Scientific Panel on Biological Hazards

Minutes of the 105th Plenary meeting

Held on 8-9 June, 2016, Parma (Italy)

(Agreed on 21 June 2016)

Participants

- Panel Members:

  Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo S. Fernandez-Escamez, Rosina Girones (apologies 9/06), Lieve Herman, Konstantinos Koutsoumanis, Roland Lindqvist, Birgit Nørrung, Antonia Ricci, Lucy Robertson, Giuseppe Ru, Moez Sanaa, Marion Simmons (apologies), Panagiotis Skandamis, Emma Snary (apologies), Niko Speybroeck, Benno Ter Kuile, John Threlfall, and Helene Wahlström.

- Hearing Experts:

  Andrew Hart (for item 6.8)

- European Commission and/or Member States representatives:

  Marina Marini (DG SANTE), Pamina Suzuki (DG SANTE, for items 5.2. and 6.4), Lucie Carrouee (DG SANTE, for items 6.7 and 7.2and), Sofie Hofkens (for item 5.2).

- 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, Giusi Amore, Frank Boelaert (Scientific staff).

  AMU unit: Elisa Aiassa, Fulvio Barizzone and Gilles Guillot (for item 6.8).

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

  Not Applicable

- Others:

  Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Rosina Girones (9/06), Marion Simmons, and Emma Snary.

Marion Simmons and Giuseppe Ru did not participate in discussions on selected items under agenda point 7.1 due to a Conflict of Interest being identified for the agenda item.

2. Adoption of agenda

The agenda was adopted without 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.

[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 104th Plenary meeting held on 27-28th April 2016, Parma (Italy)

The minutes of the 104th Plenary were agreed by written procedure on 11th May 2016.[4]

5. Scientific outputs submitted for possible adoption

5.1. Panel Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. 4: Suitability of taxonomic units notified to EFSA until March 2016[5]

The last WG meeting took place on 20 April by web conference. A total of 129 biological agents were notified to EFSA between September 2015 and March of 2016. From these, 12 taxonomic units were included in this statement for evaluation of a possible QPS status. The chair presented the assessment developed by the WG experts. The Panel adopted the statement on the 8/06 with the following conclusions: *Pediococcus parvulus*, *Bacillus flexus* and *Lactobacillus diolivorans* may be recommended for the QPS status. *Candida rugosa*, *Cellulosimicrobium cellulans*, *Geobacillus caldoproteolyticus* (*Anoxybacillus caldiproteolyticus*), *Geobacillus pallidus*, *Chryseobacterium proteolyticum*, *Klebsiella pneumonia*, *Paenibacillus macerans*, *Protaminobacter rubrum* and *Pullulanibacillus naganoensis* are not recommended for the QPS list.

5.2. Scientific Opinion concerning the risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp, including *Bacillus thuringiensis* in foodstuffs[6]

The last WG meeting took place on 4 May 2016. The WG Chair presented carefully all amendments made to the draft opinion addressing previous comments from Panel members. One major conclusion was that the levels of *B. cereus* group posing a health risk to the consumer are highly strain dependent due to their highly diverse pathogenic potential. The possibility of multiplication in foods after storage and/or handling must be taken into account when defining safe levels for human consumption, as well as the composition of the food, which can affect toxin production. All these factors can be responsible for the large variation in the estimated

[4] http://www.efsa.europa.eu/en/events/event/160427
[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00697
[6] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00254

infectious doses, which makes a valuable dose-response relationship hard to establish. The Panel suggested only some editorial changes and adopted the opinion on the 9/06.

5.3. Scientific Opinion on the growth of spoilage bacteria during storage and transport of meat[7]

The WG chair presented the changes since the last Panel meeting. A flow chart was added describing the products covered in the draft opinion. Clarifications were added to some tables as lower temperatures were not modelled for pork. Conclusions and recommendations were revised significantly since the last Panel and discussed in detail. One important conclusion was that predictive modelling results suggest that spoilage bacteria will grow faster than pathogens and will limit the target surface temperature. The Panel suggested few editorial changes and adopted the opinion on the 8/06.

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 EFSA[8]

The last WG meeting took place on 20 April by web conference. The next WG meeting will be on 20 June by web conference. The WG Chair explained to the Panel the state of the art of the extensive literature search (ELS). The second phase of this exercise, evaluation of selected articles for possible safety concerns with pre-categorisation, is finalised. The information compiled from the relevant references, related to potential safety concerns, will be the basis for the revision of the QPS recommendations and their qualifications. The search for the follow up of the ELS (between November 2015 and May 2016) was run and the references found are ready for the screening phase. Flowcharts illustrating the QPS process will be included in the draft opinion. The four EFSA Units (Feed, Pesticides, FIP and Nutrition), for which the QPS approach has been developed, have been actively participating in the refinement of the introduction and methodology sections. The Scientific Opinion is to be finalised by December 2016.

6.2 Joint EFSA and EMA (European Medicines Agency) Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the

[7] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00163
[8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189

European Union and the resulting impacts on food safety[9]

The last WG meetings were held on 28-29 April 2016 and 1 June 2016, jointly with the corresponding EMA WG. The WG Chair updated the Panel on the status of progress of WG activities. Hearing experts from ANSES and its WG on '*Alternatives to antibiotiques*' participated to the last WG meeting to exchange information with the EFSA-EMA WG on the ongoing EFSA and ANSES activities on possible alternatives to antimicrobials in food-producing animals. EFSA and ANSES agreed to remain in close contact and to further exchange information in the future months. As requested by the BIOHAZ Panel in the previous plenary meeting, the WG is working with the aim of rationalising the contents of the draft opinion and removing some duplication. The WG Chair presented to the BIOHAZ Panel a first draft of the main conclusions and recommendations of the draft opinion, in particular regarding the possible options to reduce the use of antimicrobials in food-producing animals, their advantages and disadvantages. The BIOHAZ Panel was invited to provide further comments on the draft opinion as soon as possible. The next WG meeting is scheduled for 22 June 2016, by web-conference. The deadline to deliver the EFSA-EMA Joint Scientific Opinion is 20 December 2016.

6.3 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)[10]

The WG chair presented the progress of this mandate. The approach of the WG is to draft a document that is describing the principles of HACCP and Pre-requisite Programmes in a way that small retailer can understand. This is reflected in the ranking of products instead ofranking hazards. The methodology will be described in detail and kept simple to enable small retailers to apply it to teir own business. The next WG meeting is on 29th June. The deadline to deliver the Scientific Opinion is 31 December 2016.

6.4 Scientific Opinion on Listeria monocytogenes contamination of ready-to-eat (RTE) foods and the risk for human health in the EU[11]

The third WG meeting took place on 28-29 April 2016 in Parma. The WG Chair informed that presentations were provided at that meeting on the EU-wide data on *Listeria* in RTE foods, EFSA's food consumption database

[9] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00216
[10] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00593
[11] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00597

and the *Listeria* outsourcing activity 2. Also uncertainty was discussed in the presence of the hearing expert Andy Hart who will give support to the uncertainty assessment. He shortly reminded the Panel about the approach that would be used for answering ToR1 and ToR2. He informed that Sophie Roussel has been added to the WG as hearing expert to represent the EURL *Listeria monocytogenes.* The next (fourth) WG meeting is scheduled for 20-22 June 2016 in Athens. The deadline to deliver the Scientific Opinion is 31 July 2017.

6.5 Request for an EFSA Scientific Opinion on the risk for the development of Antimicrobial Resistance (AMR) due to feeding calves with milk[12]

The third WG meeting (Web Conference) took place on 31 May 2016 in Parma. The WG chair presented 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 need to request data for colostrum generated within a Dutch project was identified. The next WG physical meeting is planned for 27 June 2016. The deadline for the delivery of the Scientific Opinion is December 2016.

6.6 Scientific Opinion on the evaluation of the safety and efficacy of Listex P 100 for reduction of pathogens on different ready to eat (RTE) food[13]

The 7th WG meetings took place on 4 May 2016 in Parma to perform the expert knowledge elicitation (EKE). The 8th WG meeting took place on 13 May 2016 by webmeeting to discuss the draft scientific opinion. At this meeting it was decided to contact the applicant regarding two clarifications. The applicant has also been contacted on the confidentiality in the production process of Listex™ P100 and provided this information on 30 May 2016. The WG Chair presented the assessment of the efficacy (ToR 2) and the outcome of the meta-analysis. This was followed by a presentation and discussion of the outcome of the EKE. The whole draft opinion was discussed in detail. The next WG meeting will take place on 10 June by webmeeting.

6.7 Request for a scientific opinion on genetic resistance to TSEs in goats[14]

[12] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00611
[13] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00428

An update of the work done so far was presented to the Panel. The deadline for adoption of the scientific opinion was originally agreed on 31 March 2017. Due to the implementation of three TSE mandates simultaneously in the second half of 2016, a request for extension of the deadline for delivery of the opinion to 30 September 2017 has been made to DG SANTE. The working group has been established and the profile of all its members was briefly described. The initial work plan was also presented which includes the first working group meeting on 28-29 June 2016. The second meeting had been provisionally scheduled for 2 August 2016, but following the extension of the deadline, the chair will discuss the possible postponement during the first working group meeting.

6.8 Self-task mandate on requirements for the development of microbiological criteria[15]

The WG Chair approved the WG composition for this new self-task mandate for a Scientific Opinion on the requirements for the development of microbiological criteria on 30 May 2016. All invited WG members expressed interest to join this WG. Currently DoIs are being submitted by experts' and evaluated internally. The first WG meeting is expected to take place in July or early September. The deadline for adoption of the Scientific Opinion is 31 October 2017.

7. New Mandates

7.1. Self-task mandate on public health risks associated with hepatitis E virus as a food-borne pathogen[16]

Rosina Girones was appointed as WG chair by written procedure on 25 May 2016. The WG chair presented the terms of reference and invited Panel members to express their interest for joining the WG. External experts have been invited and their ADoIs are currently assessed. The first WG meeting is scheduled for September 2016. The deadline for adoption of this opinion is June 2017.

7.2. Request for a scientific opinion on BSE cases born after the total feed ban[17]

On 23 May 2016, a new mandate for a Scientific Opinion has been received by EFSA from the European Commission and it has been allocated to the BIOHAZ Panel. The purpose of this mandate is to provide

[14] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00268
[15] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00227
[16] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00315
[17] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00350

updated information on the possible origin of the BSE cases born after the total feed ban. The terms of reference were discussed in detail. An *ad hoc* WG will be established. Giuseppe Ru was appointed by the Panel Chair to take the role of Chair of the WG. The original deadline for adoption of the scientific opinion was 31 March 2017. Due to the implementation of three TSE mandates simultaneously in the second half of 2016, a request for extension of the deadline for delivery of the opinion to 30 June 2017 has been made to DG SANTE.

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 78th Plenary meeting of the Scientific Committee took place in Parma on the 20 April 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 next WG meeting is planned for 5/6 July 2016.

8.1.5 Scientific Committee standing WG on Guidance review

None

[18] http://www.efsa.europa.eu/en/events/event/160420a

8.2. EFSA including its Working Groups /Task Forces

8.2.1 Scientific Network on BSE-TSE and MRA

The next BSE-TSE Network meeting will take place on 5/6 October 2016 in Parma.

The next MRA Network meeting will take place on 11/12 October 2016 in Parma.

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 of a previous mandate to EFSA, a second exercise aimed at analysing the relationships between antimicrobial use and resistance in humans, animal and food addressing available data on years 2013, 2014 and 2015 has been required by the EC. The deadline agreed for completion of this activity is end of June 2017. An interagency working group (EFSA, EMA, ECDC) is being established.

8.3. European Commission

None

9. Other scientific topics for information and/or discussion

9.1. Self-task mandates of the BIOHAZ Panel

None.

9.2. EMA mandate: Updated opinion on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health

J. Threlfall gave a presentation on the draft EMA paper on the update of the AMEG colistin advice that was released for consultation until 26th June 2016, and that can be accessed in the following links:

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

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/05/news_detail_002536.jsp&mid=WC0b01ac058004d5c1

http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500207233&mid=WC0b01ac058009a3dc

9.3. EFSA's future use of FDA-iRISK

A discussion on the iRISK tool took place. The BIOHAZ Panel noted that FDA had taken on board all recommendations made from the Panel on improvements in the past Risk Ranking BIOHAZ Opinions. Several Panel members have participated on recent web-seminars organised by FDA and provided feedback to the Panel on the suitability of the tool for future BIOHAZ risk assessments. While the tool was found optimal for application in the context of BIOHAZ needs, some aspects on data confidentiality remain to be clarified from EFSA. The Panel will gather a list of important aspects to be further clarified to be communicated to the FDA secretariat.

10. Any other business

The Panel was informed about the preliminary dates selected for the Panel meetings in 2017.

The publication of scientific papers after BIOHAZ opinions was discussed. It was concluded that the Panel will be informed beforehand at the stage of drafting the papers, and that flexibility would be allowed in order to reach the necessary agreement from all Panel members. EFSA rules in force would apply for internal approval of any manuscript.

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 7.1 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