

Scientific Panel on Biological Hazards

Minutes of the 118th Plenary meeting

Held on 14-15 March 2018, Parma (Italy)

(Agreed on 27 March 2018)

Participants

■ Panel Members:

Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo S. Fernández-Escámez, Rosina Gironés, Lieve Herman, Konstantinos Koutsoumanis, Roland Lindqvist, Birgit Nørrung, Antonia Ricci (14 March), Lucy Robertson, Giuseppe Ru, Moez Sanaa (for items 6.3, 6.5, 6.6, 8.3), Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck (15 March), Benno Ter Kuile, John Threlfall, and Helene Wahlström.

■ European Commission and/or Member States representatives:

Matjaz Klemencic (for items 6.7, 10.1); Eric Thévenard, Marina Marini (for item 8.3).

■ EFSA:

BIOCONTAM Unit: Frank Boelaert, Sandra Correia, Maria Teresa da Silva Felício, Michaela Hempen, Ernesto Liebana, Winy Messens, Angel Ortiz Pelaez, Eleonora Sarno, Pietro Stella, Daniel Thomas, Yves Van der Stede (Scientific staff).

AMU Unit: Andrea Baù (for items 8.1.3, 8.1.4).

FIP Unit: Carla Martino (for items 8.1.3, 8.1.4).

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

Not applicable

■ Others:

Not Applicable

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

1. Welcome and apologies for absence

Apologies were received from Moez Sanaa (for 14 March morning and part of 15 March), from Niko Speybroeck (for 14 March) and Antonia Ricci (for 15 March).

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.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 117th Plenary meeting held on 6-7 December 2017, Parma (Italy)

The minutes of the 117th Plenary meeting were agreed by written procedure on 20 December 2017.⁴

5. Scientific outputs submitted for possible adoption

No scientific outputs were submitted for adoption.

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 EFSA⁵

Last web meeting was held on 26 February. During this meeting, the current qualification on antimycotic resistance was discussed. It was also

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

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

⁴<http://www.efsa.europa.eu/en/events/event/171206>

⁵<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00684>

discussed an improvement of the form for the article evaluation phase. The next meeting will be held on the 2-3 May in Parma. Possible adoption of this opinion is scheduled for December 2019.

6.2. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 8: Suitability of taxonomic units notified to EFSA until March 2018⁶

A new ELS exercise to monitor possible safety concerns related to the QPS list microorganisms was launched in February and will be finalised by May/June 2018 (covering literature retrieved for the period of June to December 2017). The summary of results and possible safety concerns will be included in this Statement. EFSA Units updated with the new notifications from September 2017 until February 2018. The Panel was informed that improvement on the support provided through the QPS mandate has been discussed with the Pesticides and Nutrition Units. Two new taxonomic units were included in current draft. The draft Statement is to be presented for thorough reading at the plenary meeting in April. Possible adoption of this opinion is scheduled for June 2019.

6.3. Scientific opinion on public health risks associated with foodborne parasites⁷

The last WG meeting was held on 26 February 2018 as web-meeting. The WG chair informed the panel about the progress made and highlighted a discussion the WG members had about the importance of foodborne pathways for *Echinococcus*. The difficulty to identify the sources of infection lies in the long incubation period and lack of data. The available data will be assessed in the draft opinion. The panel suggested including figures of the parasites' life cycle instead of the food chain diagrams. The next WG meeting will be held on 17 April 2018 in Parma. The deadline for this mandate is October 2018.

6.4. Scientific opinion on hazard analysis approaches for certain small retail establishments and food donations⁸

The 4th WG meeting was held on 13 March 2018 in Parma. The WG chair updated the panel on the progress made so far and highlighted the WG's discussion on the scope of this opinion. Whereas the first HACCP opinion focussed on micro businesses, the second opinion will also include small businesses since distribution centres and supermarkets, which are included in this mandate, are usually bigger in size. Another consideration that needs to be clarified in the draft opinion relates to the difference of cooking with the aim to destroy pathogens versus "culinary" cooking in restaurants which may not be as effective in reducing pathogens but is essential part of a recipe. This could be addressed in form of PRP 13 on

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00829>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00460>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00565>

consumer information. The next WG meeting will be held on 23 April 2018 as a web-meeting. The deadline for this mandate is the end of September 2018.

6.5. Scientific opinion on *Salmonella* control in poultry flocks and its public health impact⁹

The WG chair informed the Panel that two WG meetings were held: on 16 January in Parma and on 5 March 2018 by web-meeting. The draft table of contents of the scientific opinion was shown. The data and approaches to answer the terms of reference (ToR) were presented and discussed. For ToR 1, the evidence that would be used for selecting *Salmonella* serovars of public health significance was presented. This will inform the serovar selection to conduct a qualitative comparison/correlation analysis between the *Salmonella* occurrence in breeder and production flocks. Data issues in breeder flocks were also discussed. The connection with the impact on human health would be achieved through a qualitative assessment of serovar distributions and through ToR 2. For ToR 2, a “*Salmonella* attribution model”, based on the microbial subtyping attribution approach, would be applied. For ToR 3 and ToR 4, an extensive literature search will be performed and data requested. For ToR 5, an extensive literature search will be performed. The next (third) meeting of the WG will take place on 20 April 2018 in Parma. The deadline to deliver the Scientific Opinion is 31 January 2019.

6.6. Request for a scientific opinion on an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Proteins (PAP)¹⁰

The last WG meeting took place in London on 26-27 February 2018. The WG chair presented the approaches adopted by the WG to address the ToRs of this mandate, in the first reading of the draft opinion. A general description of the feed chain from abattoir to the farm is being drafted in the first part of the opinion, including the potential routes of contamination of ruminant content potentially contaminated with the BSE agent. To address ToR 2, the 2011 EFSA model (PAP model) is in process of being updated by adding new data and two new risk pathways additional to the original one (from ruminant PAP to non-ruminant PAP and to ruminant feed), namely, ruminant PAP into non ruminant feed accidentally accessed by cattle, and fishmeal contaminated with ruminant content used in milk replacers for unweaned cattle. In order to address quantitatively ToR 3, a new model (FEED model) is being developed to simulate the impact of the implementation of the technical zero in a theoretical scenario. The Panel welcomed the approaches adopted by the WG but some members were concerned with the lack of time and suitable data, and with the difficulty to expand the current model and to develop a

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00692>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00705>

new one in the available time. In addition, the separation of uncertainty and variability needs to be considered (e.g. by second order modelling) as otherwise the outputs of the models will be difficult to interpret. The Panel recommended the assessment of the risk and the answer to the ToRs to be qualitative and only update the input data of the 2011 model.

6.7. Scientific opinion on an application received from the Dutch Competent Authority for evaluation of a new alternative processing method for animal by-products for Category 3 material (ChainCraft BV)¹¹

The last WG meeting was held on 31 March in Parma. The draft opinion was further developed with clarifications made with EC. The WG chair presented the draft opinion for thorough reading to the Panel. The evaluation of the confidentiality claim requested by the Applicant is to be finalised. The last web-conference meeting is to be held on 4 April. The draft opinion will be presented for possible adoption during April's plenary. The deadline for this mandate is 6 May 2018.

6.8. Scientific Opinion on the application and use of next generation sequencing (including whole genome sequencing) for risk assessment for foodborne microorganisms¹²

The mandate has been accepted internally and will be initiated as soon as EFSA's ongoing procurement activities on whole genome sequencing (GenCamp, ENGAGE and INNUENDO) are concluded as well as the respective final external scientific reports. These outsourcing activities are estimated to be concluded, at the latest, between end of May 2018 and mid November 2018, respectively. Thus, the next-generation sequencing self-task mandate may start between July and November 2018, and end by November 2019.

7. New Mandates

No new mandates were received.

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 87th Plenary meeting of the Scientific Committee took place in Parma on the 14-15 February 2018.¹³ The BIOHAZ Panel Chair reported that the

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00619>

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00397>

¹³ <http://www.efsa.europa.eu/en/events/event/180214>

draft EFSA Guidance on communicating uncertainty in scientific assessment was discussed, and that EFSA secretariat briefly introduced the EFSA Risk Assessment Methodology Programme (RAM-Pro).

8.1.2. Scientific Committee Working Group on Uncertainty in risk assessment

The Panel was informed that the EFSA Guidance on uncertainty analysis in scientific assessment (new concise guidance) was published,¹⁴ together with the scientific opinion on the principles and methods behind EFSA's Guidance on uncertainty analysis in scientific assessments.¹⁵ Future trainings will be organised for the Panel and EFSA staff on the implementation of the Guidance as of autumn 2018. A future Scientific Committee standing working group on Uncertainty will also provide support to Scientific Panels' WGs if needed on the implementation of the Guidance.

8.1.3. Request for a scientific opinion on the evaluation of the safety and efficacy of lactic acid to reduce microbiological surface contamination on carcasses from wild game and small stock¹⁶

A standing WG of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) "CEF Panel SWG on the evaluation of substances used to reduce microbial contamination from products of animal origin" was established in January 2018. The BIOHAZ secretariat informed the Panel about the workflow that would apply for the evaluation of this type of application¹⁷. EFSA requested the applicant provide the missing information on 25 October 2017, but has not yet been submitted and therefore the application is not yet considered valid. The deadline to deliver the Scientific Opinion is 9 months following the receipt of a valid application.

8.1.4. Request for a scientific opinion on the evaluation of the safety and efficacy of the organic acids lactic and acetic acid to reduce microbiological surface contamination on pork carcasses and pork cuts¹⁸

The same standing WG will prepare the Scientific Opinion and the same procedure will be followed as for the mandate under agenda item 10.1.3. The BIOHAZ secretariat informed the Panel that the application was considered valid on 10 January 2018. On 2 February, the first Joint WG meeting was held by teleconference during which it was agreed that additional information is needed from the applicant to be able to continue with the evaluation. A letter requesting this additional information was

¹⁴ <http://www.efsa.europa.eu/en/efsajournal/pub/5123>

¹⁵ <http://www.efsa.europa.eu/en/efsajournal/pub/5122>

¹⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00667>

¹⁷ <http://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflowdecontamination.pdf>

¹⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00666>

sent to the applicant on 22 January 2018 and the scientific evaluation was suspended until the requested data will be officially submitted to EFSA. The deadline to deliver the Scientific Opinion is 9 months following the receipt of a valid application, extended with the duration of the additional information request(s).

8.2. EFSA including its Working Groups /Task Forces

8.2.1. Scientific and technical assistance on harmonized monitoring of antimicrobial resistance in bacteria transmitted through food¹⁹

EFSA Secretariat presented the new mandate received from the European Commission in December 2017, asking to update the technical specifications for harmonised monitoring of antimicrobial resistance in bacteria transmitted through food. An ad hoc WG was composed and is expected to meet shortly, under the coordination of the EFSA BIOCONTAM Unit. The deadline for the delivery of the scientific report is March 2019.

8.2.2. Third Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report²⁰

EFSA Secretariat presented the new JIACRA mandate received, for an update of the first and second JIACRA reports with 2016-2018 data. This third JIACRA report is expected to be delivered jointly by ECDC, EFSA and EMA by December 2020.

8.2.3. Scientific Networks on BSE-TSE and MRA

No new meetings of the Scientific Networks on BSE-TSE and MRA have been held. The next meeting of the MRA Network will be held on 24-25 April 2018. The next meeting of the BSE-TSE Network will be held on 15-16 October 2018.

8.2.4. Emerging Risks

Nothing to report under this agenda item.

8.3. European Commission

Eric Thévenard (European Commission, DG SANTE, Head of Unit G4) addressed the BIOHAZ Panel with a presentation on "Food hygiene and EFSA BIOHAZ opinions" He gave an update on the follow-up by the EU risk managers of the recent scientific outputs adopted by the Panel, and on the ongoing activities of DG SANTE Unit G4, including the new official control regulation, crisis preparedness and management, and antimicrobial resistance. The presentation was followed by a questions and answers session with Panel members.

9. Other scientific topics for information and/or discussion

¹⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00051>

²⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00135>

9.1. EC request to EMA for an update of the advice on the impact on public health and animal health of the use of antibiotics in animals (categorization of antimicrobials and early hazard characterization)

The first meeting of the EMA WG related to the update of the Antimicrobial Advice Ad Hoc Expert Group (AMEG) categorisation of antimicrobials, and for a further elaboration on the proposed early hazard characterisation, took place. As in past similar activities, EFSA is involved in this EMA activity. The Panel will be kept updated on the progress of this EMA mandate.

9.2. EU Summary Report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks 2016

EFSA Secretariat presented to the Panel a summary of the findings of EU Summary Report on zoonoses and food-borne outbreaks for year 2016, published in December 2017.²¹ The Panel commented that it would be interesting to discuss in the future the possibility to perform further analyses on the data collected and summarised by the report.

9.3. EU Summary Report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2016

EFSA Secretariat presented to the Panel a summary of the findings of EU Summary Report on TSE for year 2016, published in November 2017.²²

9.4. Update on the publications published in FEMS Microbiology and Ecology related to the Scientific Opinion from the BIOHAZ Panel on 'Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs'

EFSA's Communications Department alerted the BIOCONTAM Unit that a Letter was published in reply to the BIOHAZ Panel Letter to the Editor of FEMS ME providing clarifications in response to the initial publication by Raymond and Federici criticising the 2016 BIOHAZ Panel *Bacillus* opinion. In agreement with members of the former EFSA *Bacillus* ad hoc WG, the EFSA BIOCONTAM, PESTICIDES and COMMUNICATION Units, the Panel decided that no further answer will be given to this second publication, as this did not raise any new point for clarification of the scientific aspects of the *Bacillus* opinion.

10. Any other business

²¹ <https://www.efsa.europa.eu/en/efsajournal/pub/5077>

²² <https://www.efsa.europa.eu/en/efsajournal/pub/5069>

EFSA Secretariat informed the BIOHAZ Panel about a complaint received by EFSA recently, which asked to clarify certain aspects of the scientific opinion on the evaluation of the Application for new alternative biodiesel production process for rendered fat of Cat 1 (BDI-RepCat process, AT), adopted by the BIOHAZ Panel in October 2017. EFSA, in collaboration with the Panel, is going to draft an answer to clarify those aspects of the scientific opinion.

Marion Simmons briefly updated the Panel on recent developments of the spread of Chronic Wasting Disease (CWD) in Norway, and the first case of CWD being recently detected in a moose in Finland (first EU case).

The Panel agreed to include a standing item on the agenda of the future plenary meetings to reflect on topics of scientific concern in the area of biological hazards and possible priorities for BIOHAZ Panel self-tasking work in the future.

EFSA Secretariat informed the Panel about the timelines related to the Panel renewal process. After a decision of the EFSA Management Board on the selected members of the future Panels, applicants will be informed of the results of the selection procedure.

The Panel was updated on the EFSA Conference 2018 (Science, Food, Society), planned for 18-21 September 2018 in Parma²³. Panel members interested to participate were invited to register to the Conference at their earliest convenience. The Call for Posters is open until 2 April 2018.

²³ <https://conference.efsa.europa.eu/>