

Scientific Panel on Biological Hazards

Minutes of the 115th Plenary meeting

Held on 13-14 September, 2017, Parma (Italy)

(Agreed on 28 September 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 (apologies for 13/09 afternoon), Lucy Robertson, Giuseppe Ru, Moez Sanaa (apologies for 14/09), Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck, Benno Ter Kuile, John Threlfall, and Helene Wahlström (apologies).

■ Hearing Experts:

NA

■ European Commission and/or Member States representatives:

Marina Marini, Pamina Suzuki (for item 6.7 and/or 9.1), Matjaz Klemencic (for item 6.5 and 7.1), Kris de Smet (for item 7.2), Anne Laure Gassin (for item 7.2).

■ EFSA:

BIOCONTAM Unit: Ernesto Liebana, Valentina Rizzi, Winy Messens, Sandra Correia, Maria Teresa da Silva Felício, Michaela Hempen, Angel Ortiz Pelaez, Pietro Stella, Beatriz Guerra, Yves Van Der Stede, Domenico Deserio, Pierre-Alexandre Beloeil (Scientific staff).

■ Observers: (In application of the guidelines for Observers¹)

Not applicable

■ Others:

Not Applicable

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

1. Welcome and apologies for absence

Apologies were received from Moez Sanaa (only for 14/09) and Helene Wahlström. Antonia Ricci did not participate in the afternoon of the 13/09 for which Konstantinos Koutsoumanis Chaired the Panel.

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 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.

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 114th Plenary meeting held on 5-6 July 2017, Parma (Italy)

The minutes of the 114th Plenary meeting were agreed by written procedure on 20 July 2017.⁴

5. Scientific outputs submitted for possible adoption

5.1. 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 animals⁵

This WG has worked in close collaboration with respective WGs of ECDC and EMA. The EFSA Secretariat updated the Panel on the progress made by the WG since the last Plenary meeting and feedback on questions raised by the Panel during the previous Plenary meeting, including discussions held during EFSA WG meetings (8 August and 1 September

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

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

⁴<http://www.efsa.europa.eu/en/events/event/170705>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

2017) and interagency Coordination WG meetings with ECDC and EMA (13 July and 30 August 2017). After thorough discussion of the draft opinion, the Panel adopted it with minor changes, subject to final agreement with ECDC and EMA.

6. Scientific outputs submitted for discussion

6.1. Self-task mandate on requirements for the development of microbiological criteria⁶

The WG Chair reported back to the Plenary on the progress made during the 8th WG meeting, which took place on 1 September 2017 via web-conference. Comments were provided by the Panel on the shared draft opinion. These comments will be discussed with the WG Chair on 29 September 2017 *via* web-conference. The deadline for adoption of the scientific opinion is 31 October 2017.

6.2. Request for a Scientific opinion on Chronic Wasting Disease (CWD) (ToRs 4 and 5)⁷

The WG Chair presented the draft Scientific opinion to the BIOHAZ Panel for first reading. The layout and sections of the assessment were described as well as the approaches to address the ToRs. The conclusions and recommendations of the 2004 and 2010 EFSA opinions, subject of the ToRs, have been left in the current draft in the form of bullet points. Individual comments to each of them have been inserted, when applicable. There are two sections titled 'Answers to the ToRs' and 'Recommendations', where the comments to previous opinions have been summarised, and additional/new recommendations have been added. The BIOHAZ Panel received well the explanations of the Chair and no major issues were raised by the members. The next WG meeting would be a web-conference on Thursday 14 September 2017. The final WG meeting is scheduled for Monday 30 October 2017. The deadline for adoption of this opinion is 31 December 2017.

6.3. 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 EFSA⁸

The second WG meeting was held on 23-24 May in Parma. The monitoring of possible safety concerns linked to the taxonomic units recommended for the QPS list is being done through an extensive literature search. The articles identified for the period between June of 2016 and June of 2017 are being checked by the experts. The next meetings will take place on 18

⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00227>

⁷<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00411>

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

September and 16-17 October 2017. The deadline proposed for this opinion is December 2019.

6.4. 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 2017⁹

The second WG meeting was held on 23-24 May in Parma. The monitoring of possible safety concerns linked to the taxonomic units recommended for the QPS list is being done through an extensive literature search. The articles identified for the period between June of 2016 and June of 2017 are being checked by the experts. The next meetings will take place on 18 September and 16-17 October 2017. The deadline proposed for this opinion is December 2019.

6.5. 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)"¹⁰

The 1st WG meeting was held by web conference on 31 May. The draft opinion was presented to the Panel for thorough reading. After the validation of the application the experts considered necessary to further request some clarifications to the applicant. Since some doubts persisted in relation to the specific purpose of the application, the Austrian Competent Authority was also contacted for clarification. It was confirmed that 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 next WG meetings would be held on 15 September, in Parma, and 3 October 2017, by web-conference. The deadline foreseen for the adoption of the Scientific opinion will fall in December 2017.

6.6. Self-tasking mandate for scientific opinion on public health risks associated with foodborne parasites¹¹

The WG chair informed the Panel that the setting up of the WG is almost complete and that the first WG meeting will be held on 19/20 October 2017 in Parma. The deadline for this mandate is October 2018.

6.7. Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU¹²

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

¹⁰<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00136>

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

¹²<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00597>

The Panel was informed that the endorsed draft opinion has been revised as an error was spotted in the code of the Time Series Analysis (TSA). The incidence rate of confirmed human listeriosis in the European Union and European Economic Area (EU/EEA) now only significantly increases for three age-gender groups, namely for the female 25-44 years of age group and the female and male age groups of ≥ 75 years. In consultation with the WG Chair and Panel Chair it was decided to proceed with publishing the revised version. EFSA has launched the draft scientific opinion for public consultation on 24 July with a deadline for commenting of 29 September 2017¹³. In total 37 participants have registered for the stakeholder event that will be held on 19-20 September 2017¹⁴. The deadline for adoption of the Scientific opinion is end of December 2017.

7. New Mandates

7.1. 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).¹⁵

A new application was received from the Dutch Competent Authority (Netherlands Food and Consumer Product Safety Authority) on the behalf of the company ChainCraft B.V.. It is covered by Art. 20 of Commission Regulation (EC) No 1069/2009. It is requested to assess the safety of the processing process according to Annex VII of Commission Regulation (EU) No 142/2011 and its amendment by Commission Regulation (EU) No 749/2011. 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 completeness check is due on 21 September 2017. Pablo S. Fernández-Escámez was nominated as WG Chair (conditional to screening and approval of his declaration of interests).

7.2. Second scientific opinion on hazard analysis approaches for certain small retail establishments and food donations¹⁶

The Panel Chair informed the Panel that Declan Bolton was nominated WG Chair by written procedure after the previous Plenary. The WG Chair gave a short presentation on the background and terms of reference of the mandate. The setting up of the WG is almost complete and the first meeting is planned for 17 October 2017 in Parma. Safety of food donations was considered an important first step for the Panel to address

¹³ <https://www.efsa.europa.eu/en/consultations/call/170724-0>

¹⁴ <https://www.efsa.europa.eu/en/events/event/170919-2>

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

¹⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00565>

in respect of food waste in Europe in the context of food safety. The deadline for this mandate is September 2018.

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 85th Plenary meeting of the Scientific Committee took place in Parma on the 13-14 September 2017.¹⁷ The BIOHAZ Panel Chair sent apologies, and will request feedback from the secretariat, and inform the Panel on relevant issues at the next Plenary meeting.

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.

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 12th meeting on 16-17 October 2017, in Parma. The next meeting of the MRA network is planned for 10-11 October 2017, in Parma. The preliminary agendas for the two meetings were presented to the Panel.

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

The scientific report has been published on EFSA's website, and a presentation was given to the Panel by the EFSA Secretariat on the main findings.

8.2.4 Emerging Risks

None

¹⁷<http://www.efsa.europa.eu/en/events/event/170913-1>

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

8.3. European Commission

None

9. Other scientific topics for information and/or discussion

9.1. 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 the draft background and terms of reference for this mandate. It was agreed that this mandate will cover both WGS and metagenomics of foodborne microorganisms. Case studies on foodborne outbreaks will be considered in the scope of this mandate, but the QPS example won't be considered, as there is no legal link between QPS and any analytical methodology. The EFSA secretariat will check for possible overlaps with the TORs of the 2013/2014 mandate on the evaluation of molecular typing methods and amend the TORs of this new self-task mandate to avoid this, if needed. The Panel members were invited to submit further comments and the draft will be tabled again in the following plenary meeting. It is envisaged that the BIOHAZ Panel finalises the draft for this mandate in 2017 so that this activity can be initiated in 2018.

9.2. Reply to the article *'In defense of Bacillus thuringiensis, the safest and most successful microbial insecticide available to humanity – a response to EFSA'* published in FEMS Microbiology Ecology regarding the Scientific Opinion from the BIOHAZ Panel on *'Risks for public health related to the presence of Bacillus cereus and other Bacillus spp. including Bacillus thuringiensis in foodstuffs'*

A draft Letter to the Editor of FEMS Microbiology Ecology has been prepared, in collaboration with the *Bacillus* WG members, in reply to the article *'In defence of Bacillus thuringiensis, the safest and most successful microbial insecticide available to humanity – a response to EFSA'* by Raymond and Federici published in FEMS Microbiology Ecology (volume 93, issue 7 on 1 July 2017, Pages 1-7). This letter provides clarifications which appeared necessary in relation to the published paper. The BIOHAZ Panel agreed with this approach: the draft letter will be revised by EFSA Secretariat responsible for the EFSA Journal and submitted thereafter on behalf of the BIOHAZ Panel.

9.3. New EFSA project on potential impacts of climate change for food and feed safety in the EU

The EFSA secretariat (SCER unit) gave a presentation on the topic and asked for feedback from the BIOHAZ Panel on the work plan and future collaboration in this activity. The BIOHAZ Panel will discuss the potential for future collaboration.

10. Any other business

The EFSA secretariat informed the Panel on the dates selected for Plenary meetings in 2018 (17-18 January, 14-15 March, 18-19 April, 6-7 June, 11-12 July, 26-27 September, 24-25 October, 5-6 December). The dates of the 2018 July Plenary may need to be adapted depending on the agreed date for the 2018 inaugural plenary meetings.