

Scientific Panel on Biological Hazards

Minutes of the 111th Plenary meeting

Held on 15-16 March, 2017, Parma (Italy)

(Agreed on 3 April 2017)

Participants

■ Panel Members:

Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo S. Fernandez-Escámez, Rosina Gironés, Lieve Herman, Konstantinos Koutsoumanis, Roland Lindqvist, Birgit Nørrung, Antonia Ricci (only 13/03/17), Lucy Robertson, Giuseppe Ru, Moez Sanaa, Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck (apologies), Benno Ter Kuile, John Threlfall, and Helene Wahlström (apologies).

■ Hearing Experts:

None

■ European Commission and/or Member States representatives:

Marina Marini (apologies), Pamina Suzuki (for items 6.1, 6.3, 6.4), Sylvie Coulon (for item 9.1) and Andrea Gavinelli (for item 9.3) from DG SANTE.

■ EFSA:

BIOCONTAM Unit: Ernesto Liebana, Valentina Rizzi, Winy Messens, Sandra Correia, Maria Teresa da Silva Felício, Michaela Hempen, Angel Ortiz Pelaez, Pietro Stella, Yves Van Der Stede, Frank Boelaert, Francesca Latronico, Raquel García, Domenico Deserio, Marta Hugas (Scientific staff).

FIP Unit: Carla Martino.

AMU Unit: Ana Garcia, Fulvio Barizzone.

- 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 Niko Speybroeck and Helene Wahlström (both days), and Antonia Ricci (for 16/03/17). Birgit Nørrung chaired the meeting on 16/03/17.

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.

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 109th Plenary meeting held on 30 November-1 December 2016, Parma (Italy)

The minutes of the 110th Plenary were agreed by written procedure on 1 February 2017.⁴

5. Scientific outputs submitted for possible adoption

None

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 EU⁵

The last WG meeting was held on 7-8 March 2017 in Vienna. 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 3, the comparison of isolates from different compartments along the food chain, and from humans using whole genome sequencing (WGS) analysis has been published⁶. He informed about the approach to answer the ToRs, table of contents and the data and methodologies used. The approach that would be used to evaluate the assessment questions was discussed. The WG Chair informed that the deadline for adoption of the scientific opinion has been extended to end of December 2017. The deadline for endorsement is end of July 2017. The next WG meeting will be held on 5 April 2017 by webmeeting.

6.2. Request for a scientific opinion on genetic resistance to TSEs in goats⁷

The progress of the WG was presented by the Chair including the list of potential alleles conferring genetic resistance to TSEs in goats, and the tool to determine the level of resistance of the selected alleles, in response to the recommendations by Panel members in the previous plenary. A two-tier qualitative approach (weight of evidence and level of

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

⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00597>

⁶<http://www.efsa.europa.eu/en/supporting/pub/1151e>

⁷<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00268>

resistance against the wild type in the goat *PRNP* gene) was explained in more detailed. The Panel agreed with the approach and no objections were raised. Provisional answers to ToR2, ToR3 and ToR4 were presented for the first time, as well as the work plan for the next months. The next WG meeting will take place on 5 April 2017 as a web-conference. The deadline for adoption of the Scientific Opinion is 30 September 2017.

6.3. Self-task mandate on requirements for the development of microbiological criteria⁸

The WG Chair reported back to the plenary on the progress made during the 4th WG meeting which took place as on 20 February 2017 in Murcia. Comments were provided by the Panel and DG SANTE on the shared preliminary draft opinion. These comments will be discussed with the WG during the next WG meeting on 16 to 17 March 2017 in Parma. The WG does not feel the need to organise a closed technical consultation with relevant stakeholders to collect information in order to support the answer to ToR4. 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 pathogen⁹

The last WG meeting was held on 14th March 2017. The WG chair presented the draft opinion. The panel commented that the sections where shellfish are mentioned should be reviewed in order to clarify that the source of contamination is environmental. The data extracted from the EFSA food consumption database may not be useful in order to describe geographical distribution of HEV infection and disease in humans as there is not enough detail provided on food categories and how they are prepared at home. Specific publications on food consumption and HEV infection and disease could be used instead or in addition. The draft conclusions and recommendation will be provided at the next panel meeting. The next WG meeting is on 11th May 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 ban¹⁰

The draft of the scientific opinion was presented to the BIOHAZ Panel for first reading. The main sources of evidence were described as in sections Data and Methodology of the opinion. The two different approaches to conduct the assessment, both descriptive (origin of BSE, questionnaire

⁸<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00227>

⁹<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00315>

¹⁰<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00350>

survey, epidemiology of BSE and BARB cases, review of FVO reports) and quantitative (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 using the C-TSEMM model) were described in detail, including the major conclusions driving the answers to the ToRs. The Panel suggested to include a table with the summary data of the analysis of the 60 BARB cases using the data from the questionnaire survey. The overall conclusions were accepted by the Panel but it was requested to provide more supporting text from the gathered evidence to justify the answers to the ToRs. The next WG meeting will take place as a physical meeting on 7 April in Parma. The deadline for adoption of the Scientific Opinion is 30 June 2017.

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 animals¹¹

This WG works in close collaboration with respective WGs of ECDC and EMA. The WG Chair updated the Panel on the progress made by the WG during the second and third meetings (7 February and 14 March 2017) and the discussions held during the interagency Coordination WG (9 March 2017). The three agencies' WGs agreed the structure of the draft opinion, the respective tasks and the use of an adapted EFSA template for the opinion. The BIOHAZ Panel agreed with the general approach taken by the EFSA WG in the selection of the list of primary and secondary indicators, and stressed the importance of testing them in a sensitivity analysis. The next meeting of the EFSA WG will take place on 20 April 2017.

6.7. Request for a scientific opinion on Chronic Wasting Disease (CWD) (ToRs 4 and 5) ¹²

The Chair of the WG informed that the work of Phase II has not started in earnest yet but the work plan has been drafted. The first WG meeting has been scheduled as a web-conference for the 6 June 2017. Some preliminary work has already been scheduled and will be implemented before the first WG meeting. It is foreseen to have the first physical WG meeting late in July. The deadline for adoption of the Scientific Opinion is 31 December 2017.

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00638>

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00411>

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 EFSA¹³

An *ad hoc* WG to help with the preparation of the draft Opinion and Panel Statements is being established. The dates of the first 2 WG meetings have been agreed (28 March and 23/24 May). It is planned to publish a Panel statement every six months with the assessment of new taxonomic units notified to EFSA which were not yet included in the QPS list. EFSA Units have been asked to update the notifications 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. In the meantime, AMU has already been consulted for alternative (e.g. machine learning techniques for screening of references) and improved methodologies to search for possible new safety concerns. The deadline proposed for this mandate is December of 2019.

7. New Mandates

7.1. 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)"¹⁴

A new application was received from the Austrian CA on a new "alternative biodiesel process for rendered fat of Category 1 (BDI-RepCat Process°, AT)". The reception of the application was acknowledged by EFSA on 2 March. The completeness/ validation check is due on 5 April. After this, EFSA will have 6 months to finalise the evaluation and adopt a scientific opinion as foreseen by Regulation (EU) No. 142/2011. 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 process consists of a conversion unit, where esterification and transesterification with methanol takes place, followed by water/ methanol recovery and distillation of the products biodiesel and glycerine. An *ad hoc* WG to help with the preparation of the draft Opinion will be established.

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

¹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

¹⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00136>

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

8.1.1 Scientific Committee

The 82nd Plenary meeting of the Scientific Committee took place in Brussels on the 13 February 2017.¹⁵

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. A discussion took place on the proposal of a BIOHAZ Panel member to join the Scientific Committee WG on Uncertainty. Kostas Koutsomanis expressed an interest, and the proposal will be made to the Chair of the WG.

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

None

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 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 4-5 April 2017, in Parma.

¹⁵<http://www.efsa.europa.eu/en/events/event/170213>

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 20-22 March 2017. The Panel was presented with a brief update on progress of the analysis.

8.2.3. Request for scientific and technical assistance on proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge¹⁷

The EFSA ad hoc WG established to help with the preparation of the technical report for this mandate had 2 meetings on 17 February and 9 March 2017 in Parma and via web conference respectively. The BIOHAZ team is collaborating with the AHAW and CONTAM teams to address this request. JRC and SCHEER have been invited to all WG meetings as observers and JRC has provided clarifications to the ToRs. The Panel will continue being informed at regular intervals on the progress made for this mandate. The deadline for this request is end of May 2017.

8.2.4 Emerging Risks

None

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 on the public health risks associated with foodborne parasites

The panel was introduced to a draft document with background and terms of reference for a Panel self-task on foodborne parasites. Comments from

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

¹⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00819>

Panel members were made and will be sent to the secretariat with the intention to finalise the document in the April BIOHAZ Plenary meeting.

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

A presentation was provided on the report "Analysis of EFSA methodological needs for evidence use in scientific assessments" of EFSA's project on PROmoting METHods for Evidence Use in Scientific assessments with a focus on the outcome of the survey administered to the BIOHAZ Panel and BIOHAZ Team. The outcome of the survey to assess the impact on the overall quality and resources of applying the Prometheus approach to the case study (mandate on "Evaluation of the safety and efficacy of Listex™ P100 for reduction of pathogens on different ready-to-eat (RTE) food products") was presented. Also the lessons learned and next steps were discussed.

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

EFSA's secretariat gave a presentation to the Panel, which was followed by a discussion on the main findings.

9.4. Presentation by the European Commission (SANTE G3) on the new Official Control Regulation.

The representative from DG SANTE gave a presentation to the Panel. This was followed by a round of questions and answers.

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 10th International Conference of Predictive Modelling in Food (ICPMF10)¹⁸ and manuscript "Thermal processing of live bivalve molluscs for controlling viruses: on the need for a risk-based design" with authorship including WG Members and EFSA secretariat.

The BIOHAZ Panel was also consulted on the possibility to consider a different plenary meeting regime for 2018.

¹⁸ <http://www.icpmf10.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>