European Food Safety Authority

Biological Hazards and Contaminants Unit (BIOCONTAM UNIT)

Scientific Panel on Biological Hazards
Minutes of the 93rd Plenary meeting
Held on 3-4 December, Parma (Italy)
(Agreed on 15 January 2015)

Participants

- **Panel Members:**

  Olivier Andreoletti, Dorte Lau Baggesen[1], Declan Bolton, Patrick Butaye, Paul Cook, Robert Davies, Pablo S. Fernandez-Escamez, John Griffin, Tine Hald, Arie Hendrik Havelaar, Konstantinos Koutsoumanis, Roland Lindqvist, James McLauchlin, Truls Nesbakken, Miguel Prieto, Antonia Ricci[1], Giuseppe Ru, Moez Sanaa, Marion Simmons, John Sofos (apologies), and John Threlfall.

- **European Commission and/or Member States representatives:**
  - Marina Marini, Koen Van Dijck (DG-SANCO)[1]

- **EFSA:**
  - BIOCONTAM Unit: Ernesto Liebana, Winy Messens, Sandra Correia, Maria Teresa Da Silva Felicio, Pablo Romero-Barrios, Pietro Stella (Scientific staff), Emmanouil Chantzis (trainee)
  - Legal and Regulatory Affairs (LRA) Unit: Citlali Pintado (for items 1-5)
  - Communications Channel (COMMS) Unit: Francesca Matteucci (for items 7.2 and 7.3)
  - Assessment and Methodological Support (AMU) Unit: Elisabetta Suffredini (guest science)

- **Observers: (In application of the guidelines for Observers[2])**
  - Silvia Bonardi[3] (University of Parma, Parma, Italy), Christophe Dufour (Silliker, Mérieux NutriSciences, Cergy Pontoisen, France), Rosario Musumeci (University of Milano-Bicocca, Monza, Italy), Mohamed Sharaf (General Organisation Of Import and Export control, Alexandria, Egypt), Fabio Zuccon (Istituto Zooprofilattico Piemonte, Liguria e Valle d'Aosta, Torino, Italy)

[1] Present on 4 December 2014 only.
[2] http://www.efsa.europa.eu/en/stakeholders/observers.html
[3] Present on 5 December 2014 only.

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1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from John Sofos, and from D. L. Baggesen and A. Ricci for the second day of the meeting.

2. Brief introduction of Panels /SC members and Observers

All participants were invited by the Panel Chair to introduce themselves.

3. Adoption of agenda

The agenda was adopted with changes. The item 11.1 "JIACRA Working Group – update on activities" was revised to "JIACR and AMEG WG –summary of activities".

4. Declarations of Interest of Scientific Committee/Scientific Panel/ Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director on Declarations of Interest[5], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific 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.

5. Presentation of the Guidelines for Observers

A presentation on EFSA Guidelines for Observers during open Plenary meetings was given by the acting Team Leader of the BIOHAZ Team. This included the code of conduct for Observers to be followed before, during and after attendance to the open Panel meetings. Observers were given the possibility to ask questions in relation to EFSA's work in writing beforehand in the registration form for the open Panel meeting. These questions would be answered in the dedicated session at the end of the meeting. The Panel Chair also invited the Observers to pose questions at some moments during the meeting.

6. Agreement of the minutes of the the 92nd Plenary meeting held on 22-23 October 2014 , Madrid (Spain)

The minutes of the 92nd Plenary meeting held on 22-23 October 2014 were agreed by written procedure on 27 October 2014[6].

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[6] http://www.efsa.europa.eu/en/events/event/141022-m.pdf

7. Scientific outputs submitted for possible adoption

7.1 Scientific opinion on the risk posed by pathogens in food of non-animal origin. Part 2 (other): *Salmonella*, *Yersinia*, *Shigella* and *Norovirus* in bulb and stem vegetables and carrots[7]

The last WG meeting took place in Murcia on 24 October 2014. The draft scientific opinion was presented by the WG Chair and after thorough discussion was adopted on 4 December 2014.

7.2 Scientific opinion on the development of a risk ranking toolbox for EFSA BIOHAZ Panel[8]

The last WG meeting took place on 18 November 2014 *via* web conference. The draft scientific opinion was presented by the WG Chair and after thorough discussion was adopted on 4 December 2014.

7.3 Scientific opinion on the public health risks related to the consumption of raw drinking milk[9]

The last WG meeting took place in Parma on 4-5 November 2014. The draft scientific opinion was presented by the WG Chair and after thorough discussion was adopted by on 4 December 2014.

7.4 Panel statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 1: Suitability of taxonomic units notified to EFSA until July 2014[10]

The last WG meeting took place on 12-13 November 2014 *via* web conference. The draft panel statement was presented by the WG Chair and after thorough discussion was adopted on 4 December 2014.

8. Scientific outputs submitted for discussion

8.1 Scientific opinion on the public health risks associated with Enteroaggregative *Escherichia coli* (EAggEC)[11]

The first meeting of the WG was held in Parma on 11 November 2014. The WG Chair updated the Panel on the discussions held during the meeting, in particular in relation to the interpretation of the Terms of Reference (ToRs) by the WG and on the methodology to be followed in the assessment (including a review of the literature on the subject). Of note is that in accordance with current nomenclature, 'EAggEcC' will be changed to 'EAEC'. The Panel agreed on the change of nomenclature and the interpretation of the ToRs and on the proposed methodology, and advised that an extensive literature search should be conducted and documented in detail by the WG to ensure that a transparent and harmonised process is followed in the identification of the relevant scientific literature. The deadline to deliver the scientific opinion is end of December 2015.

8.2 Scientific opinion on the update of the list of QPS recommended biological agents intentionally added to food or feed as notified to EFSA[12]

The fourth WG meeting took place on 12-13 November 2014 *via* web conference. The revision of the list of microorganism recommended for the QPS list in 2013. Their qualifications will be revised according to new scientific knowledge through an Extensive

[7] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00176
[8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00014
[9] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01026
[10] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00611
[11] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00536
[12] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00189

Literature Search (ELS) being developed by the Assessment and Methodological Support Unit (AMU), and in close collaboration with the WG. The protocol and approach to follow were further refined. The scientific opinion is to be finalised by December 2016.

9. New Mandates

None.

10. Feedback from the Scientific Committee/the Scientific Panel, EFSA, the European Commission

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

10.1.1 Scientific Committee

The Chair of the BIOHAZ Panel highlighted the main items discussed in the 70th plenary meeting of the Scientific Committee held in Parma on 11-12 November 2014. In particular the statement on fish consumption, the outcome of the public consultation of the document "Transformation to an Open EFSA", and the feedback from the Panels on Additives and Products or Substances used in Animal Feed (FEEDAP) and on Genetically Modified Organisms (GMO) and the Annual Meeting of the Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed. Other topics are discussed in more detail under 10.1.2 - 10.1.4. The minutes of this meeting will be published on the EFSA website[13].

The next Scientific Committee meeting is scheduled for 18-19 February 2015 in Parma.

10.1.2 Scientific Committee Standing Working Group on Emerging Risks[14]

No meeting has been held since the last Panel meeting in October 2014. The next meeting will be held in Parma on 8 December 2014.. The draft report on the identification of emerging risks is due in June 2015.

10.1.3 Scientific Committee Working Group on Uncertainty in Risk Assessment[15]

A presentation was provided on the progress since the last meetings that took place in Parma on 29 October 2014 and 2-3 December 2014. The next meeting will take place on 15-16 January 2015 in Brussels.

10.1.4 Scientific Committee Working Group on production and consumption of insects as food and feed[16]

This *ad hoc* WG deals with a request from the European Commission on production and consumption of insects as food and feed. Two BIOHAZ Panel experts are involved in this WG. WG meetings were held on 3 and 11 November 2014 through web conferences. The next meeting will take place on 4 December 2014 in Parma. The ToRs and the methodology that will be used were presented to the BIOHAZ Panel.

The BIOHAZ Panel agreed to include this item as a standing item on the agenda of future Panel meetings.

[13] http://www.efsa.europa.eu/en/events/event/141111.htm
[14] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00641
[15] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00738
[16] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00578

10.2 EFSA including its Working Groups / Task Forces

10.2.1 Scientific report on the evaluation of the temperature to be applied to pre-packaged fishery products at retail level (Art. 31)[17]

The second WG meeting took place in Parma on 2 December 2014. Revised ToRs of the mandate were received from the Commission. The assessment currently refers to prepacked (fresh) fishery products which include (i) fresh fishery products, (ii) thawed unprocessed fishery products and (iii) cooked and chilled products from crustaceans and molluscs. The Table of Contents of the report and the approach, including the models, that will be used were presented and agreed upon. The next meeting is scheduled for 20 January 2015. The deadline for the scientific report has been extended from 31 December 2014 to 30 June 2015.

10.2.2 Scientific report on the update on the risk of transmission of Ebola Virus (EBOV) via the food chain[18]

Following the publication of the scientific report of EFSA[19] that was focussed on the transmission of EBOV through bush meat, the Commission requested EFSA to expand the ToRs 1, 2 and 3 of the original mandate *to cover the risk of transmission of* EBOV *through food in general, and in particular* via the imports of plants/fruits/vegetables and the products thereof. EFSA proposed the ToRs in the reply to this letter as *"Assess the risk of foodborne transmission of Ebola virus to persons in Europe arising from the consumption of raw foods imported from African countries where human outbreaks due to Zaïre Ebola virus (ZEBOV) have occurred"*.

The same *ad hoc* EFSA WG will be used to help with the preparatory work in the development of this scientific report of EFSA. Winy Messens (BIOCONTAM Staff member) will be the Chair for this WG. The delivery of the report by the end of March 2015 was proposed. The report would then be tabled for endorsement at the BIOHAZ Plenary meeting on 4-5 March 2015.

The BIOHAZ Panel was informed that a fit-for-purpose risk assessment will be undertaken. The use of a risk profile approach for this was agreed.

10.2.3 Scientific Network on BSE-TSE and MRA

The last meeting of the MRA Network took place in Parma on 25-26 November 2014. A short briefing was provided; the Agenda can be found on the EFSA website[20]. The minutes will be made available under the same link. The presentations have been made available to the BIOHAZ Panel members.

The next meetings of the BSE-TSE and MRA Network are foreseen to take place in Parma during Autumn and Spring of 2015, respectively.

10.3 European Commission

The European Commission (EC) representative provided feedback on the activities of the European Commission in relation to the issued scientific opinions of the BIOHAZ Panel. The representative of the EC informed the Panel about future mandates and their request dates.

11. Other scientific topics for information and/or discussion

11.1 JIACRA and AMEG Working Group – update on activities

The presentation of the Joint ECDC-EFSA-EMA report on consumption of antimicrobials and antimicrobial resistance in animals, food and humans (JIACRA) has been postponed to the next BIOHAZ Plenary meeting.

[17] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00528
[18] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00901
[19] http://www.efsa.europa.eu/en/efsajournal/doc/3884.pdf
[20] http://www.efsa.europa.eu/en/events/event/141125.htm

A summary of the report of the Antimicrobial Advice *ad hoc* Expert Group (AMEG) "Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals" was presented to the BIOHAZ Panel. The report is expected to be released by the end of December 2014 – beginning of January 2015.

11.2 EFSA's Scientific Colloquium N°20 "Whole Genome Sequencing of food-borne pathogens for public health protection"

The draft summary report of EFSA's Scientific Colloquium N°20 "Whole Genome Sequencing of food-borne pathogens for public health protection"[21] that took place in Parma on 16-17 June 2014 is being finalised and is foreseen for publication by beginning of January 2015.

11.3 EFSA's 2nd Scientific Conference in the context of EXPO 2015

The World EXPO 2015 exhibition in Milan, which will have food as its central theme, EFSA will hold its second scientific conference "Shaping the Future of Food Safety, Together"[22] on 14-16 October 2015. The conference will focus on two major themes − Risk Analysis and Science, Innovation and Society – and will be organised in plenary and breakout sessions. One of the latter is in the field of the BIOHAZ Panel and will cover "Microbiological risk assessment: Challenges and opportunities".

11.4 Call for proposals for new grants – GP/EFSA/AFSCO/2015/01

EFSA has launched a call[23] for research proposals "New approaches in identifying and characterizing microbiological and chemical hazards" restricted to the list of competent organisations. Following areas were included: (i) Molecular approaches for identifying and characterising microbial foodborne pathogens, specifically using whole genome sequence (WGS) analysis, and (ii) Development and application of read across methodologies to the hazard assessment of chemicals in the food safety area. The deadline for submission of proposals is end of April 2015.

11.5 Consultation Draft European Union Summary Report on Zoonoses and Food-borne Outbreaks 2013

Panel experts were reminded about the consultation of the draft EU Summary report on zoonoses and food-borne outbreaks in 2013. Comments are welcomed by 8 December 2014.

12. Questions from and answers to Observers (In application of the guidelines for Observers)

The Chair and Panel members answered the written questions submitted by the observers and the Chair welcomed any additional questions.

Question 2. Considering the prevalence of *stx* in raw animal origin food such as meat or milk, what applicable approach for food industry operator for practical application based on the exclusive use of *stx* in the case of high risk food? We suggest *stx* alone could be used as a "process indicator" more than a safety criteria as suggested in the actual diagrams discussions, focusing safety criteria approach on strains with complementary virulence factor presence .

Answer to question 2. There is no consensus on the optimal strategy to characterise the virulence factors (genes) for human pathogenic STEC. It is not possible to fully define human pathogenic STEC or identify factors for STEC that absolutely predict the potential to cause human disease. The detection of shiga toxins alone or genes encoding for such shiga toxins is not a sound scientific basis for assessing the disease risk to the consumer. There is no single or combination of marker(s) that defines a „pathogenic STEC". Strains positive for shiga toxin 2 gene (*stx2*)- and *eae* (intimin production)- or [*aaiC* (secreted protein of EAEC) plus *aggR*

[21] http://www.efsa.europa.eu/en/events/event/140616.htm
[22] http://www.efsaexpo2015.eu/
[23] http://www.efsa.europa.eu/en/art36grants/article36/gpefsaafsco201501.htm

(plasmid-encoded regulator)] genes are associated with a higher risk of more severe illness than other virulence factor combinations. Other virulence gene combinations and/or serotypes may also be associated with severe disease in humans, including haemolytic uraemic syndrome (HUS). This molecular approach has been recently proposed in a scientific opinion by the BIOHAZ Panel[24], utilising genes encoding virulence characteristics additional to the presence of *stx* genes. This molecular approach must be regarded as provisional because screening STEC for the presence of *eae, aaiC or aggR* genes is not routinely undertaken. The performance of this proposed approach needs to be verified with well-characterised isolates from cases of human infection and from food-producing animals and foods.

If the diagrams mentioned in this question are those included in the "Draft guidance document on the application of article 14 of Regulation No. 178/2002 as regards food contaminated with STEC, it should be noted that these are still under discussion with member states (MSs) and the European Commission.

Question 3. Considering the prevalence observed on Norovirus GI, GII in food such as berries, vegetables or molluscs should safety criteria be exclusively based on presence / absence of specified virus or include quantitative approach?

Answer to question 3. The establishment of microbiological criteria should ideally be based on: (i) the current health risk associated to the considered food/pathogen and (ii) the evaluation of the extent of public health protection provided by each specific criterion. The impact of the safety criterion class (2-class, 3-class) and parameter values (n, c, m, M) on public health risk can be evaluated via risk assessment. The final selection of a safety criterion is a risk management decision. It needs to be noted that a presence/absence criterion is also quantitative in which the threshold limit (value of parameter m) is the detection limit of the analytical method. The sensitivity and specificity of the analytical method are also important when establishing safety criteria since they can significantly affect the uncertainty of the estimated impact of the criteria to public health risk.

In conclusion, the recommendation of safety criteria for Norovirus in food such as berries, vegetables or molluscs should ideally be based on the assessment of the public health risk associated to this hazard, the impact of the proposed criteria to public health and the accuracy of the available analytical methods.

Question 4. How can BIOHAZ play a role in food safety field?

Answer to question 4. The BIOHAZ Panel provides independent scientific advice on biological hazards in relation to food safety and food-borne diseases. This covers (i) food-borne zoonoses (animal diseases transmissible to humans), (ii) Transmissible spongiform encephalopathies (BSE/TSEs), (iii) Food microbiology and (iv) Food hygiene and associated waste management issues.

BIOHAZ carries out risk assessments in order to produce scientific opinions and advice for risk managers. The Panel's risk assessment work is based on reviewing scientific information and data, together with mathematical risk modelling where appropriate, in order to evaluate the risks posed by a given issue. This helps to provide a sound foundation for European policies and legislation and supports risk managers in taking effective and timely decisions. More information can be found on EFSA's website[25].

13. Any Other Business

13.1 New features of the Declarations of Interest system

The BIOHAZ Panel members were informed about the new rules on Declarations of Interest (DoIs) in 2014. EFSA's framework on DoI policy since 2003 and the current policy were highlighted.

[24] http://www.efsa.europa.eu/en/efsajournal/doc/3138.pdf
[25] http://www.efsa.europa.eu/en/panels/biohaz.htm

13.2 New advanced trainings for panel members

Panel Members were reminded about the four additional training courses that have been fixed for 2015: (i) Evidence base for risk assessment (9-11 February 2015), (ii) Variability and uncertainty (11–13 February 2015), (iii) Exposure assessment (16-18 February 2015), and Evidence base for risk assessment (20-22 April 2015). The deadline for applications is 10 December (for the courses taking place in February) and 23 February (for the April course).

Item(s) for Closed Session

14. Scientific outputs submitted for discussion

14.1 Scientific opinion on the treatment by successive filtration as an alternative method for the HTST pasteurization of bovine colostrum (category 3 animal by-product)[26]

The request for a scientific opinion for the evaluation of a new sanitizing treatment method of bovine colostrum by-products category 3 from the French Competent Authority was officially received by EFSA. An *ad hoc* WG has been established to help with the preparatory work in the development of the scientific opinion. The current status of the application was explained to the Panel. The applicant provided missing information which is currently being checked for completeness. The deadline to deliver the scientific opinion is 6 months following receipt of a complete application.

[26] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00703