

## Scientific Panel on Biological Hazards

### Minutes of the 113<sup>rd</sup> Plenary meeting

**Held on 7-8 June, 2017, Parma (Italy)**

**(Agreed on 22 June 2017)**

#### **Participants**

■ Panel Members:

Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo S. Fernandez-Escámez, Rosina Gironés (apologies for 7/6/17), Lieve Herman, Konstantinos Koutsoumanis, Roland Lindqvist, Birgit Nørrung, Antonia Ricci (apologies), Lucy Robertson (apologies), Giuseppe Ru, Moez Sanaa, Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck, Benno Ter Kuile, John Threlfall, and Helene Wahlström.

■ Hearing Experts:

NA

■ European Commission and/or Member States representatives:

Marina Marini (by teleconference), Pamina Suzuki (for items 5.1, 6.1, 6.3) from DG SANTE.

■ EFSA:

BIOCONTAM Unit: Ernesto Liebana, Valentina Rizzi, Winy Messens, Sandra Correia, Maria Teresa da Silva Felício, Michaela Hempen, Angel Ortiz Pelaez, Pietro Stella, Yves Van Der Stede, Frank Boelaert, Beatriz Guerra, Raquel García, Domenico Deserio, Marta Hugas (Scientific staff).

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

Jianghui Zhu

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

- Others:

Not Applicable

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

Apologies were received from Antonia Ricci, Lucy Robertson, and Rosina Gironés (for 7/6/17).

In the absence of A. Ricci, B. Nørrung Vice Chair of the BIOHAZ Panel took the role of Chair for the meeting and welcomed the participants.

Marion Simmons and Giuseppe Ru did not participate in discussions on selected items under agenda point 6.2 due to a Conflict of Interest being identified for the agenda item.

## **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.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

## **4. Agreement of the minutes of the 112<sup>th</sup> Plenary meeting held on 26-27 April 2017, Parma (Italy)**

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

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

The minutes of the 112<sup>th</sup> Plenary were agreed by written procedure on 11 May 2017.<sup>4</sup>

## **5. Scientific outputs submitted for possible adoption**

### **5.1. Self-task mandate on public health risks associated with hepatitis E virus (HEV) as a food-borne pathogen<sup>5</sup>**

The last WG meeting was held on 11<sup>th</sup> May 2017. The WG chair presented the draft opinion with special emphasis on abstract, summary, conclusions and recommendations. The panel suggested to be more precise in the description of the surveillance in human HEV cases which was provided by ECDC. Some modifications in the text were made accordingly including referencing to the ECDC report on HEV which will be published together at the same time as the EFSA opinion. The conclusions were expanded to include blood products, in particular meat glue (fibrinogen) as its use as a food ingredient and dietary supplement may play a role in the transmission of food-borne HEV. The opinion was then adopted on 8 June 2017.

### **5.2. Request for a scientific opinion on BSE cases born after the total feed ban<sup>6</sup>**

The draft scientific opinion was presented to the BIOHAZ Panel for adoption. The answers to the ToRs and recommendations were reviewed thoroughly by the Panel. The approach towards the qualitative assessment of the uncertainty was discussed and some modifications were requested. The Vice-Chair of the Panel requested to refer on the specific points where uncertainty is mentioned to the EFSA guidance document on uncertainty. The opinion was then finally adopted.

### **5.3. Self-task mandate for a statement on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA. 6: Suitability of taxonomic units notified to EFSA until March 2017<sup>7</sup>**

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<sup>4</sup><http://www.efsa.europa.eu/en/events/event/170426>

<sup>5</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00315>

<sup>6</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00350>

<sup>7</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00827>

The second WG meeting was held on 23/24 May in Parma and the sixth Panel statement was finalised by the WG. The draft Panel statement was presented to the Panel. It includes the assessment of the 10 taxonomic units notified to EFSA between September of 2016 and March 2017 which were not yet included in the QPS list. From these, only one was recommended for the QPS list (*Lactobacillus animalis*). After re-evaluation, the Panel has agreed that *Escherichia coli* and *Streptomyces* spp. will be excluded from further QPS evaluations within the current mandate. The opinion was adopted by the Panel.

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

### **6.1. Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU<sup>8</sup>**

The last WG meeting was held on 10-11 May 2017 in Parma. The Chair of the WG presented the draft scientific opinion to the BIOHAZ Panel for thorough reading. The suggestions made by Panel members during the first reading had been addressed. The conclusions to answer to the ToR 1 were discussed. With regards to the ToR 2, the *L. monocytogenes* generic QMRA model was presented: a detailed presentation was made of the methodology section and the section to evaluate the assessment questions (factors that may explain the epidemiological trend). At the next plenary meeting, the changes to the document will be presented together with the conclusions, summary and abstract. The deadline for endorsement of the scientific opinion is end of July 2017; for adoption it is end of December 2017. The next WG meeting will be held on 19 June 2017 by web-meeting.

### **6.2. Request for a scientific opinion on genetic resistance to TSEs in goats<sup>9</sup>**

The progress made in the last WG meeting, reflected in an updated draft opinion was presented by the Chair. The Opinion was deemed to be by the WG Chair and members in an advanced stage and it may be presented for possible adoption during July's plenary. The final version of the tool for assessing genetic resistance was presented along with the

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<sup>8</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00597>

<sup>9</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00268>

draft answers to the ToRs and further recommendations. The preliminary conclusions of the opinion were well received by the Panel and no major objections or comments were made. The final WG meeting will take place on 19 June 2017, as a physical meeting.

### **6.3. Self-task mandate on requirements for the development of microbiological criteria<sup>10</sup>**

The WG Chair reported back to the plenary on the progress made during the 6<sup>th</sup> WG meeting which took place on 15 May 2017 as a web conference. Comments were provided by the Panel on the shared preliminary draft opinion. These comments will be discussed with the WG during the next WG meeting on 8-9 June 2017 in Parma. The deadline for adoption of the Scientific Opinion is 31 October 2017.

### **6.4. Request for a joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals<sup>11</sup>**

This WG works in close collaboration with respective WGs of ECDC and EMA. The WG Rapporteur updated the Panel on the progress made by the WG during the fifth meeting (15 May 2017) and during an interagency Coordination WG with ECDC and EMA that took place on 3 May 2017. The Panel was informed that contributions on the draft opinion by ECDC and EMA may be available only after the July's Plenary meeting, and therefore the BIOHAZ Panel might be able to see the overall draft opinion with indicators from the three agencies only when the draft opinion is presented for possible adoption. The BIOHAZ Panel was presented with a refined proposal for primary and secondary indicators in the field of AMR in food-producing animals and food, and with the updated results of a test-run using the latest official surveillance data for 2014 and 2015. The BIOHAZ Panel agreed with the approach taken by the WG and provided few comments on the draft indicators for the consideration of the WG. The next meeting of the EFSA WG will take place on 4 July 2017.

### **6.5. Request for a scientific opinion on Chronic Wasting Disease (CWD) (ToRs 4 and 5)<sup>12</sup>**

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<sup>10</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00227>

<sup>11</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

<sup>12</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00411>

As a follow up of the information provided in the previous meeting, the BIOHAZ Secretariat informed the Panel about the request for clarifications of the CWD opinion Phase I recently received by the EC. The EC Standing Committee on Animals, Food and Feed approved on 17 May 2017 the draft of amended TSE Regulation including the CWD surveillance programme for six MS. The WG Chair informed that the WG had a meeting on 6 June 2017, as a web-conference, where the approaches to answer ToR4 and Tor5 were brainstormed. There are several activities on-going: a literature review on CWD diagnostic methods, contacts for information with manufacturers of authorised rapid tests for CWD in the USA, and the review of the 2004 and 2010 EFSA opinion, as required by the ToRs. The next meeting will take place on 21 July, as a physical meeting. The deadline for adoption of the Scientific Opinion is 31 December 2017.

#### **6.6. 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>13</sup>**

The second WG meeting was held on 23/24 May in Parma. The state of the art of scientific opinion, and the approach to follow for the scientific Opinion was explained to the Panel. The changes made in the approach for the extensive literature search (ELS) were also described. It is foreseen to run a new search for possible safety concerns published in literature at the end of June, concerning the taxonomic units included in the QPS list. AMU is supporting the WG on this latter activity as well on developing a “machine learning technique” pilot trial for screening references related to possible new safety concerns. The chair and EFSA secretariat provided some feedback from the collaboration with the Units, namely with FIP and Pesticides. The deadline proposed for this mandate and this opinion is December of 2019.

#### **6.7. Application received from the Austrian Competent Authority for evaluation of a “New alternative biodiesel process for rendered fat of Category 1 (BDI-RepCat Process, AT)”<sup>14</sup>**

The 1<sup>st</sup> WG meeting related to the evaluation of the application received from the Austrian CA on a new “alternative biodiesel process for rendered fat of Category 1”, was held by web conference on 31 May. The state of

<sup>13</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

<sup>14</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00136>

the art of the mandate was explained to the Panel. In the follow up of the completeness check, some missing data were requested to the applicant and received on 5 May. EFSA will have 6 months to finalise the evaluation and adopt a scientific opinion as foreseen by Regulation (EU) No. 142/2011. It was requested to recognise this process as equivalent to the already existing and approved biodiesel process in Chapter IV Section 2 D of Annex IV of Regulation (EU) No. 142/2011. The deadline for adoption of the Scientific Opinion is 5 November 2017.

## **7. New Mandates**

None

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

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

#### **8.1.1 Scientific Committee**

The 83<sup>rd</sup> Plenary meeting of the Scientific Committee took place in Parma on the 26/27 April 2017.<sup>15</sup> It was attended by the BIOHAZ Panel Vice Chair (K. Koutsoumanis) who will provide feedback to the Panel at the next Plenary meeting (5-6 July 2017).

#### **8.1.2 Scientific Committee Working Group on Uncertainty in risk assessment**

None.

#### **8.1.3 Scientific Committee Working Group on Biological Relevance**

None.

#### **8.1.4 Scientific Committee Working Group on Weight of Evidence**

None.

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<sup>15</sup><http://www.efsa.europa.eu/en/events/event/170426-0>

## **8.2. EFSA including its Working Groups /Task Forces**

### **8.2.1 Scientific Networks on BSE-TSE and MRA**

The Scientific Network on BSE-TSE will have its 12<sup>th</sup> meeting on 16-17 October 2017, in Parma. The next meeting of the MRA network is planned for 10-11 October 2017, in Parma.

### **8.2.2 Joint interagency antimicrobial consumption and resistance analysis (JIACRA) report-follow up-request for data analysis from 2013 and 2014<sup>16</sup>**

As a follow up to a previous mandate to EFSA, a second report aimed at analysing the relationships between antimicrobial use and resistance in humans, animal and food addressing available data for years 2013, 2014 and 2015 is required by the EC. The deadline agreed for completion of this activity is the end of June 2017. The Panel was given a brief update on progress after the end of the data collection network consultation.

### **8.2.3. Request for scientific and technical assistance on proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge<sup>17</sup>**

The 4<sup>th</sup> WG meeting took place on 5 May via web conference. DG Environment, JRC and SCHEER participated as observers. The adopted Opinion from SCHEER is aligned with EFSA's technical report. EFSA accepted the invitation from DG-ENVI to present via videoconference the final technical report on 23 June at the 3<sup>rd</sup> meeting of the CIS Ad-hoc Task-Group on water reuse. The final technical report was approved by the Head of RASA Department and will be published on EFSA website in the beginning of July. The publication date of EFSA's technical report still needs to be agreed with DG Environment.

### **8.2.4 Emerging Risks**

None

## **8.3. European Commission**

None

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<sup>16</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00029>

<sup>17</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00819>

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

### **9.1. Self-task mandates of the BIOHAZ Panel: proposal for a mandate on the public health risks associated with foodborne parasites**

The mandate has been proposed to EFSA's Executive Director as a self-task of the BIOHAZ Panel. After internal approval of the activity the mandate will be tabled for the July BIOHAZ Plenary meeting.

## **10. Any other business**

The Panel was consulted on the tentative dates booked for plenary meetings in 2018, these are: 17-18 January, 14-15 March, 18-19 April, 6-7 June, 11-12 July, 5-6 (Please note that these dates will overlap with the SC Plenary meeting) or 26-27 September, 24-25 October, and 5-6 December.

## Annex I

### Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

**CONFLICT OF INTEREST:** In the ADoI and SDoI filled for the present meeting Dr. M. Simmons declared the following interest: *Consultancy support provided at the request of the European Commission to the design and interpretation of the Cypriot studies into genetic resistance in Cypriot goats*, and Dr. Giuseppe Ru declared the following interest: *Based on a specific mandate from the Italian Ministry of Health he was involved in drafting a scientific dossier titled "The K222 allele of the goat PRNP gene as candidate for selective culling in scrapie outbreaks and for future breeding programs for TSE resistance in Italian goat breeds"*.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>18</sup> and the Decision of the Executive Director on Declarations of Interest<sup>19</sup>, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a Conflict of Interest.

This results in exclusion of the experts from any discussion, voting or other processing of the above mentioned reports under agenda item 6.2 by the concerned scientific group.

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<sup>18</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>19</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>