

Biological Hazards and Contaminants Unit (BIOCONTAM UNIT)

Scientific Panel on Biological Hazards
Minutes of the 102nd Plenary meeting
Held on 20-21 January 2016, Parma (Italy)
(Agreed on 1st March 2016)

Participants

• **Panel Members:**

Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo S. Fernandez-Escamez, Rosina Girones (only for item 8.1)¹, Lieve Herman, Konstantinos Koutsoumanis, Roland Lindqvist, Birgit Nørrung, Antonia Ricci, Lucy Robertson (apologies), Giuseppe Ru, Moez Sanaa, Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck, Benno Ter Kuile, John Threlfall, and Helene Wahlström (apologies).

• **European Commission and/or Member States representatives:**

– Sylvie Coulon (for item 5.9), Lucie Carrouee (for item 7.2.1) both (DG-SANTE)¹.

• **EFSA:**

- BIOCONTAM Unit: Ernesto Liebana, Valentina Rizzi, Winy Messens, Sandra Correia, Maria Teresa da Silva Felício, Beatriz Guerra, Michaela Hempel, Angel Ortiz Pelaez, Pietro Stella, Yves Van Der Stede, Giusi Amore, Frank Boelaert (Scientific staff), Mirena Ivanova (trainee)
- AMU Unit: Fulvio Barizzone (for item 8.2), Elisa Aiassa, Ana Garcia (for item 5.9)
- SCER Unit: Nikolaos Georgiadis (for item 7.1.3), Dimitrios Spyropoulos (for item 9.1)
- Quality Management Team: Lesley Koschel (for item 9.1)

¹ Attended by web-meeting.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received for Rosina Girones (only attended for item 8.1), Lucy Robertson, and Helene Wahlström

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, 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 ADol or the SDol, please refer to Annex. 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 101st Plenary meeting held on 2-3 December 2015, Brussels (Belgium)

The minutes of the Plenary meeting were agreed by written procedure on 8/01/2016 and are published on the EFSA website.

5. Scientific outputs submitted for discussion

5.1 Scientific Opinion on the update of the list of QPS recommended biological agents intentionally added to food or feed as notified to EFSA⁴

The last WG meeting took place on 25 September 2015 by web conference. Four new WG meetings are being organised for 2016, the next will be on 9 February in Parma. The WG Chair updated the Panel on the state of art of the extensive literature searches coordinated by the Assessment and Methodological Support (AMU) Unit and the follow up of these activities. The Panel discussed the importance of keeping a good level of collaboration with the four EFSA units for which the QPS activity is developed. The Scientific Opinion is to be finalised by December 2016.

5.2 Panel Statement on the update of the list of QPS recommended biological agents intentionally added to food or feed as notified to EFSA 4: Suitability of taxonomic units notified to EFSA until March 2016⁵

The last WG meeting took place on 25 September 2015 by web conference. Next WG meeting will be on 9 February in Parma. Seventy new microorganisms have been recently notified to the EFSA units, from which eight taxonomic units have been considered to be evaluated within the current Panel Statement for a possible QPS recommendation. General aspects concerning the assessment of the new taxonomic units have been discussed by the Panel. The Panel statement is to be finalised by June 2016.

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

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

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00697>

5.3 Joint EFSA and EMA (European Medicines Agency) Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union and the resulting impacts on food safety⁶

The last WG meeting was held on 15 December 2015, jointly with the corresponding EMA WG. The WG Chair updated the Panel on the status of progress of WG activities. During their last meeting the WG discussed the draft scientific opinion and identified some data gaps. Based on these two questionnaires with request for information on the use of antimicrobials in the different animal species and production systems, and on examples of agreements between farmers and retailers on the use of antimicrobials in food-producing animals were sent to selected stakeholders. The WG Chair reported that one new WG member has joined the WG, bringing additional expertise on animal health and welfare. The Panel Chair invited all BIOHAZ Panel members to provide remarks and suggestions on this topic once the draft opinion is presented in more detail to the Panel during the next Plenary meeting. The deadline to deliver the EFSA-EMA Joint Scientific Opinion is 20 December 2016.

5.4 Request for a Scientific Opinion concerning the risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp., including *Bacillus thuringiensis* in foodstuffs⁷

The last WG meeting was held before the Panel plenary meeting on 18-19 January 2016. The first day of this WG was dedicated to the technical consultation with representatives from the industry, namely from the International Biocontrol Manufacturers Association (IBMA). The WG Chair updated the Panel briefly on the status of progress of WG activities, presented the current structure of the Scientific Opinion and asked the Panel for advice on how best to describe in the Opinion the approach taken by WG members for their general literature reviews. The WG Chair also updated the Panel on the ongoing literature review on occurrence and levels of *B. thuringiensis* in foods, as well as on the outcomes of the consultations at the Member State level via the: (i) Pesticides Monitoring Network, (ii) Pesticides Steering Network and (iii) DG SANTE. The Panel was also informed on the confidentiality issues that the WG is facing when dealing with available information from the Draft Assessment Reports (DARs) for *B. thuringiensis* biopesticides as well as the characterisation of the alleged food poisoning associated to *B. thuringiensis* in Germany. The next WG will take place on 4 March 2016 as a webconference and the deadline to deliver the Scientific Opinion is 30 June 2016.

5.5 Request for a Scientific Opinion on hazard analysis approaches for certain small retail establishments in view of the application of their food safety management system⁸

The WG Chair summarised the Terms of Reference of the mandate as agreed with the EC and presented the preliminary Table of Contents of the Opinion. The first WG meeting will take place right after the BIOHAZ Panel meeting and an update on activities will be presented during the next Panel meeting in March 2016. The deadline to deliver the Scientific Opinion is 31 December 2016.

5.6 Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU⁹

The *ad hoc* WG helping with the preparatory work in the development of this Scientific Opinion has been set-up, with R. Lindqvist as WG Chair. The first WG meeting was held on 19 January 2016. The WG Chair presented the outcome of this first WG meeting. He showed the draft Table of Contents and explained the tentative approach that was suggested to answer to the TORs: for TOR 1 it would mainly consist of developing a conceptual model and performing a qualitative analysis to select in a systematic way the most important drivers for

⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216>

⁷<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00593>

⁹<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00597>

Listeria contamination and illness. The hypotheses generated as an outcome of this would be evaluated to answer TOR 2. The next (second) meeting of the WG is scheduled for 3 March 2016 by web meeting; the third one for 28-29 April 2016 in Parma. The deadline to deliver the Scientific Opinion is 31 July 2017.

5.7 Scientific Opinion on the growth of spoilage bacteria during storage and transport of meat¹⁰

The clarifications requested by the EC were presented as well as the approaches to perform the additional work. The approach will depend on the availability of warm transport temperature profiles. If such data are available, then these will be used for the modelling. In their absence, a hypothetical approach based on assumptions will be used. The next WG meeting is on 29 January 2016. The deadline for the delivery of the Scientific Opinion is 30 June 2016.

5.8 Request for an EFSA Scientific Opinion on the risk for the development of Antimicrobial Resistance (AMR) due to feeding calves with milk¹¹

The first meeting of the WG will take place in Parma on the 22nd February 2016.

5.9 Scientific Opinion on the evaluation of the safety and efficacy of Listex P 100 for reduction of pathogens on different ready to eat (RTE) food¹²

The Panel was informed that the second missing information from the applicant has been received on 29 December 2015. The application was considered valid on 13 January 2016 and the deadline to deliver the Scientific Opinion is therefore 13 July 2016 (i.e. 6 months following the receipt of a valid application). The first WG meeting took place on 17th December 2015 via web-conference. The WG Chair presented the outcome of this first WG meeting. She showed the draft Table of Contents and reminded the BIOHAZ Panel that this Opinion has been selected for the testing phase of the PROMETHEUS project. The proposed protocol that the WG will apply was agreed by the BIOHAZ Panel. It consists of a more traditional approach for TOR1, 3 and 4 and a more systematic approach for TOR2 (efficacy assessment). This protocol will be discussed and finalised at the second WG meeting on 15-16 February 2016 in Parma. Scoring of the studies is expected to be carried out between WG meeting 2 and 3 (17 (PM) and 18 March 2016 in Parma).

5.10 Scientific Opinion on the safety of a method for processing animal fats intended for technical purposes with the aim to establish the end point in the manufacturing chain^{13,14}

Nothing to report.

6. New Mandates

6.1 Joint interagency antimicrobial consumption and resistance analysis (JIACRA) report-follow up-request for data analysis from 2013 and 2014¹⁵

The Panel was informed of a letter received by EFSA, EMA and ECDC to re-do the analysis on the correlation between consumption of antimicrobials and occurrence of resistance. This is a follow up of a previous mandate to EFSA. The deadline is under negotiation with the requestor. A joint EFSA/EMA/ECDC Working Group will be established in due time.

¹⁰<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00163>

¹¹<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00611>

¹²<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00428>

¹³<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00351>

¹⁴<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00352>

¹⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00029>

7. Feedback from the Scientific Committee/the Scientific Panel, EFSA, the European Commission

7.1 Scientific Committee and/or Scientific Panel(s) including their Working Groups

7.1.1 Scientific Committee

None.

7.1.2 Scientific Committee Working Group on Uncertainty in Risk Assessment¹⁶

Information on the dates of the training sessions on uncertainty in 2016 was provided to Panel members.

7.1.3 Scientific Committee Standing Working Group on Biological Relevance¹⁷

G. Ru updated the Panel members on the status of progress of the WG activities. A scientific Officer from the SCER Unit gave a presentation on the progress of this working group, and put into context the case study selected on biological agents (zoonotic potential of scrapie).

7.1.4 Scientific Committee Working Group on Weight of Evidence¹⁸

None.

7.1.5. Scientific Committee standing WG on Guidance review

The Panel was informed of the terms of reference for this mandate. No formal involvement of the BIOHAZ Panel is required at this point in time¹⁹.

7.2 EFSA including its Working Groups / Task Forces

7.2.1. Request for scientific and technical assistance concerning the revision of the BSE monitoring regime in Croatia²⁰

Emma Snary did not participate in the discussion due to her Conflict of Interest identified regarding this item. The last WG meeting took place on 7 January in Parma. The draft Opinion was presented by the scientific secretariat. Comments by two BIOHAZ Panel members had been received in advance of the plenary meeting. Additional minor comments and suggestions were made by the BIOHAZ Panel members during the discussion and all will be taken into account by the WG when preparing the final version of the scientific report. The policy officer of DG SANTE in charge of the TSE portfolio joined this point of the agenda. No major issues were raised by the EC. After a review of the scientific report, this was endorsed by the Panel on the 20 January 2016.

7.2.2. Scientific Network on BSE-TSE and MRA

The 2016 annual meetings of the MRA Network are scheduled for 12-13 April and 11-12 October 2016.

The 2016 dates for the annual meeting of the BSE-TSE Network will be decided in February.

7.3. European Commission

None.

¹⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00738>

¹⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00748>

¹⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00007>

¹⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00129>

²⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00350>

8. Other scientific topics for information and/or discussion

8.1 Self-task mandates of the BIOHAZ Panel

R. Girones presented the background and the Terms of Reference of the proposal for a self-tasking mandate for Scientific Opinion on public health risks associated with Hepatitis E Virus (HEV) as a food-borne pathogen. A discussion took place and the Panel members were invited to send via email to the Scientific Secretariat any further comments on the draft proposal.

B. Nörrung presented the proposal for a self-tasking mandate for a Scientific Opinion on the requirements for the development of Microbiological Criteria. Comments and suggestions were provided by the Panel members. The Panel agreed with the final version after thorough discussion.

8.2 Prometheus Project (PROmoting METHods for Evidence Use in Scientific assessments)

A presentation was given by an EFSA staff member from the AMU Unit to explain the contents of the survey on the “methodological needs” for evidence use in scientific assessments. This will be part of the second deliverable (report) of the PROMETHEUS project. The Panel members and BIOCONTAM staff proceeded with completing the online survey. The Panel members that were not attending the meeting were asked to complete the survey remotely. The results will be summarized and used to provide input to the plenary discussion at the next BIOHAZ plenary meeting.

8.3 EUSR (European Union Summary Report) on zoonoses

The results from the 2014 EUSR on zoonoses were presented to the Panel.

9. Any other business

9.1. Feedback on customer feedback exercise

A presentation was given to the Panel with information on the results from the 2015 exercise.

9.2. Feedback from Open Plenary 2-3 December 2015

A presentation was given to the Panel with a summary of the information from the feedback forms received from observers and Panel members after the Open plenary meeting.

9.3. Joint session with AHAW Panel in 2016

A joint session of the BIOHAZ and AHAW Panels is being organised for the 27 April 2016. The agenda will be defined in the coming months.

9.4. Information on upcoming mandates

The panel was informed on the imminent arrival of several mandates in the area of TSEs.

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 her SDoI filled for the present meeting **Ms. EMMA SNARY** declared the following interest: *The C-TSEMM model was developed within the APHA Biomathematics & Risk Research workgroup (ES is the workgroup leader) within the Department of Epidemiological Sciences. EFSA have recently requested that the APHA provide expert assistance in updating the CTSEMM model for the scientific and technical assistance concerning the revision of the BSE monitoring regime in Croatia (Negotiated procedure reference: NP/EFSA/BIOCONTAM/2015/04). A proposal is currently being prepared. ES will not be part of this project team, but would like the panel to be aware of this potential conflict of interest.*

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes²¹ and the Decision of the Executive Director on Declarations of Interest²², and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in exclusion of the expert from any discussion, voting or other processing of item 7.2.1 by the concerned scientific group.

²¹<http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

²²<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>