
Biological Hazards and Contaminants Unit (BIOCONTAM UNIT)

**Scientific Panel on Biological Hazards
Minutes of the 103rd Plenary meeting
Held on 16-17 March 2016, Parma (Italy)
(Agreed on 18 April 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 (only on 16/03), Lucy Robertson, Giuseppe Ru, Moez Sanaa (apologies), Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck (apologies), Benno Ter Kuile, John Threlfall, and Helene Wahlström (apologies).

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

- Marina Marini, Aidan Cahill (for item 5.7)¹, and Sofie Hofkens (for item 5.4)¹, and Sylvie Coulon (for item 5.9)¹ from DG-SANTE.

• **EFSA:**

- BIOCONTAM Unit: Ernesto Liebana, Valentina Rizzi, Winy Messens, Sandra Correia, Maria Teresa da Silva Felício, Beatriz Guerra, Michaela Hempen, Angel Ortiz Pelaez, Pietro Stella, Yves Van Der Stede, Giusi Amore, Frank Boelaert, Marta Hugas (Scientific staff), Mirena Ivanova (trainee)
- AMU Unit: Fulvio Barizzone (for items 5.9 and 8.2)
- FIP Unit: Anne Theobald (for item 5.9)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received for Moez Sanaa, Helene Wahlström, Niko Speybroeck, and Antonia Ricci (only on 17/03).

2. Adoption of the agenda

The agenda was adopted without changes.

¹ Attended by web-meeting.

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 Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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. Agreement of the minutes of the 102nd Plenary meeting held on 20-21 January 2016, Parma (Italy)

The minutes of the Plenary meeting were agreed by written procedure on 01/03/2016 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 meetings took place on 9 February 2016 in Parma and on 2 and 10 of March by web conference [these two focusing on the extensive literature searches (ELS)]. The next WG meeting will be on 20 April by web conference. The WG Chair explained to the Panel the state of art of the extensive literature searches which are being finalised by the experts. Suggestions for improving the next ELS exercises are being collected. 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 9 February 2016 in Parma. The next WG meeting will be on 20 April by web conference. Seventy new microorganisms have been notified to the EFSA units, from which only two will be considered to be evaluated within the current Panel Statement for a possible QPS recommendation. Some new agreements have been made with the pesticides Unit concerning the timing and opportunity of the QPS assessment. The Panel statement is to be finalised by June 2016.

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 7 March 2016, 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 reviewed the answers to two questionnaires circulated to selected EU stakeholders 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. The WG Chair

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

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

reported that one WG member has recently resigned from the WG, for personal reasons. The BIOHAZ Panel provided some suggestions on the draft opinion for consideration of the WG, in particular in relation to shortening the introduction. The next WG meeting is scheduled for 28-29 April 2016, in Parma. 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 as a webconference on 4 March 2016. The WG Chair presented the complete draft opinion highlighting the most important statements for each section and discussed with the Panel a proposal to describe in the Opinion the approach taken by all WG members for their general literature reviews. Overall, this proposal was accepted and will be fine-tuned with the WG during the next meeting. The WG Chair also updated the Panel on the ongoing literature review, with support from AMU, 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 next WG will take place on 8 April 2016 in Parma 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 second WG meeting took place on 10 March 2016. The WG chair presented the approach to addressing the terms of reference and it was agreed with the Panel that all potential hazards, biological, chemical (contaminants, animal drug residues, pesticide residues, allergens, additives and food contact materials), physical and allergens, will be listed or described on a general level. Only relevant hazards will be described in more detail with a brief discussion on control options. In most cases such control will be outside the responsibility of the small retailer and limited to seeking certification/assurance from the suppliers that raw materials comply with current legislation and hence control will be provided through PRPs. It was further agreed that the general risk ranking approach will be based on processes/products, not on specific hazards with the aim of making the document more useful for small retailers on a practical level. 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 second WG meeting was held on 3 March 2016 by webmeeting. The WG Chair presented the revised Table of Contents and explained that the conceptual model for answering to ToR1 would consist of a *Listeria* food chain model including post and pre-processing. The hypotheses generated would be evaluated using a generic risk assessment model (to answer to the TOR 2). The next (third) meeting of the WG is scheduled for 28-29 April 2016 in Parma; the fourth one for 20-21 June 2016 in Athens. The deadline to deliver the Scientific Opinion is 31 July 2017.

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>

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

The last WG meeting was on 28th January 2016. The WG chair presented the modelling results addressing the additional clarifications requested from the EC. Most requests could be provided, however, it was not possible to get temperature profile on “warm transport”. In agreement with EC, this scenario was not modelled in the absence of data. Since the draft opinion is already advanced, it was suggested by the Panel Vicechair to present it for possible adoption at the Panel meeting on 27/28 April 2016. The next WG meeting is on 6 April 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 WG meeting took place on 22 February 2016 in Parma. The next WG meeting is planned for the 18 April 2016. The deadline for the delivery of the Scientific Opinion is December 2016. The WG chair presented the preliminary table of contents and the approach to answer the terms of reference. Information on the Questionnaire performed by EC to the MSs on rules/guidance and farming practices that could be relevant for the mandate was also presented. The opinion has been selected for the “uncertainty guidance” trial exercise in the BIOCONTAM unit.

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 second WG meeting took place on 15-16 February 2016 in Parma. An additional meeting was scheduled for 3 March 2016 by webmeeting to show the functionalities of the DistillerSR® software. The WG Chair presented the protocol which was fixed up to section 3.2.4. Records have been screened for eligibility and experiments have been defined. Data extraction and appraisal of included experiments took place. Discrepancies will be discussed at the next WG meeting taking place on 17-18 March 2016 in Parma. She informed that a proposal for uncertainty assessment will also be discussed at that meeting. The next WG meeting will take place on 4 May 2016 in Parma. The deadline to deliver the Scientific Opinion is 13 July 2016.

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

None

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

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>

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 Assessment¹⁵

The Panel was informed that the Opinion of the Scientific Committee is ready to be published on the EFSA web page.

7.1.3 Scientific Committee Standing Working Group on Biological Relevance¹⁶

G. Ru updated the Panel members on the status of progress of the WG activities.

7.1.4 Scientific Committee Working Group on Weight of Evidence¹⁷

The EFSA secretariat updated the Panel members on the status of progress of the WG activities.

7.1.5. Scientific Committee standing WG on Guidance review

None.

7.2 EFSA including its Working Groups / Task Forces

7.2.1. Scientific Network on BSE-TSE and MRA

The next meeting of the MRA Network will take place in Parma on 12-13 April 2016. The draft agenda was shared with the BIOHAZ Panel members for their information

The next meeting of the BSE-TSE Network will take place in Parma on 5-6 October 2016.

7.2.2 Joint interagency antimicrobial consumption and resistance analysis (JIACRA) report-follow up-request for data analysis from 2013 and 2014¹⁸

As a follow up of a previous mandate to EFSA, a second exercise aimed at analysing the relationships between antimicrobial use and resistance in humans, animal and food addressing available data on years 2013, 2014 and 2015 has been required by the EC. The deadline agreed for completion of this activity is end of June 2017. An interagency working group (EFSA, EMA, ECDC) is being established.

¹⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00738>

¹⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00748>

¹⁷<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00007>

¹⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00029>

7.3. European Commission

The official from DG SANTE informed the BIOHAZ Panel on recent changes in the organisation and management of this EC Directorate.

8. Other scientific topics for information and/or discussion

8.1 Self-task mandates of the BIOHAZ Panel

EFSA's secretariat informed the Panel on the comments received from DG SANTE on the proposal for a self-tasking mandate for a Scientific Opinion on the requirements for the development of Microbiological Criteria. The Panel Vice-Chair informed that EFSA's internal procedure for the approval of this self-task mandate is ongoing. The Panel agreed on the establishment of an ad hoc working group for helping with the preparation of this opinion. B. Nörrung was suggested as the Chair for this new WG. Panel members interested to be involved in this activity expressed their interest.

R. Girones presented the background and the Terms of Reference of the proposal for a self-tasking mandate for a Scientific Opinion on public health risks associated with Hepatitis E Virus (HEV) as a food-borne pathogen. The Panel members agreed with the final version of this proposal.

J. Threlfall presented the background and the Terms of Reference of the proposal for a self-tasking mandate for a Scientific Opinion on the application and use of whole genome sequencing for risk assessment. The Panel members were invited to submit further comments on the proposal to the EFSA secretariat.

B. Ter Kuile gave a presentation on two new proposals for possible self-task mandates on: (i) The distribution of zoonoses by routes other than food, and on (ii) The risk-assessment of complete food chains from farm to fork. Panel members participated in a round the table discussion on these proposals. Comments were noted, and the proposals will be added to the reserve list of self-tasks for 2017-2018.

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

The outcome of the results of the survey on the "methodological needs" for evidence use in scientific assessments was presented. The results of the survey were summarized and presented for plenary discussion to generate collective answers to some of the questions. The outcome of the survey results will be presented in the second deliverable of the EFSA PROMETHEUS project (Promoting methods for evidence use in scientific assessments), in the EFSA scientific report "Analysis of EFSA methodological needs for evidence use in scientific assessments".

8.3 EUSR (European Union Summary Report) on antimicrobial resistance 2014

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

8.4 European Medicines Agency advice on the impact on public health and animal health of the use of antibiotics in animals (Colistin)

The Panel was informed about a new mandate to EMA to update and revise the existing document entitled “*Use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health*” (EMA/755938/2012) in light of recent findings

EFSA will collaborate closely with this activity and will provide the group with data colistin phenotypic resistance data extracted from the recently published report “European Union summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2014”.

The first meeting of the EMA working group took place on the 26/02/2016, and the dates of the next two physical meetings are agreed for the 4 April and 6 June 2016. The deadline for completing this activity is 30/06/2016.

8.5 Joint session with AHAW Panel in 2016

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

9. Any other business

9.1 EFSA Journal changes

The Panel members were informed about the new provisions for professional editing services for the EFSA Journal.

9.2 Question from COST Action network Cystinet regarding EFSA report on bovine meat inspection

A query was received from Cystinet on methods for alternative procedures for detection of bovine cysticercosis during meat inspection if palpation and incision are removed from bovine meat inspection. This is related to the EFSA Panel on Biological Hazards Scientific Opinion on the public health hazards to be covered by inspection of meat (bovine animals). EFSA Journal 2013;11(6):3266, 261 pp. The BIOHAZ is liaising with the AHAW Panel to provide an answer to this question.

9.3 Probability of freedom classical scrapie document to EC (for information only)

The document describing the application of Bayesian statistics to the calculation of the probability of freedom of classical scrapie analysing historical surveillance data was submitted to the EC following agreement of the BIOHAZ Panel in the October 2015 plenary meeting. The document was previously circulated to the chair and to Helen Wahlström, and has been uploaded prior to this plenary for information.