Scientific Panel on Biological Hazards

Minutes of the 107th Plenary meeting

Held on 7-8 September, 2016, Brussels (Belgium)

(Agreed on 19 September 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, Lucy Robertson, Giuseppe Ru, Moez Sanaa, Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck (apologies for 08/09), Benno Ter Kuile, John Threlfall (apologies), and Helene Wahlström.

- Hearing Experts:

  None

- European Commission and/or Member States representatives:

  Eric Thevenard, Pamina Suzuki, Kris de Smet, Wolfgang Trunk, and Marina Marini, from DG SANTE.

- EFSA:

  BIOCONTAM Unit: Marta Hugas, Ernesto Liebana, Valentina Rizzi, Beatriz Guerra, Michaela Hempen, Angel Ortiz Pelaez, Pietro Stella, COMMUNICATIONS Unit: Francesca Avanzini.

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

  Natalie Arnich, Pascale Delzenne, Matteo Fadenti, Anna Hoegberg, Balamurugan Jagadeesan, Petra Kostolaniova (only 8/09), Svend Laulund, Rodrigo Nova, Nicolette Quaedvlieg, Hans Peter Schons, Inge Van Damme

[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 John Threlfall, and Niko Speybroek (08/09 only).

Marion Simmons and Giuseppe Ru did not participate in discussions on selected items under agenda point 7.7 due to a Conflict of Interest being identified for the agenda item.

2. Brief introduction of Scientific Panel Members and Observers

The Panel Chair invited the participants to the meeting (Panel Members, EFSA staff and observers) to introduce themselves (name, affiliation, and field of expertise/interest).

3. Adoption of agenda

The agenda was adopted without changes.

4. 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.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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.

5. Presentation of the EFSA Guidelines for Observers

EFSA's secretariat proceeded to explain the Code of conduct, and rules for Interventions and questions from observers, available in the EFSA's Guidelines for Observers for open plenary meetings (which are effective since 19 January 2016).

6. Agreement of the minutes of the 106th Plenary meeting held on 7-8th July 2016, Parma (Italy)

The minutes of the 106th Plenary were agreed by written procedure on 19th July 2016.[4]

7. Scientific outputs submitted for discussion

7.1 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 20 June by web conference. The next and last WG meeting will be on 6 and 7 October in Madrid. The WG Chair explained to the Panel that the overall extensive literature search, including the recent follow up of the ELS (between November 2015 and May 2016), is almost finalised. The evaluation of the microorganisms in the QPS list is being done by the WG based on the ELS results (potential safety concerns) and experts' knowledge. The initial two chapters of the opinion (1. Introduction; 2. Data and Methodologies) were presented to the Panel. Some suggestions for improvement and requests for clarification were discussed and will be suggested to the WG in the next meeting. The Panel raised some questions concerning the overall scope of the QPS exercise. The EFSA Units (Feed, Pesticides, FIP and Nutrition) are actively participating in the drafting of the introduction and data/ methodology chapters. Special focus was given to Table 2, which intends to describe the remit and areas of the risk assessment for each EFSA area. The Scientific Opinion is to be finalised by December 2016.

[4] http://www.efsa.europa.eu/en/events/event/160707
[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189

7.2 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 20 June by web conference. The next and last WG meeting will be held on 6 and 7 October in Madrid. The WG Chair described 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 were asked to update the list of notifications until the beginning of September 2016. New taxonomic units may still be included in the current statement if required. These two TU were evaluated for a possible QPS recommendation. Some suggestions for improvement and requests for clarification were included in the draft Opinion. The Panel Statement is to be adopted on December 2016.

7.3 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 22 June 2016, jointly with the corresponding EMA WG. The deputy 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 during the previous Plenary meeting were addressed. The deputy WG Chair presented in detail to the BIOHAZ Panel the sections of the draft opinion dealing with '*measures to reduce the use of antimicrobials*', and the draft conclusions and recommendations of the draft opinion, including the draft answers to the terms of reference of the mandate. The BIOHAZ Panel provided feedback to the deputy WG Chair, suggesting some adaptations of the text. The WG deputy Chair invited the BIOHAZ Panel to provide further comments on the draft opinion as soon as possible, so that these can be discussed with the WG during the next WG meeting, scheduled for 20 September 2016, in London. The deadline to deliver the EFSA-EMA Joint Scientific Opinion is 20 December 2016.

7.4 Request for a Scientific Opinion on hazard analysis approaches for certain small retail establishments in

[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

view of the application of their food safety management system (HACCP)[8]

The last WG meeting took place on 6 September 2016. The WG chair presented the progress of this mandate. In the draft Opinion, the classical approach of hazard analysis and an alternative, simplified approach were presented. Hazards will be grouped in categories and processing steps will be described in terms of their potential effect on risk. Tools to control these risks will be described as well. The previously suggested product ranking has been abandoned for a more simplified approach. Instead, a table will be produced for each of the five small retail enterprises that describe possible control measures for each processing step of the flow diagram. The next WG meeting is on 7 October 2016. The deadline to deliver the Scientific Opinion is 31 January 2017.

7.5 Scientific Opinion on *Listeria monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU[9]

The Chair of the WG provided a short introduction to the Terms of Reference (ToRs) of the self-task mandate and the three outsourcing activities under "Closing gaps for performing a Risk Assessment on *Listeria monocytogenes* in RTE foods". He informed the BIOHAZ Panel about the approaches to be used to answer the ToRs. He also informed the panel that no WG meeting has been held since the last BIOHAZ plenary meeting. The requested aggregated listeriosis data (TESSy) have been received from the European Centre for Disease Prevention and Control (ECDC) and human population data have been extracted. The final deliverables of the three outsourcing activities are due in September 2016. The consortium of the third activity on Whole Genome Sequencing (WGS) will be invited to the 5th WG meeting that will take place by web conferencing on 21 September 2016. At the 6th WG meeting, scheduled for 17-18 October 2016, special attention will be given to the assessment questions. There was discussion about the organisation of a stakeholder event linked to this Opinion, further details will be provided in the next plenary meeting. The deadline to deliver the scientific opinion is 31 July 2017.

7.6 Request for an EFSA Scientific Opinion on the risk for the development of Antimicrobial Resistance (AMR) due to feeding calves with milk[10]

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

The fifth WG meeting (Web Conference) took place on 23 August 2016. 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. The WG chair presented in detail the current draft Opinion, which covers the following subjects: farming practices, antimicrobial residues, occurrence and epidemiology of AMR (both in bacteria isolated from waste/milk and colostrum and isolated from cattle faeces), development of AMR, and possible mitigation options. 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". The uncertainty analysis approach followed by the WG supported by a hearing expert (member of the EFSA Working Group on Uncertainty in Risk Assessment) was discussed. Additional feed-back from Panel members suggesting adaption of the text was also given. The next physical WG meeting is scheduled for the 4-5th October but will be preceded by a short Web meeting on 14 September. The deadline for the delivery of the Scientific Opinion is December 2016.

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

An update of the work done so far was presented to the Panel by the WG chair. The second WG meeting, a web-conference, was held on 5 September 2016. The objectives of the meeting were: to report discussion with the EC on the clarification of the ToRs, to review the outputs of the literature review and agree the collation of data on potentially alleles conferring resistance and to discuss the approaches for the assessment of ToRs 1,2 and 3. The WG Chair reported back to the Plenary the decisions agreed during the meeting, with the main focus on the layout of the Assessment section of the draft scientific opinion.

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

The first WG meeting took place on 2 September in Copenhagen. The WG Chair reported back to the plenary on the agreements made regarding the approach to be followed in order to answer ToRs 1 to 4. The European Commission will follow this WG as an Observer and it was clarified with them that this mandate does not intend to review the microbiological criteria currently defined in the EU regulation nor to propose new microbiological criteria and that the focus of this mandate will be on risk assessment methodologies.

[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

An additional WG member will be invited to join the WG. A closed technical consultation with relevant stakeholders from the European Commission, industry-related organisations as well as risk managers and other hearing experts will be organised once the draft answers to ToR 1 to ToR 3 are consolidated in order to collect relevant information to support an answer to ToR 4. The next WG meeting will take place in Parma from 20 October to 21 October 2016 and the deadline for adoption of the Scientific Opinion is 31 October 2017.

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

The first meeting of the WG was held on 30-31 August 2016. The WG agreed on a structure for the document and table of contents. To answer the terms of reference the scientific literature will be extensively reviewed. The next WG meeting is planned for October 2016. The deadline for adoption of this opinion is June 2017.

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

An update of the initial discussion and preliminary work was presented to the Panel by the WG Chair. The first WG meeting took place in Brussels on 6 September 2016. The importance of analysing each of the 61 cases included in the mandate was highlighted. In this regard, a questionnaire survey delivered through the BSE/TSE Network prior to the first WG meeting was presented. The importance of addressing the survey to the competent authorities was stressed by Panel members and observers. The list of hypotheses for possible origin of the BARB cases as brainstormed during the first meeting was presented. Some Panel members encouraged the WG to investigate the causes that could explain the most likely origin, even if it could be due to non-compliance with the legislation. A provisional table of contents outlined during the meeting was presented as well. An uncertainty analysis will be included in the risk assessment, given the difficulty to demonstrate the cause-effect relationship.

7.11 Request for a scientific opinion on Chronic Wasting Disease (CWD) in cervids

An update of the initial discussion and preliminary work was presented to the Panel by the WG chair. The first WG meeting took place in Parma on 1 September 2016. The WG chair informed the BIOHAZ Panel of the interpretation of the ToRs adopted by the WG in agreement with the EC.

[13] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00315
[14] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00350

The situation of CWD in Norway was presented to the Panel as reported in the WG meeting. The approaches to address the ToRs of phase I of this mandate were also presented, emphasizing the uncertainties and lack of data about the susceptibility of cervids, cervid data population, presence of CWD in other European countries, consumption of cervid products, etc. Several targeted literature reviews will be used as the main data sources to address the ToRs. A provisional table of contents outlined during the meeting was presented as well.

8. New Mandates

None

9. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

9.1 Scientific Committee and/or Scientific Panel(s) including their Working Groups

9.1.1 Scientific Committee

The 79th Plenary meeting of the Scientific Committee took place in Parma on the 6 July 2016.[15]

9.1.2 Scientific Committee Working Group on Uncertainty in risk assessment

None

9.1.3 Scientific Committee Working Group on Biological Relevance

None

9.1.4 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. An example for a weight of evidence approach from a

[15] http://www.efsa.europa.eu/en/events/event/160706

chemical risk assessment has been suggested and during the next meeting it will be discussed whether an example from a biological risk assessment should be developed. The next WG meeting is on 12-14 September 2016.

9.1.5 Scientific Committee standing WG on Guidance review

None

9.2 EFSA including its Working Groups /Task Forces

9.2.1 Scientific Network on BSE-TSE and MRA

The next BSE-TSE Network meeting will take place on 5/6 October 2016 in Parma. The draft agenda for the meeting was presented to the Panel members.

The next MRA Network meeting will take place on 11/12 October 2016 in Parma. There will be joint session with the EFSA Scientific Network on Zoonoses Monitoring Data on the second day.

9.2.2 Joint interagency antimicrobial consumption and resistance analysis (JIACRA) report-follow up-request for data analysis from 2013 and 2014[16]

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 second meeting of the Working group is scheduled for 9 September 2016 in London.

9.2.3 Emerging Risks

None.

9.3 European Commission

E. Thevenard, Head of Unit G4 in SANTE addressed the Panel with a presentation on "Food hygiene and EFSA BIOHAZ opinions". This was followed by a question and answer session with Panel members.

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

10. Other scientific topics for information and/or discussion

10.1 Discussions on H2020 topics

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 received was discussed and will be communicated to the SCER Unit in EFSA who are taking the lead on preparing a report encompassing all EFSA's suggestions.

11. Answers to questions from Observers (in application of the EFSA Guidelines for Observers)

Three questions were received in writing from the observers, and the answers are provided below:

1. Is there any proposal to revise the existing food safety criteria outlined in (EC) No 2073/2005 for *L. monocytogenes* consequent to any new findings (e.g. new risk assessment)?

EFSA's main mission is to provide independent and objective scientific advice for the EU's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. In particular, the mandate of the Scientific Panel on Biological Hazards (BIOHAZ Panel) is to issue scientific opinions based on risk assessment on areas related to food safety and foodborne diseases. As such it does not have regulatory or enforcement powers. The EU's policy-making institutions (such as the Council of Ministers, European Parliament (EP), European Commission (EC) and EU Member States) have remained the risk managers, in charge of adopting the decisions.

The BIOHAZ Panel can initiate self-tasking activities. One example of these was the self-tasking mandate on microbiological criteria and targets based on risk assessment, which resulted in a Scientific Opinion published in 2007. This opinion aimed to provide an overview of the different concepts and their use with special considerations to the applicability of microbiological criteria and targets in the food chain at EU-level based on risk assessment. At that time, it was recognized that risk-based food safety management was still evolving and this Opinion should be subject to periodical review. The BIOHAZ Panel has just started another self-tasking activity on the requirements for the development of microbiological criteria which will be concluded in 2017. The BIOHAZ Panel has additionally just started another self-tasking activity on L. monocytogenes contamination of ready-to-eat foods and the risk for human health in the EU which will be concluded in 2017.

2. EFSA's experience/ opinion on recent reports of *L. monocytogenes* detection in dry foods (e.g, sunflower seeds) and implications if any.

In 2008, the BIOHAZ Panel responded to a request from the EC for updating the former SCVPH opinion on Listeria monocytogenes risk related to ready-to-eat foods and scientific advice on different levels of L. monocytogenes in ready-to-eat foods and the related risk for human illness.

The BIOHAZ Panel has just started another self-tasking activity on L. monocytogenes contamination of ready-to-eat foods and the risk for human health in the EU which will be concluded in 2017. This activity is being supported by 3 EFSA ongoing outsourcing activities under "Closing gaps for performing a risk assessment on L. monocytogenes in RTE foods". The first activity aims to perform a systematic review on L. monocytogenes in a wide range of RTE foods. In the second activity, a quantitative risk characterization on L. monocytogenes in RTE foods, starting from the retail stage, will be developed to estimate the public health risks from consumption of various RTE food categories contaminated with L. monocytogenes. In the third activity, whole genome sequencing (WGS) will be applied to compare isolates from different compartments along the food chain, and in humans.

In these mentioned activities the Panel has not so far looked at the issue of dry foods (e.g. seeds)

3. Is EFSA waiting on more scientific clarity (e.g, understanding strain variations, spatial distribution, genome stability etc.) and adapting the legal framework before 'routinely' implementing WGS?

Recently the BIOHAZ Panel developed a self-tasking mandate on the evaluation of molecular typing methods for major food-borne microbiological hazards and their use for attribution modelling, outbreak investigation and scanning surveillance: Part 1 (evaluation of methods and applications) and Part 2 (surveillance and data management activities). The conclusions of the resulting scientific opinions highlighted that the revision of the legal basis of programs for pathogen reduction based on historic organism nomenclature may be necessary following the increased use of WGS and the subsequent identification of more biologically relevant groupings of organisms.

In June 2014, EFSA organized its 20th Scientific Colloquium on the use of whole genome sequencing (WGS) of food-borne pathogens for public health protection. This gave the opportunity to leading scientists, representatives of international and European organizations and national food safety authorities to came together to assess the latest scientific information, strengthen alliances with the relevant EU and international bodies, to initiate discussions on the use of WGS methods for food safety applications, and to drive EFSA's ongoing efforts in the collection of molecular typing data by proactively anticipating the particular requirements relating to WGS data. On this occasion it was recommended that (i) the legal consequences of the large-scale application of WGS should be reviewed and proposals should be made for any changes in food safety rules and regulations that may be needed, and (ii) EU stakeholders in public health should work together with EU Member States' competent bodies in food safety and public health towards a joint strategy and action plan to roll out WGS across sectors for enhanced One-Health surveillance of food-borne diseases.

EFSA is currently managing several contracts and grants on the use of WGS in Food Safety applications. The outcome of this will be published after completion of the outsourced projects as external reports in due time. It remains the mission of the European risk managers to translate the scientific opinions and risk assessments into risk management measures (e.g. legislation) after consultation with MSs, taking into account not only the scientific advice but also socio-economic parameters.

12. Any other business

None.

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[17] and the Decision of the Executive Director on Declarations of Interest[18], 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 7.7 by the concerned scientific group.

[17] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[18] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf