

Scientific Panel on Biological Hazards

Minutes of the 106th Plenary meeting

Held on 7-8 July, 2016, Parma (Italy)

(Agreed on 19 July 2016)

Participants

■ Panel Members:

Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo S. Fernandez-Escamez (apologies), 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 (apologies), Benno Ter Kuile, John Threlfall, and Helene Wahlström.

■ Hearing Experts:

None

■ European Commission and/or Member States representatives:

Marina Marini (DG SANTE), Pamina Suzuki (DG SANTE, for items 5.2. and 6.4), Sylvie Coulon (DG SANTE, for item 5.1).

■ 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 (Scientific staff), Mirena Ivanova.

AHAW Unit: Andrea Gelpermeyer (for item 6.3)

AMU Unit: Elisa Aiassa, Gilles Guillot (for item 5.1)

FEED Unit: Rosella Brozzi (for item 6.3)

SCER Unit: Andrea Germini (for item 8.2.3)

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

Not Applicable

- Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Pablo Fernandez-Escamez, and Niko Speybroek.

Marion Simmons and Giuseppe Ru did not participate in discussions on selected items under agenda point 6.7 due to a Conflict of Interest being identified for the agenda item.

2. Adoption of agenda

The agenda was adopted without 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.

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.

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

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

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

4. Agreement of the minutes of the 105th Plenary meeting held on 27-28th April 2016, Parma (Italy)

The minutes of the 105th Plenary were agreed by written procedure on 21st June 2016.⁴

5. Scientific outputs submitted for possible adoption

5.1. Scientific Opinion on the evaluation of the safety and efficacy of Listex P 100 for reduction of pathogens on different ready to eat (RTE) food⁵

The 9th and 10th WG meetings took place on 10 and 27 June 2016 respectively by web-meeting to discuss the draft scientific opinion. The applicant replied to EFSA's request for clarification on 23 June 2016. EFSA has concluded on the confidentiality decision of the production process of ListexTM P100. The WG Chair presented the changes since the last plenary meeting. Conclusions and recommendations were discussed in detail. The Panel suggested few editorial changes and adopted the scientific opinion on 7 July 2016.

The Panel suggested revising the guidance document on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption. This will be further discussed at the next plenary meeting.

6. Scientific outputs submitted for discussion

6.1 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 20 June by web conference. The next WG meeting will be on 6 and 7 October in Madrid. In the absence of the WG Chair, Lieve Herman explained to the Panel the state of the art of the overall extensive literature search (ELS). The initial 3 years interval (2013 to November of 2015) ELS is finalised and the follow-up ELS (between November 2015 and May 2016) was launched with support from AMU. Experts started the screening of the new references. Evaluation of the microorganisms in the QPS list was initiated by the WG based on the ELS results (potential safety concerns) and experts' knowledge. A few issues

⁴<http://www.efsa.europa.eu/en/events/event/160427>

⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00428>

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

related to the approach to be taken for the QPS mandate after 2017 were presented to the Panel. The EFSA Units (Feed, Pesticides, FIP and Nutrition) are participating in the drafting of the introduction and data/methodology chapters. The Scientific Opinion is to be finalised by December 2016.

6.2 Panel Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 5: Suitability of taxonomic units notified to EFSA until September 2016⁷

The last WG meeting took place on 20 June by web conference. The next and last WG meeting will be on 6 and 7 October in Madrid. In the absence of the WG Chair, Lieve Herman explained to the Panel the state of the art of the current Statement. From a total of 33 new notifications received until beginning of June, 3 were considered for the QPS evaluation, corresponding to two taxonomic units (TU). EFSA Units will be asked to update the list of notifications until September 2016. These two TU were initially screened for a possible QPS recommendation. The Panel Statement is to be adopted on December 2016.

6.3 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 safety⁸

The last WG meeting was held on 22 June 2016, jointly with the corresponding EMA WG. The WG Chair updated the Panel on the status of progress of WG activities, and on the feedback received from the European Commission. The WG Chair presented in detail to the BIOHAZ Panel the sections of the draft opinion dealing with '*alternative measures to antimicrobials*', '*animal management and husbandry procedures reducing the need for antimicrobials in livestock production systems*', and '*circumstances and diseases of food animal production where antimicrobials are most intensively used*'. The BIOHAZ Panel provided feedback to the WG Chair, suggesting some adaptations of the text. The WG Chair invited the BIOHAZ Panel to provide further comments on the draft opinion as soon as possible. The next WG meeting is scheduled for 20 September 2016, in London. The deadline to deliver the EFSA-EMA Joint Scientific Opinion is 20 December 2016.

⁷<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00018>

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216>

6.4 Request for a Scientific Opinion on hazard analysis approaches for certain small retail establishments in view of the application of their food safety management system (HACCP)⁹

The last WG meeting took place on 29th June 2016. The WG chair presented the progress of this mandate. The approach of the WG is to draft a document that provides practical guidance to small retailers and hence the hazard ranking will be approached as a product ranking that focusses on the control options using PRPs or HACCP. The next WG meeting is on 6th September 2016. The deadline to deliver the Scientific Opinion has been extended to 31 January 2017.

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

The 4th WG meeting took place on 20-22 June 2016 in Athens. The WG Chair provided an update of the approach that would be used for answering ToR1 and ToR2 using a flowchart. The proposed two activities for the listeriosis cases Time Series Analysis was agreed by the Panel. The preliminary approach to generate hypotheses and assessment questions and their evaluation was presented. The WG Chair informed the panel that presentations and discussions were held on the *Listeria* outsourcing activity 2 (quantitative risk characterization). The generic *Listeria* risk assessment model combined with a multi-population dose response model was presented by a WG member. The next WG meeting is scheduled for 21 September 2016 by web meeting. The deadline to deliver the scientific opinion is 31 July 2017.

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

The fourth WG meeting took place on 27 June 2016 in Parma. The WG chair presented a short update on progress since the last meeting. The next WG meeting is planned for 23 August as a web-meeting. The deadline for the delivery of the Scientific Opinion is December 2016.

6.7 Request for a scientific opinion on genetic resistance to TSEs in goats¹²

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-2015-00611>

An update of the work done so far was presented to the Panel. The first working group meeting took place on 28-29 June 2016. The objectives of the meeting were: to present/clarify mandate and ToRs, to discuss/agree the scope and approaches to answer the ToRs, to discuss/agree structure of the draft opinion (the EFSA template for scientific opinions was presented) and to assign tasks to WG members. The EC participated via teleconference during both sessions. An intense discussion in the WG resulted in a proposal for a modification of ToRs that were submitted to the EC. The EC proposed a list of three points to be addressed in the interpretation of the ToRs. The WG in discussion produced a list of 9 points that summarises the interpretation of the ToRs by the WG. This list was sent to the EC for information after the meeting, and the points were agreed with the Panel during the plenary meeting. The WG following the advice from the Panel will continue the production of the scientific opinion using their interpretation of the ToRs. A literature search will be conducted to address ToR1-3 and a list of key words and potential data sources was brainstormed from which to draw important data. Equally the table of contents of the EFSA template for scientific opinions was revised and some main points to consider in the assessment were agreed as sub-sections of section 3 Assessment. The next meeting will be a web-conference on Monday 5 September 2016.

6.8 Self-task mandate on requirements for the development of microbiological criteria¹³

The first WG meeting will take place on 2 September in Copenhagen. As the ToRs of this mandate ask for guidance and recommendations, the WG Chair suggested exploring internally the possibility to draft this scientific output as (i) a guidance or (ii) an opinion combined with a guidance. The deadline for adoption of the Scientific Opinion is 31 October 2017.

6.9 Self-task mandate on public health risks associated with hepatitis E virus as a food-borne pathogen¹⁴

The WG chair presented the WG composition. The first physical meeting of the WG is planned on 30/31 August 2016. The deadline for adoption of this opinion is June 2017.

6.10 Request for a scientific opinion on BSE cases born after the total feed ban¹⁵

¹²<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00268>

¹³<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00227>

¹⁴<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00315>

¹⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00350>

An update of the work done so far was presented to the Panel. Giuseppe Ru was appointed by the BIOHAZ Panel Chair to take the role of Chair of the WG. The WG composition has been agreed by BIOCONTAM Head of Unit and by the WG chair. The first WG meeting will take place in Brussels on 6 September 2016.

7. New Mandates

7.1. Request for a scientific opinion on Chronic Wasting Disease (CWD) in cervids¹⁶

A new mandate was received on 8 June 2016 for a scientific opinion Chronic Wasting Disease (CWD) in cervids. As a result of the confirmation of two cases of CWD in Norway in May and June 2016, EFSA has received a mandate to deliver a scientific opinion by 31 December 2016 (a third case was confirmed in the meantime). The tight schedule, and the number and content of the ToRs, together with the implementation of other TSE mandates in the Unit at the same time, made EFSA to propose a stepwise implementation of this mandate. After negotiation with the EC, it was agreed to deliver ToR 1,2,3 on 31 December 2016 and ToR 4 and 5 on 31 December 2017. The Panel decided to establish an *ad hoc* WG to help with the preparation of the draft Opinions. Marion Simmons was proposed by the Panel Chair to take the role of Chair of the WG, and she accepted. The first meeting has been initially scheduled for 1 September 2016 in Parma.

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 79th Plenary meeting of the Scientific Committee took place in Parma on the 6 July 2016.¹⁷

8.1.2 Scientific Committee Working Group on Uncertainty in risk assessment

None

¹⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00387>

¹⁷ <http://www.efsa.europa.eu/en/events/event/160706>

8.1.3 Scientific Committee Working Group on Biological Relevance

None

8.1.4 Scientific Committee Working Group on Weight of Evidence

H. Wahlström updated the Panel members on the status of progress of the WG activities. The document has been developed further since the last meeting. Until the next meeting an example for a weight of evidence approach from a chemical risk assessment will be developed. The next WG meeting is planned for 12-14 September 2016.

8.1.5 Scientific Committee standing WG on Guidance review

None

8.2. EFSA including its Working Groups /Task Forces

8.2.1 Scientific Network on BSE-TSE and MRA

The next BSE-TSE Network meeting will take place on 5/6 October 2016 in Parma. A draft agenda for the meeting is under development.

The next MRA Network meeting will take place on 11/12 October 2016 in Parma.

8.2.2 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 for years 2013, 2014 and 2015 is required by the EC. The deadline agreed for completion of this activity is end of June 2017. An interagency working group (EFSA, EMA, ECDC) has been established. The first meeting of the Working group is scheduled for 11th July 2016 by teleconference.

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

8.2.3 Emerging Risks

The SCER unit gave a presentation to the Panel with an update on the EMRISK team activities in the area of identification and prioritization of emerging risks. Discussion on proposals to further structure the collaboration with Panel and Unit followed.

8.3. European Commission

None

9. Other scientific topics for information and/or discussion

9.1. Presentation from Dr. T. Hald "The global burden of foodborne disease – a WHO endeavour"

Dr. Hald delivered her presentation, and a question and answer session took place with the Panel members.

9.2. EMA mandate: Updated opinion on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health

J. Threlfall gave an update on the result of the EMA public consultation.

10. Any other business

The Panel confirmed the preliminary dates selected for the Panel meetings in 2017.

EFSA has had the task over the past years to identify together with its scientific panels and the Advisory Forum priority thematic research projects for the Horizon 2020 Framework Programme and to provide input to EC in the form of a technical report. The development of the next Work Programme 2018-2020 will be initiated over the coming months, and this will provide us with a timely opportunity for EFSA's input for the last Work Programme under Horizon 2020. The BIOHAZ Panel members were asked to identify potential thematic research projects that address issues relevant to EFSA and that can be anchored to EFSA's own priorities under the EFSA Strategy 2020 (https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/strategy2020.pdf), also taking into consideration the criteria for the

2018-2020 Work programme. Feedback is expected before the next Plenary meeting on 7-8 September 2016.

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 Processes¹⁹ and the Decision of the Executive Director on Declarations of Interest²⁰, 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 7.1 by the concerned scientific group.

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

²⁰ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>