



# SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

## MINUTES OF THE 127<sup>TH</sup> PLENARY MEETING

**Held on 11 April 2019, web-conference  
(Agreed on 25 April 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 Experts<sup>1</sup>:

Not applicable

#### ■ European Commission and/or Member States representatives:

Sara Perucho-Martinez (European Commission, DG Health and Food Safety, Unit G4; for item 6.6)

Wolfgang Trunk (European Commission, DG Health and Food Safety, Unit E5; for item 7.1)

#### ■ EFSA:

##### ■ BIOCONTAM Unit:

Bianca Bottoni, Sandra Correia, Maria Teresa da Silva Felício, Michaela Hempen, Maria Francesca Iulietto, Ernesto Liebana, Winy Messens, Angel Ortiz Pelaez, Pietro Stella, Cristiana Ventura

##### ■ AHAW Unit:

Alessandro Broglia (for Item 7.1)

##### ■ FEED Unit:

Matteo Lorenzo Innocenti (for Item 7.1)

#### ■ Observers:

Not applicable

<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 of Working Groups members

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(s) of Interest made at the beginning of the meeting, please refer to the Annex.

## 4. Agreement of the minutes of the 126<sup>th</sup> Plenary meeting held on 9-7 March 2019, Parma (Italy)

The minutes of the 126<sup>th</sup> Plenary meeting were agreed by written procedure on 21 March 2019.

## 5. Scientific outputs submitted for possible adoption or endorsement

No scientific outputs were submitted for possible adoption or endorsement.

## 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 EFSA<sup>4</sup>

Last meeting was held on 21 January by web-conference. The article evaluation step of the ELS exercise (articles published between July and December 2018) started, the data extraction phase is to be finalised beginning of April and its summary will be incorporated in the Panel Statement part 10 beginning of May. The next working group (WG) meeting will be held on 21 PM and 22 May in Valencia. The deadline for adoption of this scientific opinion is December 2019.

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<sup>4</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>



## **6.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 10: Suitability of taxonomic units notified to EFSA until March 2019<sup>5</sup>**

Last meeting was held on 21 January by web-conference. The article evaluation step of the ELS exercise (articles published between July and December 2018) started, the data extraction phase is to be finalised beginning of April and its summary will be incorporated in this Panel Statement beginning of May. Between October 2018 and March 2019, the QPS notification list was updated with 45 microorganisms from applications for market authorisation. Of these, 19 biological agents already had QPS status, 18 were excluded from the QPS exercise by the previous QPS mandate (11 filamentous fungi) or from further evaluations within the current mandate (7 notifications of *Escherichia coli*). *Sphingomonas elodea*, *Gluconobacter frateurii*, *Corynebacterium ammoniagenes*, *Corynebacterium casei*, *Burkholderia ubonensis*, *Phaeodactylum tricornutum*, *Microbacterium foliorum* and *Euglena gracilis* were evaluated for the first time. The next working group (WG) meeting will be held on 21 PM and 22 May in Valencia. The deadline for adoption of this Panel Statement is June 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 STEC<sup>6</sup>**

The WG Chair briefly updated the Panel on the progress of work made. The next WG meeting will take place as a web conference on 2 May 2019 as a web conference. 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 microorganisms<sup>7</sup>**

The WG Chair updated the Panel on the progress of work made. The Panel agreed with the approaches presented to answer terms of reference 1 and 2. A preliminary version of the uncertainty analysis performed for this opinion was presented by the WG Chair. The Panel agreed with it requesting to add something about the impact of the identified sources of uncertainty on the conclusions. The next WG meeting will take place on 20 May 2019 as a web conference. 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 production<sup>8</sup>**

The WG chair updated the panel on the progress made and the upcoming WG meetings. Two additional meeting days are required for the implementation of the uncertainty guidance. This was followed by a presentation of the approach taken for the uncertainty analysis and the challenges faced by the WG to carry out the analysis within the timelines of the mandate given its complexity. The panel chair recommended to the WG to discuss during the next WG meeting the general form of the conclusions which should help identifying the related uncertainties. There was no WG meeting since the last BIOHAZ plenary, hence the WG chair gave a brief overview of the draft opinion and updated the panel on the ongoing literature search activities

<sup>5</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00831>

<sup>6</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00293>

<sup>7</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00397>

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



that are carried out. The next meeting is on 7 May 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 cervids<sup>9</sup>**

The Chair of the WG presented for the first time a draft of the scientific opinion for information, mostly the layout and contents of the Section 3 (Assessment). The logical flow adopted by the WG consists of a general description of what is a strain in TSE, what we know about strains and CWD pathogenesis in North America and Europe, the transmissibility to host non-human species, studies about the ability of the human prion protein (PrP) to convert *in vivo* and *in vitro* in the presence of the CWD agent; the consideration of the exposure assessment rather than the estimation of the actual risk to answer term of reference 2 and the review of risk factors in tabular format for term of reference 3, considering: two forms of disease (contagious and non-contagious), the biological plausibility, the step in the risk pathway and the preventability. There were no comments or questions to the presentation of the WG chair. The next meeting will be a web-conference on Tuesday 30 April 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 processing<sup>10</sup>**

The WG Chair informed that the *ad hoc* WG has been composed and that the first WG meeting was held on 18 March 2019 in Parma. A hearing expert was invited to provide insights from US outbreaks and recalls related to the microbial safety of frozen food, produce, and vegetables. The background of the mandate was reminded, and the interpretation and clarification of the three terms of reference presented. The proposed tentative approaches to answer the terms of reference was discussed. A timeline for WG meetings in 2019 was shown; the next WG meeting will take place on 7 May by web-conference. 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 *ad hoc* WG has been composed and the first WG meeting was held on 25 March 2019 by web-conference. The WG Chair reminded about the background and terms of reference of the mandate. The outcome of the first WG meeting was presented including (a) the interpretation and clarification of the terms of reference based on the discussion with the EU representatives and (b) the proposed six steps to answer the terms of reference. It was clarified that the assessment can be restricted to biological hazards and histamine on the meat surface and fish meat and that the fish quality is out of scope. The conditions to be considered in the assessment are as follows: (i) first transport and storage of fishery products in fresh or sea water/ice (tub) and then unload and place in ice (box) when in first on-land establishment (control) and (ii) first transport and storage of fishery products in fresh or sea water water/ice (tub) and then unload and place in fresh water/ice (tub) when in first on-land establishment (alternative). According to what clarified with the requestor, transport of fishery products in ice (box) until the first on-land establishment is out of the scope of the assessment. A timeline for WG meetings in 2019 was shown; the next meeting will take place on 7-8 May 2019 in Parma. The deadline for adoption is March 2020.

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

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



## **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 about the progress in establishing the WG. The first WG meeting is anticipated for June 2019. Some clarification was requested from the EC on the diseases/conditions to be included or excluded from the terms of reference and confirmed that *Toxoplasma*, VTEC and *Yersinia* are excluded. *Salmonella* is included and the panel is requested to compare the sensitivity of *Salmonella* detection immediately after slaughter before chilling with the sensitivity of detection 24 hours and 72 hours after slaughter and chilling. The deadline for this mandate is December 2020.

## **7. New Mandates**

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

EFSA Secretariat presented to the Panel the background and term of reference of this mandate, received on 11 March 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). The Panel chair also nominated FEEDAP AHAW panel member Vasileios Bampidis as vice-Chair of this WG (conditional to screening and approval of his declaration of interests). The BIOHAZ Panel is the leading panel for this mandate and specific sections will be endorsed by AHAW and FEEDAP Panel. The mandate will be tackled in collaboration with EMA (EMA expert will be invited to be part of the *ad hoc* WG). The BIOHAZ Panel briefly discussed with the European Commission the terms of reference. The EC clarified that EFSA is asked to assess in collaboration with EMA the impact of the presence of low-level concentration in feed of 24 antimicrobial active substances listed in the Mandate on animal health, human health and, where possible, on the environment. The EC confirmed that the endpoint for this assessment should be the excretion of resistant bacteria from the animals, assessing, if possible, general consequences that this could have in the environment. It was also clarified that the public health and animal health aspect refers only to the development of resistance in those bacteria of importance in humans and animals.

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

### **8.1. Scientific Committee**

The 92<sup>nd</sup> Plenary meeting of the Scientific Committee (SC) took place on 19-21 February 2019,<sup>11</sup> as already reported during the previous BIOHAZ Panel plenary. The BIOHAZ Panel chair reported feedback about the SCER cross cutting WG on Uncertainty.<sup>12</sup> The next SC meeting will take place on 24 April 2019.

<sup>11</sup> <https://www.efsa.europa.eu/en/events/event/190219>

<sup>12</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-uncertainty.pdf>



## 8.2. European Commission

EFSA Secretariat updated the Panel on the exchanges of views with the European Commission on a draft mandate in relation to the date marking and related food information, and future possible mandates to be sent to EFSA on BIOHAZ topics.

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

### 9.1. Follow-up of the training on the implementation of the guidance on uncertainty analysis in scientific assessments

EFSA Secretariat presented a summary of the main points discussed by the Panel during the training and March plenary meeting that took place on 5-7 March 2019. The trainers are expected to provide a revised version of case-studies, a revised version of a checklist to assist working groups in the implementation of the uncertainty guidance, and a report about the training. The BIOHAZ Panel agreed again on the importance of the implementation of the guidance in BIOHAZ outputs. BIOHAZ assessments are very different one to the other and therefore implementation of the guidance will have to be considered on a case-by-case basis depending on the nature of the questions, on the specific needs of the specific mandates, and obviously on the resources available. Progress has been already made in implementing the guidance in the Panel and its working groups according to the checklist (e.g. reviewing in detail the formulation of the questions, discussing the need to quantify uncertainties, etc.), further progress is expected in the future, also based on the experience that will be gained in the process. This agenda item will be kept for further discussion in future plenaries.

### 9.2. Request to participate in 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, reminded to the BIOHAZ Panel the remit of this EMA activity, and updated the Panel on the progress made in the first EMA expert group meetings.

## 10. Any other business

EFSA Secretariat presented a document summarising the discussions held at the previous BIOHAZ plenary meeting related to the EFSA guidance on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption. Panel members will provide any additional comment before the next plenary, if needed.



## Annex

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

With regard to this meeting, Prof. Friederike Hilbert declared the following interest: recent election as chair of the Section on Food of Animal Origin of the Austrian Veterinary Association. In accordance with EFSA's Policy on Independence<sup>13</sup> and the Decision of the Executive Director on Competing Interest Management<sup>14</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>13</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>14</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)