

Scientific Panel on Biological Hazards

Minutes of the 110th Plenary meeting

Held on 18-19 January, 2017, Parma (Italy)

(Agreed on 1 February 2017)

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 (only 19/01/17), Moez Sanaa, Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck, Benno Ter Kuile, John Threlfall, and Helene Wahlström.

■ Hearing Experts:

Joke van der Giessen and Marieke Opsteegh (for agenda item 9.1)

■ European Commission and/or Member States representatives:

Marina Marini, Kris de Smet (for item 5.1), Lucie Carrouee (for items 6.2, 6.5 and 6.7), Angela Bolufer de Gea (for item 6.6), and Pamina Suzuki (for items 6.1, 6.3, 6.4) 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, Frank Boelaert, Francesca Latronico, Domenico Deserio, Marta Hugas (Scientific staff).

COMMUNICATIONS Unit: Francesca Matteucci.

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

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

Not Applicable

■ Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Giuseppe Ru for 18/01/17.

Marion Simmons and Giuseppe Ru did not participate in discussions on selected items under agenda point 6.2 due to a Conflict of Interest being identified for the agenda item.

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.

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.

4. Agreement of the minutes of the 109th Plenary meeting held on 30 November-1 December 2016, Parma (Italy)

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

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

The minutes of the 109th Plenary were agreed by written procedure on 16 December 2016.⁴

5. Scientific outputs submitted for possible adoption

5.1. 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)⁵

The last WG meeting took place on 14 December 2016. The WG Chair presented the changes made since the last panel meeting, in particular the addition of a table on monitoring and record keeping for the prerequisite programmes. The BIOHAZ Panel adopted the opinion. The European Commission provided positive feedback on the opinion and communicated the possibility for further mandates related to HACCP.

6. Scientific outputs submitted for discussion

6.1. Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU⁶

Two WG meetings were held by web meeting on 19 December 2016: one was a sub-WG meeting to discuss the *Listeria* outsourcing activity 2, while the other was a full WG meeting. The last WG meeting was held on 16-17 January 2017 in Parma. The Chair of the WG provided a short update on the three outsourcing activities under “Closing gaps for performing a Risk Assessment on *Listeria monocytogenes* in RTE foods” and informed that the report of activity 1, an extensive literature search and study selection with data extraction on *L. monocytogenes* in a wide range of RTE food has been published⁷. The outcome of the 2008-2015 global aggregated and disaggregated age-sex group Time Series Analysis (TSA) was presented and the groups that would be selected for further analysis agreed. The reworded assessment questions were presented. The WG Chair informed that the stakeholder event would be combined with a public consultation of the endorsed scientific opinion in line with EFSA’s policy on openness and transparency. It has therefore been proposed to extend the deadline for adoption of the scientific opinion to end of December 2017, while the deadline for endorsement would be end of July 2017 (i.e. the current adoption deadline). It was decided to perform a reduced uncertainty

⁴<http://www.efsa.europa.eu/en/events/event/161130>

⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00593>

⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00597>

⁷<https://www.efsa.europa.eu/en/supporting/pub/1141e>

analysis and it was proposed not to proceed with the full case study of uncertainty. The next WG meeting will be held on 7-8 March 2017 in Vienna.

6.2. Request for a scientific opinion on genetic resistance to TSEs in goats⁸

The progress of the WG was presented by the Chair including the list of potential alleles conferring genetic resistance to TSEs in goats, following the main output of the first literature review. The main approach of how to assess the genetic resistance of the candidate alleles was explained for the first time. A two-tier qualitative approach will be applied: the number, size and types of studies available will be considered on one side, and the strength of the resistance assessed in the outputs of the studies, using the known level of resistance of the ARR allele in sheep in 2001 as the benchmark, on the other. The Panel agreed with the approach but required the WG to explain clearly the approach and how this will be translated into a ranking of alleles. Plans to address ToR4 and 5 were also presented together with the background sections of the draft opinion. The next WG meeting will take place in Parma on 14 February 2017.

6.3. Self-task mandate on requirements for the development of microbiological criteria⁹

The WG Chair reported back to the plenary on the agreements made during the 3rd WG meeting which took place as a web conference on 16 December 2016. All BIOHAZ opinions where microbiological criteria are considered in relation to specific food/pathogen combinations will be reviewed and explanations will be provided to the question of “clear separation between risk assessment and risk management”. If needed, a future closed technical consultation with relevant stakeholders may be organised to collect information in order to support the answer to ToR4.

The next WG meeting will take place on 20 February 2017 and the deadline for adoption of the Scientific Opinion is 31 October 2017.

6.4. Self-task mandate on public health risks associated with hepatitis E virus as a food-borne pathogen¹⁰

The last WG meeting was held on 12th January 2017. The draft opinion has been restructured describing HEV in the order of animal, food and environment. The Panel agreed to describe HEV occurrence at the slaughterhouse level (meat, liver) in the food section instead of animal prevalence. The section on control measures along the food chain has

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00268>

⁹<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00227>

¹⁰<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00315>

been elaborated further since the last meeting. The next WG meeting is on 14th March 2017. The deadline for adoption of this opinion is June 2017.

6.5. Request for a scientific opinion on BSE cases born after the total feed ban¹¹

The progress of the WG was presented by the Chair including both descriptive and analytical approaches. Amongst the former, the results of the questionnaire survey conducted under the auspices of the BSE/TSE Network, to be extracted in an *ad hoc* template developed for this purpose in order to describe the 60 cases included in the mandate, and the review of the FVO reports. Amongst the latter, the modelling of the decline of BSE cases in the EU, the test of the exponential decline to zero vs. exponential decline to a constant, and the comparison of the power of surveillance between MS with/without BARB cases. This was the first time the methodology was presented to the Panel. The overall approach was agreed by the Panel and some suggestions were provided by Panel members. The next WG meeting will take place on 7 March 2017, in London.

6.6. 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 animals¹²

An *ad hoc* WG to help with the preparation of the draft Opinion was established, and the first WG meeting was held on 19 December 2016. This WG will work in close collaboration with respective WGs of ECDC and EMA, which are being established. The WG Chair reported back to the plenary the discussions held during the first meeting, especially on the terms of reference of the mandate and approach to be followed for designing the indicators for AMR in food-producing animals and food thereof. A note requesting some clarifications on the terms of reference was sent to the European Commission. The European Commission during the plenary indicated that indicators should be limited in number as requested by the mandate and should be applicable to all Member States, with the purpose being to allow assessing the effectiveness of the management measures taken at national level to contrast AMR and not to compare the AMR situation between Member States. The next meeting of the EFSA WG will take place on 7 February 2017.

¹¹<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00350>

¹²<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

6.7. Request for a scientific opinion on Chronic Wasting Disease (CWD) (ToRs 4 and 5) 13

The Chair of the WG informed the Panel that the Opinion for ToRs 1-2-3 (Phase I), adopted in December 2016, was published on Wednesday 18 January 2017. The outputs will be presented to member states in Brussels to the TSE Working Group on 26 January 2016. With regards to Phase II, the Chair informed that the work has not started yet. Due to conflicting commitments with other TSE mandates, the first WG meeting is provisionally scheduled for June. It is expected that there will be some preliminary work to be agreed and implemented before the first WG meeting.

6.8. Self-task mandate for Scientific opinion/statements on the update of the list of QPS-recommended biological agents intentionally added to the food or feed as notified to EFSA¹⁴

An *ad hoc* WG to help with the preparation of the draft Opinion is being established. It is planned to publish a Panel statement every six months with the assessment of new taxonomic units notified to EFSA and not present in the QPS list. After a 3 years period, a scientific Opinion with the evaluation of all QPS list members for possible new safety concerns that could result in excluding them from the list or changing or including a possible qualification, will be published. The deadline proposed is December of 2019.

7. New Mandates

None

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 81st Plenary meeting of the Scientific Committee took place in Brussels on the 16 November 2016.¹⁵

¹³<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00411>

¹⁴<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

¹⁵<http://www.efsa.europa.eu/en/events/event/161116>

8.1.2 Scientific Committee Working Group on Uncertainty in risk assessment

EFSA's secretariat informed the Panel on the activities underway for evaluating the pilot phase of this activity.

8.1.3 Scientific Committee Working Group on Biological Relevance

G. Ru updated the Panel about the latest stages of finalisation of this Scientific Committee Opinion, and the BIOHAZ example that was chosen for this activity (zoonotic potential of scrapie).

8.1.4 Scientific Committee Working Group on Weight of Evidence

The Scientific Committee secretariat presented their request for a BIOHAZ example for the weight of evidence approach in a table format with the intention to add these examples to an annex of the guidance document. H. Wahlström presented an example of such a table using the decision tree for hazard ranking from the meat inspection opinion (poultry). The draft guidance will be presented to the Scientific Committee in February 2017 for endorsement, which is then followed by public consultation.

The BIOHAZ Panel Chair in consultation with the Panel Members agreed not to choose at this stage any examples from past BIOHAZ Opinions for this activity. There was a consensus request from the BIOHAZ Panel to the Scientific Committee secretariat to get a document/presentation with clarifications in scope/application between (i) uncertainty, (ii) weight of evidence, (iii) biological relevance and (iv) PROMETHEUS Opinions/Guidance. The BIOHAZ Panel Chair will also raise these concerns in the next upcoming Scientific Committee Plenary meeting.

8.1.5 Scientific Committee standing WG on Guidance review

None

8.2. EFSA including its Working Groups /Task Forces

8.2.1 Scientific Networks on BSE-TSE and MRA

The terms of reference of the two BIOHAZ Networks were endorsed by EFSA's advisory Forum on 8 December 2016 for the next three years.

8.2.2 Joint interagency antimicrobial consumption and resistance analysis (JIACRA) report-follow up-request for data analysis from 2013 and 2014¹⁶

As a follow up to a previous mandate to EFSA, a second report 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 next meeting of the Working group is scheduled for 20 January 2017. Analyses of the relationships between AMR and AMC at the animal species level are to be performed for the next physical meeting on 27 January 2017. Multivariate analyses will be started soon and the approach presented at the same physical meeting.

8.2.3 Emerging Risks

SCER secretariat gave 2 presentations on (i) *Echinococcus multilocularis* and (ii) Antimicrobials in honey bees. These topics had previously been discussed at the 16th EREN meeting (14-15 November 2016)¹⁷. The Panel informed that there are discussions ongoing on a future BIOHAZ Panel self-task on foodborne parasites and that issue of *Echinococcus* could be reviewed there.

8.3. European Commission

The representative from DG SANTE informed the Panel about progress in the Official Controls legislation. A presentation will be provided to the Panel at a future date.

9. Other scientific topics for information and/or discussion

9.1. Request for a scientific and technical assistance on proposed of EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge

This is a mandate for technical assistance (In accordance with Article 31 of Regulation (EC) No 178/2002). The BIOCONTAM unit in collaboration with the ALPHA Unit will be addressing this request. An EFSA *ad hoc* WG

¹⁶<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00029>

¹⁷<http://www.efsa.europa.eu/en/events/event/161114>

is being established to help with the preparation of the report and the deadline for this request is under negotiation. EC has also requested the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) for scientific advice on this issue. The Panel will be informed at regular intervals on the progress made for this mandate.

9.2. Presentation on Weight of Evidence, the French (ANSES) experience

M. Sanaa gave a presentation to the Panel. This was followed by a discussion, also in the context of the developing guidance by the EFSA Scientific Committee (see agenda point 8.1.4)

9.3. Presentation on PROMETHEUS project and case study on "Safety and efficacy of Listex™ P100 for reduction of pathogens on ready-to-eat food products"

This point was postponed for the next Plenary meeting.

9.4. Presentation of the European Union Summary Report on Zoonoses (EUSR) 2015

EFSA's secretariat gave a presentation to the Panel, which was followed by a discussion on the finding as and possible improvements for future reports.

9.5. Presentation of the European Union Summary Report on TSEs 2015

This point was postponed for the next Plenary meeting.

10. Any other business

The BIOHAZ Panel was informed by the secretariat about the preparation of an abstract ("Evaluation of heat treatments of live bivalve molluscs") for the upcoming 11th International Conference on Molluscan Shellfish Safety¹⁸ with authorship including WG Members and EFSA secretariat.

The BIOHAZ Panel was also informed about the future date for an open plenary meeting that will be held in Parma on 6-7 December 2017.

¹⁸ www.icmss2017.com

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 6.2 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>