Scientific Panel on Biological Hazards

Minutes of the 109th Plenary meeting

Held on 30 November-1 December, 2016, Parma (Italy)

(Agreed on 16 December 2016)

Participants

- Panel Members:

  Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo S. Fernandez-Escamez, Rosina Girones (only 30/11/16), 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.

- Hearing Experts:

  None

- European Commission and/or Member States representatives:

  Kris de Smet (for item 6.1) 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, Katleen Baert, Marta Hugas (Scientific staff).

  ALPHA Unit: Denise Candiani (for item 5.3)

  COMMUNICATIONS Unit: Francesca Matteucci (for item 5.3).

- Observers: (In application of the guidelines for Observers[1])

  Not Applicable

[1] http://www.efsa.europa.eu/en/stakeholders/observers.html

- Others:

  Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from R. Girones for 1/12/16.

Marion Simmons and Giuseppe Ru did not participate in discussions on selected items under agenda point 6.3 due to a Conflict of Interest being identified for the agenda item.

2. Adoption of agenda

New items were added under sections 6 and 9. Then 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 Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], 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 108th Plenary meeting held on 19-20 October 2016, Parma (Italy)

The minutes of the 108th Plenary were agreed by written procedure on 31 October 2016.[4]

[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/161019

5. Scientific outputs submitted for possible adoption

5.1. Scientific Opinion on the update of the list of QPS recommended biological agents intentionally added to food or feed as notified to EFSA[5]

The last WG meeting took place on 6 and 7 October in Madrid. The WG Chair presented the draft opinion. The comments made by the Panel during the last plenary in October were taken into consideration by the WG and changes were made accordingly. The improvements made in the two first chapters, "Introduction" and "Data and methodology" were described. The changes made in the third chapter "Assessment" were presented and minor amendments made after discussion. The draft conclusions and recommendations as well the abstract and summary, were thoroughly discussed and amendments made. The annexes of this opinion were shortly described. The Chair thanked the support provided by the EFSA Units (Feed, Pesticides, FIP and Nutrition, AMU) throughout the process. After thorough discussion, the BIOHAZ Panel adopted the draft opinion.

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. 5: Suitability of taxonomic units notified to EFSA until September 2016[6]

The last WG meeting took place on 6 and 7 October in Madrid. The WG Chair presented the current draft statement. From a total of 59 new notifications received from April until the beginning of September 2016, four notifications were considered for QPS evaluation. Three TUs were evaluated for a possible QPS recommendation. Only one of those received a recommendation for a QSP status. After thorough discussion, the BIOHAZ Panel adopted the draft opinion.

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 safety[7]

The last WG meeting was held on 25 October 2016, jointly with the corresponding EMA WG. The WG Chair updated the Panel on the status of progress of WG activities, on the development of the draft opinion since the previous BIOHAZ Plenary meeting, and on how the comments and advice of the BIOHAZ Panel raised were addressed. The WG Chair

[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189
[6] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00018
[7] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216

indicated that a section of the document previously endorsed by the AHAW Panel had been further revised in order to take into account additional comments by the WG and the AHAW Panel. This section was re-discussed and re-endorsed by the AHAW Panel on 29 November 2016. The WG Chair presented in detail to the BIOHAZ Panel the draft conclusions and recommendations of the draft opinion, including the draft answers to the terms of reference of the mandate, and the draft abstract and summary. After thorough discussion, the BIOHAZ Panel adopted the draft opinion, and highlighted a few suggestions for possible consideration by the EMA Committee for Medicinal Products for Veterinary Use (CVMP), who will discuss the same document on 6-8 December 2016 and consider it for adoption.

5.4. Request for an EFSA Scientific Opinion on the risk for the development of Antimicrobial Resistance (AMR) due to feeding calves with milk[8]

The 8th WG meeting took place on 7 November by Web conference. The WG chair updated the BIOHAZ Panel on the progress of the draft Opinion and the activities of the WG since the last Panel Plenary meeting. All comments received from expert members, together with comments received from the last BIOHAZ Panel Plenary, were addressed. The WG Chair presented in detail the draft conclusions and recommendations, including the answers to the terms of reference of the mandate, as well as the summary and abstract. After thorough discussion, the BIOHAZ Panel adopted the draft opinion. The scientific opinion is one of the selected opinions for an EFSA pilot study to evaluate and give feedback on the Draft for Internal Testing of the "Guidance on Uncertainty in EFSA Scientific Assessment".

5.5. Request for a scientific opinion on Chronic Wasting Disease (CWD) in cervids (ToRs 1, 2 and 3)

The last WG meeting of Phase I took place in Oslo on 15-16 November. As advised by the chair in the last BIOHAZ plenary meeting, the draft opinion was submitted to the Panel on 23 November 2016, one week before the plenary meeting, to allow panel members to review it and send comments. The chair presented the background information included in the opinion, and there after the sections specifically answering the ToRs and the further recommendations. The Opinion was well received by the Panel. Comments sent by panel members prior to the plenary, and those sent by the EC were addressed during the discussions at the plenary meeting. Three members of the Panel expressed reservations on the surveillance programme initially proposed in answer to ToR1. On day two, a revised version of the opinion was submitted addressing the issues

[8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00611

raised in day 1 on the surveillance recommendations. After thorough discussion, consensus was achieved on ToR1. The sections covering the other two ToRs and the further recommendations were also discussed and agreed with minor changes. Finally the scientific opinion was adopted as presented with minor changes.

6. Scientific outputs submitted for discussion

6.1. 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)[9]

The last WG meeting took place on 10 November 2016. The WG chair presented the progress of this mandate. The sections on chemical hazards were endorsed by the CONTAM Panel on 23 November 2016. Following a recommendation from the BIOHAZ Panel, a new table has been included suggesting limits, record keeping and corrective actions for pre-requisite programmes, also food waste disposal has been added where appropriate. The European Commission has provided positive feedback on the draft opinion. The next WG meeting is on 14 December 2016. The deadline to deliver the Scientific Opinion is 31 January 2017.

6.2. Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU[10]

A sub-WG meeting was held by web conference on 27 October 2016 in order to discuss the final deliverable of the *Listeria* outsourcing activity 2. The last WG meeting was held on 28-29 November 2016 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 the 2008-2014 disaggregated age-sex group Time Series Analysis (TSA). This analysis will be repeated with global aggregated data and disaggregated age-sex groups (2008-2015 period). The plans for addressing the uncertainty analysis and an example of the reformulated assessment questions were presented. Although the timelines of the uncertainty guidance and adoption of this Scientific Opinion are not well aligned, the WG and Panel decided to proceed with the case study. The next two WG meetings will be held by web meeting on 19 December 2016: one will be a sub-WG meeting to discuss the *Listeria* outsourcing activity 2, while the other will be a full WG meeting. On 26 January 2017, a training session has been scheduled in

[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

Parma on the model used in the *Listeria* outsourcing activity 2. Interested panel members are to inform EFSA by 11 December 2016. The current deadline to deliver the scientific opinion is 31 July 2017. Now that the organisation of a stakeholder event linked to this Opinion has been approved by EFSA, the adoption date needs to be postponed. This will be tabled for discussion at the next plenary meeting.

6.3. Request for a scientific opinion on genetic resistance to TSEs in goats[11]

There was no time to report the work progress of the mandate, following the last meeting that took place on 31 October 2016. This will be presented in the next BIOHAZ plenary meeting.

6.4. Self-task mandate on requirements for the development of microbiological criteria[12]

The WG Chair reported back to the plenary on the agreements made during the 2nd WG meeting which took place in Parma from 20 to 21 October 2016. This scientific output will be drafted as an EFSA guidance for the BIOHAZ Panel. The aim will be to guide the risk assessors, but some relevant reflections for risk managers will be also added, in particular for ToR 4 regarding the requirements and tasks of risk assessors, compared to risk managers in relation to Microbiological Criteria. The concept of targets will be also considered and put into the context of this self-task mandate. The answer to ToR1 will be only based on the EFSA opinions/reports which directly relate to microbiological criteria. There is a pending discussion regarding the possibility to organise a closed technical consultation with relevant stakeholders.

The Panel was informed that an additional WG member has joined the WG. The next WG meeting will take place as a web conference on 16 December 2016 and the deadline for adoption of the Scientific Opinion is 31 October 2017.

6.5. Self-task mandate on public health risks associated with hepatitis E virus as a food-borne pathogen[13]

The last WG meeting was held on 24th November 2016. Sections on HEV control options and persistence in the environment have been added and the sections on prevalence in animals have been summarised in a table. ECDC is providing public health information related to HEV. The next WG meeting is on 12th January 2017. The deadline for adoption of this opinion is June 2017.

[11] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00268
[12] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00227
[13] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00315

6.6. Request for a scientific opinion on BSE cases born after the total feed ban[14]

There was nothing new to report to the Panel because there had not been any meetings since the previous BIOHAZ plenary meeting. Work continues as planned. The second WG meeting took place immediately after the BIOHAZ plenary meeting, on 1-2 December.

6.7. Request for a scientific opinion on establishing of the end point mentioned in the art. 5 of the Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 for distilled fatty acids, stearin and glycerin produced by high standard processing method[15]

A new application on "Installation for processing technical animal fats and vegetable oils for distilled fatty acids, stearin and glycerine" was received in September from the Polish competent authority (CA). The application received was for an evaluation related to Article 5 ("*end point in the manufacturing chain*" of Regulation (EC) No 1069/2009. The animal by-product alternative method in the application cannot be considered as approved at EU level. In line with the explanations provided during the last plenary, and in consultation with the EC, EFSA will inform the CA and applicant that this application is not accepted and that a new complete application based on Article 20 should be resubmitted to EFSA.

6.8. 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 animals[16]

An *ad hoc* WG to help with the preparation of the draft Opinion is being established. This WG will work in close collaboration with respective WGs of ECDC and EMA. The first meeting is possibly taking place in December 2016, subject to the finalisation of the WG composition.

[14] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00350
[15] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00584
[16] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638

7. New Mandates

7.1. 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 EFSA[17]

The internal mandate on QPS with draft terms of reference (ToR) was approved by EFSA executive Director. The deadline proposed is December of 2019. Lieve Herman was appointed as WG Chair. An *ad hoc* WG to help with the preparation of the draft Opinion will be soon established.

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.[18]

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

H. Wahlström updated the Panel members on the status of progress of the WG activities. The BIOHAZ Panel will be asked to provide tabulated

[17] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684

[18] http://www.efsa.europa.eu/en/events/event/161116

information on a published opinion using Weight of Evidence approach. The draft guidance will be presented to the Scientific Committee in February 2017 for endorsement, which is then followed by public consultation. The next WG meeting is on 8/9 December 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 Networks on BSE-TSE and MRA

The draft annual reports are being drafted and published in December 2016.

8.2.2 Joint interagency antimicrobial consumption and resistance analysis (JIACRA) report-follow up-request for data analysis from 2013 and 2014[19]

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 12 December 2016.

8.2.3 Emerging Risks

None.

8.3. European Commission

None.

9. Other scientific topics for information and/or discussion

[19] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00029

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

The Panel was informed about the recent arrival in EFSA of 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 will be established to help with the preparation of the report and the deadline for this request still needs to be agreed. EC has also requested the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) for scientific advice on this issue.

10. Any other business

The BIOHAZ Panel was informed by the secretariat about the ongoing preparation of an abstract ("*EFSA and predictive microbiology. Evaluation of heat treatments of live bivalve molluscs*") for the upcoming Q-safe Conference with authorship including WG Members and EFSA secretariat.

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 Processes[20] and the Decision of the Executive Director on Declarations of Interest[21], 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 6.3 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