

## Scientific Panel on Biological Hazards

### Minutes of the 117<sup>th</sup> Plenary meeting

**Held on 6-7 December 2017, Parma (Italy)**

**(Agreed on 20 December 2017)**

#### Participants

■ Panel Members:

Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo S. Fernández-Escámez, Rosina Gironés, Lieve Herman, Konstantinos Koutsoumanis, Roland Lindqvist, Birgit Nørrung, Antonia Ricci, Lucy Robertson, Giuseppe Ru, Moez Sanaa (for item 7.1), Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck, Benno Ter Kuile, John Threlfall, and Helene Wahlström.

■ European Commission and/or Member States representatives:

Pamina Suzuki (for item 9.1).

■ EFSA:

BIOCONTAM Unit: Frank Boelaert, Sandra Correia, Maria Teresa da Silva Felício, Michaela Hempen, Ernesto Liebana, Winy Messens, Angel Ortiz Pelaez, Pietro Stella (Scientific staff).

SCER Unit: Nikolaos Georgiadis (for items 13.1, 13.2), Caroline Merten (for item 10.1.2).

AFSCO Unit: Nicoline Le Gourierec (for item 11.3).

■ Observers: (In application of the guidelines for Observers<sup>1</sup>)

Shih-Kuo Lin (physical observer); Cristina Arroyo-Casabona, Vangelis Economou, Stefanie Geiser, Heidi Hyytiäinen, Eleonora Sarno, Leena Seppä-Lassila, Nico van Belzen (online observers through web-streaming)

■ Others:

Not Applicable

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<sup>1</sup><http://www.efsa.europa.eu/en/stakeholders/observers.html>

## **1. Welcome and apologies for absence**

Apologies were received from Moez Sanaa (for 6 December morning and for 7 December).

## **2. Adoption of agenda**

The agenda was adopted without further changes.

## **3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Panel Members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, or at the Oral Declaration of Interest at the beginning of this meeting.

## **4. Brief introduction of Panel members and observers**

The BIOHAZ Panel members, EFSA staff and the physical observer briefly introduced themselves.

## **5. Presentation of the EFSA Guidelines for observers**

EFSA Secretariat introduced the EFSA Guidelines for observers, including the rules for attending the meeting both physically and through web-streaming, and explained when in the agenda specific slots for answering questions from the observers have been placed.

## **6. Agreement of the minutes of the 116<sup>th</sup> Plenary meeting held on 18-19 October 2017, Parma (Italy)**

The minutes of the 116<sup>th</sup> Plenary meeting were agreed by written procedure on 3 November 2017.<sup>4</sup>

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<sup>2</sup><http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>3</sup><http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>4</sup><http://www.efsa.europa.eu/en/events/event/170913>

## 7. Scientific outputs submitted for possible adoption

### 7.1. Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU<sup>5</sup>

The event report of the stakeholder meeting on the draft scientific opinion on *Listeria monocytogenes* contamination of ready-to-eat foods and the risk for human health in the EU (19-20 September 2017) has been published<sup>6</sup>. The WG Chair presented the updated version of the scientific opinion considering the comments received through the public consultation and the feedback provided at the previous plenary meeting. A discussion took place and the scientific opinion was adopted on 6 December 2017. The technical report on the outcome of the public consultation will be published together with the scientific opinion. The panel was informed that French Agency for Food, Environmental and Occupational Health & Safety (Anses) and EFSA agreed that there is no divergence between the opinion by the Anses expert committee "Assessment of the biological risks in foods" (BIORISK)<sup>7</sup> and the EFSA opinion.

### 7.2. Request for a Scientific opinion on Chronic Wasting Disease (CWD) (ToRs 4 and 5)<sup>8</sup>

The WG Chair presented the draft scientific opinion to the BIOHAZ Panel for adoption. The chair presented in detail the answers to the ToRs, recommendations, summary and abstract, since the body of the text had not changed substantially since the thorough reading, nor the main conclusions. The Panel made minor suggestions to improve the understanding and ease of the reading, like to number the conclusions and recommendations from the previous opinion that are still valid, and the explanation of the comparison between the prevalence in infected herds in the US and in a region of Norway. The Panel adopted the opinion subject to minor changes to be done after the plenary.

### 7.1. Self-task mandate for a scientific statement on the update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA. 7: Suitability of taxonomic units notified to EFSA until September 2017<sup>9</sup>

The last WG meeting was held on 16-17 October in Parma. Between April and September 2017, the QPS (Qualified Presumption of Safety)

<sup>5</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00597>

<sup>6</sup><https://www.efsa.europa.eu/en/supporting/pub/1343e>

<sup>7</sup><https://www.anses.fr/fr/system/files/BIORISK2017SA0189.pdf>

<sup>8</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00411>

<sup>9</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00828>

notification list was updated with 46 applications for market authorisation. From these, only 2 new taxonomic units (*Komagatella phaffii* and *Kitasatospora paracochleata*) were included for evaluation of a possible QPS recommendation. The results of the Extensive Literature Search (ELS) for the period June 2016-17 were included (possible safety concerns that could affect any QPS recommendation or qualification). A recommendation concerning a possible extension of the QPS approach to genetically modified production strains was discussed and included in the statement. The statement was presented by the chair and adopted by the Panel on 6 December.

## **8. Scientific outputs submitted for discussion**

### **8.1. Self-task mandate for Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA<sup>10</sup>**

The WG chair presented the results of the ELS exercise for the period June 2016-17, which was finalised. The data extracted from the relevant articles were analysed for any possible safety concern that could affect any QPS recommendation or qualification. The final conclusions were also included in the statement adopted during this Plenary. WG meeting dates for 2018 are to be decided. Possible adoption of this opinion is foreseen for December 2019.

### **8.2. Self-tasking mandate for scientific opinion on public health risks associated with foodborne parasites<sup>11</sup>**

The WG chair informed the Panel that the WG experts are currently drafting their contributions. The panel discussed briefly whether the title of the draft opinion should be narrowed to three parasites assessed, then concluded that no change was necessary as the background to the mandate explains the reasoning for selecting these parasites. The next WG meeting will be held on 18/19 January 2017 in Parma. The deadline for this mandate is October 2018.

### **8.3. Second scientific opinion on hazard analysis approaches for certain small retail establishments and food donations<sup>12</sup>**

The second WG meeting was held on 4 December 2017 as web-meeting. The WG discussed the flow diagrams and tables for control activities. The panel suggested to the WG to provide a definition of what is considered “small” retail establishment. This is particularly relevant for distribution centres, which are part of the supermarket food chain and rarely “small”

<sup>10</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

<sup>11</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00460>

<sup>12</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00565>

as defined in the first HACCP opinion. The draft opinion also needs to address the difference between culinary versus industrial cooking which serve different purposes. Freezing for food donations needs thorough consideration as there are no clear EC guidelines and responsibilities lie with MS. The next WG meeting will be held on 16 January 2016. The deadline for this mandate is the end of September 2018.

#### **8.4. Request for an opinion on *Salmonella* control in poultry flocks and its public health impact<sup>13</sup>**

The WG chair informed the Panel that the WG is being composed, pending DoI approval. As the Terms of Reference 3 and 4 concern the occurrence of *Salmonella* in laying hens and broilers in relation to housing conditions and other welfare indicators, an AHAW Panel member with relevant expertise on the topic has additionally been appointed in the WG. The first WG meeting will be held on 16 January 2018 in Parma. The deadline to deliver the Scientific Opinion is 31 January 2019.

#### **8.5. Request for a scientific opinion on an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Protein (PAP)<sup>14</sup>**

The WG chair informed that no major progress had been made since the last plenary, apart from the establishment of the working group. The chair expressed her concern about the difficulties of this mandate, reflected by the difficulty to recruit experts, in her opinion, due to the short timescale for delivery of the opinion. She gave the floor to the secretariat who informed the Panel of the current membership of the working group, two of the six members still to be confirmed following the approval of their DoIs, and the dates of the first two meetings that have already been fixed: a web-conference on 15 December 2017 and a physical meeting in Parma on 10-11 January 2018.

#### **8.6. Application received from the Dutch Competent Authority (the Netherlands Food and Consumer Product Safety Authority) for evaluation of a new alternative processing method for animal by-products for Category 3 material (ChainCraft BV)<sup>15</sup> (discussed under session closed to the public on 6 December afternoon)**

The application received from the Dutch Competent Authority (Netherlands Food and Consumer Product Safety Authority) on behalf of the company ChainCraft B.V. was considered valid on 27 November. The application proposes a new alternative method for category 3 material of animal by-products for the production of a solid powder of fatty acids salts intended to be used for feed. The applicant requested parts of the application to be claimed as confidential; this will be evaluated by EFSA.

<sup>13</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00692>

<sup>14</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00705>

<sup>15</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00619>

The experts for the *ad-hoc* WG to deal with this evaluation are being nominated. The first WG meeting will be organised on 20 December 2017 by web conference. WG meeting dates for 2018 are to be decided. The deadline for this mandate is 27 April 2018 (6 months following the receipt of a valid application).

## 9. New Mandates

No new mandates were received.

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

### 10.1. Scientific Committee and/or Scientific Panel(s) including their Working Groups

#### 10.1.1. Scientific Committee

The 86<sup>th</sup> Plenary meeting of the Scientific Committee took place in Parma on the 15-16 November 2017.<sup>16</sup> The BIOHAZ Panel Chair reported that the EFSA Guidance on Uncertainty Analysis in Scientific Assessment (new concise guidance) and its supporting opinion were adopted during the meeting.

#### 10.1.2. Scientific Committee Working Group on Uncertainty in risk assessment

EFSA Secretariat (SCER Unit) presented an update on the adoption of the new concise guidance on Uncertainty Analysis in Scientific Assessment, and informed the BIOHAZ Panel that future trainings will be organised for the Panel and EFSA staff on the implementation of the Guidance as of autumn 2018. The SC WG on Uncertainty will provide support to Scientific Panels' WGs if needed.

#### 10.1.3. 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<sup>17</sup>

A standing WG of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) "CEF Panel SWG on the evaluation of substances used to reduce microbial contamination from products of animal origin" is being established. Three BIOHAZ Panel members will be involved for the Terms of Reference 2 (efficacy) and one BIOHAZ Panel member for the ToR 3 (potential emergence of reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials). Panagiotis Skandamis has been appointed vice-chair of the WG, pending

<sup>16</sup> <http://www.efsa.europa.eu/en/events/event/171115-0>

<sup>17</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00667>

DoI approval. EFSA has requested the applicant missing information on 25 October 2017. The applicant has been granted an extension of the original deadline of 30 days for the submission of the requested information. The deadline to deliver the Scientific Opinion is 9 months following the receipt of a valid application. The first WG meeting is foreseen in January 2018 (date to be confirmed).

**10.1.4. Request for a scientific opinion on the evaluation of the safety and efficacy of the organic acids lactic and acetic acid to reduce microbiological surface contamination on pork carcasses and pork cuts<sup>18</sup>**

The same standing WG will prepare the Scientific Opinion and the same procedure will be followed as for the mandate under agenda item 10.1.3. EFSA has requested the applicant missing information on 25 October 2017. The applicant has provided missing information on 13 November 2017; however the application was not yet considered valid on 4 December 2017 and additional information has been requested. The deadline to deliver the Scientific Opinion is 9 months following the receipt of a valid application.

**10.2. EFSA including its Working Groups /Task Forces**

**10.2.1. Scientific Networks on BSE-TSE and MRA**

No new meetings of the Scientific Networks on BSE-TSE and MRA have been held. Minutes and annual reports for the two Networks are now published or being finalised for publication in December 2017. The next meeting of the MRA Network will be held on 24-25 April 2018. The next meeting of the BSE-TSE Network will be held in autumn 2018.

**10.2.2. Emerging Risks**

None

**10.3. European Commission**

None

**11. Other scientific topics for information and/or discussion**

**11.1. EFSA Workshop on PROMETHEUS**

The draft EFSA report on the outcome of the EFSA workshop on PROMETHEUS (PROmoting METHods for Evidence Use in Scientific assessments) has been shared with the participants of the workshop that took place on 9-10 October 2017.

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<sup>18</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00666>

### **11.2. EC request to EMA for an update of the advice on the impact on public health and animal health of the use of antibiotics in animals (categorization of antimicrobials and early hazard characterization)**

The first meeting of the EMA WG related to the update of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) categorisation of antimicrobials, and for a further elaboration on the proposed early hazard characterisation, is going to take place in December 2017. As in past similar activities, EFSA will be involved in this EMA activity.

### **11.3. European Food Risk Assessment Fellowship Programme (EU-FORA)**

EFSA Secretariat (AFSCO Unit) introduced to the Panel the background of the EU-FORA<sup>19</sup> initiative and reminded the deadlines for applications for both hosting sites (including consortia) and fellows.

### **11.4. Self-task mandates of the BIOHAZ Panel: proposal for a mandate for a Scientific Opinion on the application and use of whole genome sequencing (WGS) and metagenomics for risk assessment of foodborne microorganisms**

The Panel discussed all comments received from EC on the draft background and terms of reference which had been approved for this self-task mandate during the October plenary meeting. A few minor amendments were introduced and clarifications provided to the EC. The mandate will be now subject to internal acceptance in EFSA, before it can be initiated.

## **12. Answers to questions from observers**

Before the plenary meeting, observer Shih-Kuo Lin provided the Panel with two questions, in relation to: i) the possible applications of WGS data in improving safety in the supply chain; ii) the possible ways to control skin-superficial *Salmonella* at farm and slaughterhouse level. During the meeting, panel member Lieve Herman answered the first question, giving an overview on the application of WGS and on some recent EFSA activities in relation to WGS. Panel member Robert Davies answered the second question, giving an update on the main *Salmonella* prevention and control measures in poultry. During the meeting observer Shih-Kuo Lin asked the Panel about coverage of animal health concerns within the mandate for a scientific opinion on public health risks associated with foodborne parasites (see agenda item 8.2), and about inclusion in the mandate of "ingestion" of parasites not through food. Panel experts Birgit Nørrung and Lucy Robertson explained that the mandate is covering risks

<sup>19</sup> <http://www.efsa.europa.eu/en/engage/fellowship>



for public health rather than animal health and therefore it is under the sole responsibility of the BIOHAZ Panel, and that the mandate is covering transmission of parasites through food only.

### **13. Any other business**

EFSA Secretariat (SCER Unit) presented an update on the recent Scientific Committee Guidances on the use of weight of evidence approach in scientific assessment and on the assessment of the biological relevance of data in scientific assessments. Examples of how these topics were addressed in past opinions from the BIOHAZ Panel were provided. The Panel was informed of the ongoing development of an overall guidance document that would further clarify how to implement in an integrated way these guidances and the one on uncertainty.

Additional items discussed under session closed to the public on 6 December afternoon:

The Panel revised the dates for 2018 Plenary meetings. The first plenary meeting in 2018 will take place on 14-15 March 2018 (instead of January 2018).

Panel member Pablo S. Fernández-Escámez briefly presented the preliminary results of a study on a model in relation to spread of food-borne outbreaks.

EFSA Secretariat and panel member Kostas Koutsoumanis informed the Panel on a paper that will be drafted in relation to an intervention made on the use of predictive modelling in recent work of the EFSA BIOHAZ Panel, during the EFSA Symposium on Quantitative Microbial Risk Assessment held during the ICPMF10 Conference in September 2017.