
Biological Hazards and Contaminants Unit (BIOCONTAM UNIT)

Scientific Panel on Biological Hazards
Minutes of the 101st Plenary meeting
Held on 2-3 December 2015, Brussels (Belgium)
(Agreed on 08 January 2016)

Participants

- **Panel Members:**

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

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

- Wolfgang Trunk (for items 9.1), Kris De Smet, Marina Marini (DG SANTE - European Commission (EC)).

- **EFSA:**

- BIOCONTAM Unit: Marta Hugas (on the 2nd December), Ernesto Liebana, Valentina Rizzi, Winy Messens, Sandra Correia, Maria Teresa da Silva Felício, Angel Ortiz Pelaez (on the 2nd December)

- **Observers:**

- Diane Cuzzucoli (ANSES)
- Tomasz Grudnik (FEFANA asbl - EU Association of Specialty Feed Ingredients and their Mixtures)
- Rodrigo Nova (School of Veterinary Medicine and Science, University of Nottingham) (only on 3rd December)
- Marianne Sandberg (The Danish Agriculture and Food Council) (only on 2 December)
- Adriaan Vanheule (trainee at DG SANTE) (only on 2nd December)

OPEN SESSION

2 December 2015, 9.00-17.00

3 December 2015, 9.00-17.00

1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies were received.

2. Brief introduction of Panel members and Observers

The Panel members and the Observers introduced themselves.

3. Adoption of the agenda

The agenda was adopted without changes.

4. Declarations of Interest of Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², 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.

5. Presentation of the *EFSA Guidelines for Observers*

The Panel Chair gave a short presentation on the code of conduct during open plenary meetings for the observers.

6. Agreement of the minutes of the 100th Plenary meeting held on 21-22 October 2015, Parma (Italy)

A comment was received via email from a Panel member regarding the mandate on HACCP and the minutes were amended accordingly. The minutes of the 100th Plenary meeting held on 21-22 October 2015 were agreed by written procedure on 20 November 2015 and published on the EFSA website on 23 November 2015.

7. Scientific outputs submitted for possible adoption

7.1 Panel Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 3: Suitability of taxonomic units notified to EFSA until September 2015³

The last WG meeting took place on 25 September 2015 via web-conference. The evaluation of the four taxonomic units, previously notified to the EFSA units and included in this

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00696>

Statement, has been presented by the WG Chair and after a thorough discussion was adopted on 2 December 2015.

7.3 Scientific Opinion on the public health risks associated with Enteroaggregative *Escherichia coli*⁴

The seventh WG meeting took place on 12-13 November 2015 in Parma. The draft Opinion was presented by the WG Chair. Comments and suggestions from the BIOHAZ Panel members were taken into account and after a thorough discussion the Opinion was adopted on 2 December 2015.

7.4 Scientific Opinion on the evaluation of heat treatments, that could be applied to live bivalve molluscs in order to eliminate pathogenic micro-organisms⁵

The fifth and sixth WG meetings were held on 23 October 2015 in Parma and on 20 November 2015 via web-conference. The draft Opinion was presented by the WG Chair. Comments and suggestions were made from the BIOHAZ Panel members in particular with reference to the section on uncertainty and were taken into account in the final version of the document. After a thorough discussion the Opinion was adopted on 3 December 2015.

8. Scientific outputs submitted for discussion

8.1 Scientific Opinion on the update of the list of QPS recommended biological agents intentionally added to food or feed as notified to EFSA⁶

The last WG meeting took place on 25 September 2015 via web-conference. New WG meetings are being organised for 2016. 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 Scientific Opinion is to be finalised by December 2016.

8.2 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 safety⁷

The third WG meeting was held on 29 October via web-conference jointly with the corresponding EMA WG. The WG Chair updated the Panel on the status of progress of WG activities and presented the Table of Contents of the Scientific Opinion. The deadline to deliver the EFSA-EMA Joint Scientific Opinion is 20 December 2016.

8.3 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 foodstuffs⁸

The third and fourth WG meetings were held as web conferences on 18 and 24 November 2015 respectively. The WG Chair updated the Panel briefly on the status of progress of WG activities and presented the Table of Contents of the Scientific Opinion as well as a summary of the proposed approach for the literature review on occurrence and levels of *B. thuringiensis* in foods. This approach was approved. The deadline to deliver the Scientific Opinion is 30 June 2016.

⁴<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00536>

⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00161>

⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189>

⁷<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216>

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254>

8.4 Request for a Scientific Opinion on hazard analysis approaches for certain small retail establishments in view of the application of their food safety management system⁹

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 deadline to deliver the Scientific Opinion is 31 December 2016.

8.5 Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU¹⁰

The self-task mandate has been accepted by EFSA on 26 October 2015. The Panel Chair informed the Panel members that R. Lindqvist has been appointed via written procedure on 5 November 2015 as Chair person for the *ad hoc* WG helping with the preparatory work in the development of this Scientific Opinion. The set-up of the *ad hoc* WG is on-going. The first WG meeting has tentatively been scheduled on 19 January 2016. The deadline to deliver the Scientific Opinion is 31 July 2017.

8.6 Scientific Opinion on the growth of spoilage bacteria during storage and transport of meat¹¹

The clarifications requested by the EC were presented as well as the approaches to perform the additional work. The proposed extended deadline for the delivery of the Scientific Opinion is 30 June 2016, to be confirmed by the EC.

9. New Mandates

9.1 Request for an EFSA Scientific Opinion on the risk for the development of Antimicrobial Resistance (AMR) due to feeding calves with milk¹²

The Panel confirmed the agreement on the need to set up an *ad hoc* WG to help in the preparation for this Opinion. The Panel Chair informed the Panel members that L. Herman has been appointed via written procedure as Chair person for the *ad hoc* WG helping with the preparatory work in the development of this Scientific Opinion. The representative from the EC presented the background of the mandate, and the appointed Chair gave a presentation on the terms of reference, expertise needed and possible approach to answers the questions received.

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

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

10.1.1 Scientific Committee

None.

10.1.2 Scientific Committee Working Group on Uncertainty in Risk Assessment¹³

B. Nörrung informed the Panel that the guidance document on uncertainty will be presented for adoption at the Scientific Committee plenary meeting in February 2016.

⁹<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00593>

¹⁰<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00597>

¹¹<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00163>

¹²<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00611>

¹³<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00738>

The selection of the two Opinions for the testing phase was discussed and the following ones were selected:

- Self-tasking mandate for Scientific Opinion on investigation of the increasing trend of listeriosis in the EU/EEA over the period 2009-2013;
- Request for an EFSA Scientific Opinion on the risk for the development of Antimicrobial Resistance (AMR) due to feeding calves with milk.

Information on the dates of the training sessions on uncertainty will be provided to Panel members as soon as possible.

10.1.3 Scientific Committee Standing Working Group on Biological Relevance¹⁴

G. Ru updated the Panel members on the status of progress of the WG activities. Detailed information on the case study on biological agents will be given at the next plenary meeting and the WG Scientific Officer will be invited.

10.1.4 Scientific Committee Working Group on Weight of Evidence¹⁵

H. Wahlström has been appointed member of this WG. She will update the Panel at the next plenary meetings.

10.2 EFSA including its Working Groups / Task Forces

10.2.1. Request for scientific and technical assistance concerning the revision of the BSE monitoring regime in Croatia¹⁶

Emma Snary did not participate in the discussion due to her Conflict of Interest identified regarding this item. The third meeting of the WG was held on 24 November via web-conference. The Scientific Officer led the thorough reading of the Scientific Report and the feedback from the BIOHAZ Panel was positive. The draft report will be finalised taking into account the comments and suggestions received from the BIOHAZ Panel members. The deadline for delivery is 31 January 2016. The final draft will be submitted for endorsement to the next plenary meeting on 20-21 January 2016.

10.2.2. Scientific Network on BSE-TSE and MRA

The annual meeting of the MRA Network took place on 27-28 October 2015 in Parma. Meeting documents have been made available to the Panel members in DMS.

The Scientific Secretariat informed the Panel that for both Networks an annual report will be published on the EFSA website by the end of the year.

10.3. European Commission

None.

11. Other scientific topics for information and/or discussion

11.1 Self-task mandates of the BIOHAZ Panel

The Scientific Secretariat informed the Panel that only a couple of proposals for self-task mandates will be discussed in detail at each plenary meeting, based on the prioritisation done following the EFSA strategy and the feedback received from the EC.

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

¹⁴<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00748>

¹⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00007>

¹⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00350>

(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 Scientific Opinion on scientific information and criteria relevant for suggestion of Microbiological Criteria. Comments and suggestions were provided by the Panel members. Further contribution could be sent via email to the Scientific Secretariat.

12. Answers to questions from Observers (in application of the EFSA Guidelines for Observers)

One question was received in advance from Tomasz Grudnik regarding the mandate on *Bacillus*.

Question: The last Opinion of the BIOHAZ Panel published on *Bacillus cereus* and other *Bacillus* spp. in foodstuffs is dated January 2005. Since that time a lot of scientific evidence has been published* demonstrating the significant ecological diversification in the *Bacillus cereus* group. Such new scientific evidences demonstrate that within the *Bacillus cereus* group, apart from the known food poisoning strains (e.g. *Bacillus cereus* sensu stricto, *Bacillus anthracis*, *Bacillus cytotoxicus*), there are other strains that are not toxic at all. The recent scientific evidence has also provided powerful tools to clearly differentiate the pathogenic strains from the non-pathogenic strains within the *Bacillus cereus* group: Has the BIOHAZ Panel taken into account such new scientific evidence to prepare the new Scientific Opinion concerning the risks for public health related to *B. cereus*, other *Bacillus* and *B. thuringiensis* in foodstuffs?

Answer: The on-going mandate on “the risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp., including *Bacillus thuringiensis* in foodstuffs” is actually an update of the 2005 Opinion on the same topic, as clearly mentioned in the Terms of Reference. The requestor (EC) as well as the BIOHAZ Panel recognise the need for such an update, driven by the advances in the scientific literature about the characterisation and pathogenic potential of these microorganisms. The ad hoc WG established to draft the Opinion has already thoroughly discussed the difficulties of characterising and differentiating members of the *Bacillus cereus* group by means of traditional techniques, and acknowledged the usefulness of molecular methods, and Whole Genome Sequencing in particular, to allow a precise identification of these strains, also in order to evaluate their pathogenicity. In the Opinion a specific chapter will be dedicated to analytical methods, including the most innovative ones.

Another question was raised by Rodrigo Nova during the meeting regarding the mandate on hazard analysis approaches.

Question: It was asked if the *ad hoc* WG plans to consult small retail establishments during the preparation of the Scientific Opinion.

Answer: It was clarified that the activities of the WG have not yet started. But the WG will discuss in the preliminary phase of the activities what approach to take, including the possible consultation of relevant stakeholders.

13. Any other business

13.1 Prometheus Project

Regarding the Prometheus Project (PROMoting METHods for Evidence Use in Scientific assessments), the Panel members were informed that they will be asked to fill in an online

survey during the next BIOHAZ plenary meeting in January 2016. The survey will be shared with the Panel members beforehand.

It was also discussed about the selection of one Opinion for the testing phase of this project. The Scientific Opinion on the evaluation of the safety and efficacy of Listex P 100 for reduction of pathogens on different ready to eat (RTE) food was chosen for this purpose.

13.2 EUSR (European Union Summary Report) on zoonoses

The Panel was informed that the 2014 EUSR on zoonoses is in the approval phase in EFSA. The Scientific Secretariat thanked all Panel members for the comments provided during the consultation period. The Scientific Report will be published by the end of the year on the EFSA website. A colleague will be invited at the next plenary meeting to present the results from the 2014 EUSR on zoonoses.

CLOSED SESSION

2 December 2015, 17.00-18.00

14. Scientific outputs submitted for discussion

14.1 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^{17,18}

None.

14.2 Request for a Scientific Opinion on the evaluation of the safety and efficacy of Listex P 100 for reduction of pathogens on different ready to eat (RTE) food¹⁹

The Panel was informed that missing information from the applicant has been received on 27 November 2015. The first WG meeting will take place on 17 December 2015 via web-conference. The deadline to deliver the Scientific Opinion is 6 months following the receipt of a valid application.

¹⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00351>

¹⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00352>

¹⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00428>

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 Processes²⁰ and the Decision of the Executive Director on Declarations of Interest²¹, 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 7.2.5 by the concerned scientific group.

²⁰<http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

²¹<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>