestions including the addition of a new ToR asking which good hygiene practices are recommended to ensure appropriate microbiological quality requirements of water used for post-harvest handling and processing operations of ffFVHs. The Panel agreed with the inclusion of this ToR. The EC expects this self-task mandate to supplement the 2017 Commission Notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene (OJ 2017/C 163/01), including good hygiene practices related to the use of irrigation water and water used in on-farm post-harvest associated operations, by providing possible recommendations on additional hygienic control measures that could be implemented on stages from harvest on. The charter for this project will be updated and submitted for EFSA's internal approval, and would include associated outsourcing activities. The proposed length of this mandate is 3 years. It is expected to have an ad hoc WG established by the end of summer 2021.

With regard to possible future selftasks, EFSA Secretariat provided an overview of the exercise carried out within the BIOHAZ Panel in 2018 to identify and prioritise relevant and important topics for self-task mandates. The Panel and Secretariat agreed to collect ideas on topics that

would merit consideration for development of future self-tasks and to discuss and prioritise them in the next Plenary meetings.

With regard to topics of scientific concern in the BIOHAZ area, Panel member Elisabetta Suffredini updated the Panel on recently published scientific papers investigating the presence of SARS-CoV-2 in shellfish and on the role shellfish can have in monitoring.

## **10. Any other business**

EFSA Secretariat reminded the Panel about the new election of the Panel Chair and Vice-Chairs that will take place during the next Plenary meeting (7-8 July 2021). Written information about this had also been recently shared with all Panel members. Panel members will be able to express their interest to run for the election, or to propose other Panel members for the election until the day of the election; however, they were encouraged to inform the Unit and Panel members, if possible, by 2 July 2021.

EFSA Secretariat informed the Panel that physical Plenary and Working Group meetings will not take place at least until the end of 2021.

EFSA Secretariat introduced to the Panel some information related to the new internal workflow for generic mandates and to the new concept of tollgates, used to implement quality checks during the risk assessment process.

## **Annex**

### **Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting**

With regard to this meeting, Prof. Panagiotis Skandamis declared the following interest: participation as expert in a newly established national scientific council of the Greek National Food Safety Authority, as expert on biological hazards in foods, to provide advice relevant to exposure assessment or means to control of biological hazards, which does not involve risk management activities nor advice to private entities. In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)