Scientific Panel on Animal Health and Welfare

Minutes of the 99th Plenary meeting

Held on 13-14 September 2016, Parma, (Italy)

(Agreed on 30 September 2016)

Participants

- Panel Members

Anette Bøtner, Dominique Bicout, Andy Butterworth, Paolo Calistri, Klaus Depner, Sandra Edwards, Margaret Good, Christian Gortazar Schmidt, Virginie Michel, Miguel Angel Miranda, Simon John More, Mohan Raj, Søren Saxmose Nielsen, Liisa Sihvonen, Hans Spoolder, Jan Arend Stegeman, Hans-Hermann Thulke, Antonio Velarde Calvo, Preben Willeberg, Christoph Winckler

- EFSA

ALPHA UNIT: Francesca Baldinelli, Alessandro Broglia, Denise Candiani, Ewelina Czwienczek, Sofie Dhollander, Andrea Gervelmeyer, Andrey Gogin, Giuseppe Stancanelli, Frank Verdonck

- EUROPEAN COMMISSION

Marina Marini, Pierangelo Bernorio, Laszlo Kuster, Barbara Logar, Laura Perez Alvarez (DG SANTE)

1. Welcome and apologies for absence

The chair welcomed the meeting participants. Apologies were received by Bruno Garin-Bastuji.

2. Adoption of the agenda

The agenda was adopted without changes

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Declarations of Interests (DoI), EFSA screened the Annual (ADoI) and Specific Declaration of Interest (SDoI) provided by the Panel Members for the present meeting. The Panel members were asked to confirm that no further interests had to be declared in the context of the agenda of the meeting. No conflict of interest has been identified.

4. Agreement of the minutes of the 98th Plenary meeting held on 20 and 21 June 2016, Parma (Italy)

The minutes of the previous plenary meeting have been adopted by written procedure.

5. New Mandates

- **Request for scientific and technical assistance on Lumpy Skin Disease**

EC presented the mandate and reported the positive feedback to EFSA about the outputs produced this year and the good collaboration.

An update was given about the situation of LSD in the last year till today. Due to the need of continuous updating the validity of control measures, it was remarked to try to collect data also in order to confirm what was predicted by the model on vaccination effectiveness.

It would be useful to estimate within-herd transmission and estimating effectiveness of vaccination within-farm (the needed vaccine coverage to reduce within farm transmission) and to estimate between farm transmission, as R_0 or infection kernel, which is now incorporated in the model still according to Israel reality.

There should be a need of collecting demographic, animal movements, epidemiological, and vector-related data (abundance, land cover, climatic). Gaps in information will be most likely on vector role, a check will be made with MS to explore if, where and what kind of data on which possible LSD vector is collected (mosquitoes, stable flies, blood sucking insects, ticks), otherwise possible proxies will explored (seasonality according to previous outbreaks). Data model will be prepared and share with MS to check what kind of information is available. Lessons learnt from the collaboration on ASF will be considered.

- **5.1. Request for a scientific and technical assistance and a scientific opinion concerning the risk of survival, establishment and spread of *Batrachochytrium salamandrivorans* (Bsal) in the EU**

The Commission presented the background and the terms of reference of the mandate.

It was agreed that after the delivery of the scientific and technical assistance it should be critically assessed if a full risk assessment under Art 29 is warranted or feasible. No full risk assessment would be needed, if i) not enough scientific evidence has been identified to conclude that an infection with Bsal leads to disease/mortality or ii) the available scientific evidence allows to conclude that Bsal is not associated with disease/ mortality in salamanders.

Panel members were invited to volunteer for providing feedback on the proposed approach for the scientific and technical assistance (data and methodology to be used) during the planning stage and peer-reviewing the draft scientific report.

6. Scientific outputs submitted for possible adoption

a. Scientific opinion on health of honey bee colonies (EFSA-Q-2015-00047)

The draft scientific opinion was discussed, in particular the parts related to TOR4. The target audience for this part of the opinion was clarified and it was noted that stratification (e.g. bee subspecies, production type) would be useful to implement when analysing collected data. Decisions based on expert opinion would be required in any method aiming to differentiate the health status of a honeybee colony. The 'health status index' concept was discussed in detail and a paragraph was added regarding the absence of a gold standard, weighting of indicators and setting of thresholds. The four approaches describing examples of how bee health data could be analysed, were moved to the Appendix. A few conclusions and recommendations were edited to clarify their meaning. The opinion was unanimously adopted by the Panel.

7. Scientific outputs submitted for discussion

- **Scientific opinion on entry routes into the EU of vector borne diseases (EFSA-Q-2014-00187)**

The preliminary results of the assessment of the rate of entry, the level of transmission and the probability of establishment of bluetongue (BTV) and Main Drain virus (MDV), as well as the extent of spread, the probability of persistence and the annual impact were discussed with the Panel. Additionally, an update on the developments regarding the on-line version of the Mintrisk model, and the storymaps of MDV and BTV were presented for discussion.

- **Request for a joint EFSA and EMA 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 (EFSA-Q-2015-00216)**

The AHAW Panel was requested to read and provide feedback on the sections prepared by AHAW (Abstract, Summary, Chapter 1.7: circumstances and diseases that require most AM, Chapter 3.2.1 and 3.2.2.: management and husbandry procedures reducing the need for AM). In addition, the Panel provided input into the overall report, especially on recommended options to reduce AM usage including advantages and disadvantages for animal health and welfare (chapter 3.3.1), conclusions (chapter 4.3), and recommendations (chapter 4.5). The Panel revised some recommendations e.g. on the need of identification of CIAs, on the quantification of AM usage at farm level, on the limitation/banning of prophylaxis and metaphylactic use, on the need to consider AMR resulting from human AM usage, on the tertiary prevention and the need to highlight

more on housing aspects, and to put more emphasis on the fact that animal welfare aspects should be considered before implementing primary and secondary prevention measures. Several comments on the vaccination section were raised and will be passed to the author of the section. The revised recommendations will be discussed at the next RONAFA meeting on 20 September 16. The scientific opinion will be tabled for endorsement at the October AHAW Panel plenary meeting, before adoption by the BIOHAZ Panel/EMA Committee for Medicinal Products for Veterinary Use (CVMP) in November/December.

8. Feedback from the ad-hoc Working Groups of the AHAW Panel

- **Scientific opinion on avian influenza (EFSA-Q-2015-00214)**

The Panel was informed that Yali Si joined the working group. An explanation was provided how her group created the predictive risk map of HPAI H5N1 occurrences in wild birds in Europe (published in 2010). The model was generated using 309 data points (2005-2006) and validated using 23 data points (2007-2008). An analysis of additional data collected by the AI consortium resulted in the identification of 45 additional, non-common data points. The Panel agreed to ask Yali Si to use these 45 points to further validate the model. Furthermore, an update was provided on the main changes of the HPAI introduction model that are currently under investigation: insertion of natural mortality, virus persistence in the environment, a non-linear relation between the probability of a poultry holding to become infected and the number of infected wild birds. It is foreseen to have an in depth discussion on the HPAI model description and the preliminary model outcomes during the October plenary. A text will be provided before the meeting with the request to provide comments that need to be discussed. The need to collect poultry population data at EU level was supported by the Panel. These data would be very useful in the analysis of the surveillance activities and would maybe allow testing the HPAI entry model for a specific area.

- **Scientific Opinion on the listing and categorisation of animal diseases in the framework of the Animal Health Law (EFSA-Q-2015-00713; EFSA-Q-2016-00156)**

The mandate received in June 2016 on the listing and categorization of further 13 animal diseases in the framework of the AHL (EFSA-Q-2016-00156) was presented to the Panel experts.
The methodology for the overall approach to the mandates was recapped and the Panel was updated on the inputs required by Panel members for the steps of reviewing the factsheets and for the expert judgement. The list of the Panel members volunteering

(i) for reviewing the disease fact-sheets that are drafted by external disease experts following the criteria laid down in art.7;
(ii) for taking part of the Expert Judgement (EJ) for the eligibility of the diseases for listing according to art.5 and for categorization according to art.9 criteria

was presented.

The Panel agreed that the reviewers need to have scientific expertise on the disease to be reviewed as they need to assess the integrity of the fact-sheet, (i.e. they go through the first draft of the factsheet and highlight knowledge gaps, missing/wrong information, missing references, possible biases introduced by the author (e.g. overestimation of impact of the disease), check if the factsheets cover what is requested by the criteria of art. 7, so that the judgement regarding the eligibility of the diseases for

listing according to art.5 and for categorization according to art.9 criteria is possible). Instructions/guidelines will be provided to reviewers to facilitate their work. It was agreed that EFSA staff pre-screens the fact-sheets checking the completeness of the fact-sheets. A reviewer can take care of more than one disease/fact-sheet on the basis of his/her expertise. Panel members with expertise on animal welfare volunteered for reviewing the assessment of those parameters concerning the impact of the disease and of the disease control measures on the animal welfare of affected population across the diseases. In addition, they can review other parameters in case they are comfortable in doing that.
All Panel members can participate in the judgement regarding the eligibility of the diseases for listing according to art.5 and for categorization according to art.9 criteria, since for this step no have in-depth knowledge on the single disease is needed. Participants to the EJ will be requested to integrate the evidence provided with the fact-sheets to give a categorical answer (Y/N/na) the fulfilment of the art.5, art.9 and art.8 AHL criteria. It was noted that all panel members are able to contribute to this assessment for all diseases as the basis for the judgement is the factsheet.
With the aim of clarifying the role of the factsheet reviewers and of the participants to the EJ, an example of i) art.7 parameters to be reviewed; and of ii) art.5 criteria to be assessed in the EJ on the basis of the information provided for art.7 parameters were presented. Panel members were invited to indicate their availability to contribute to the two activities to finalise the list of reviewers (at least 2 reviewers per disease) and of the participants to the EJ.

- **Scientific opinion on Bluetongue (EFSA-Q-2016-00160)**

The mandate from the Commission on Bluetongue (BT) includes 5 TORs. The assessment of ToR 1-3 will be tabled for adoption in January 2017, the assessment of the ToR 4-5 will be presented for adoption in June 2017.

For the TOR 1.1 (assessment of the duration of a BT vaccination campaign intended to achieve disease freedom in a country) it was communicated that the proposed approach is to use a BT spread model to simulate a spread in a certain area after incursion of the virus, and test how many vaccination campaigns are required to make the epidemic to fade out.

For the TOR 1.2 (assessment of the probability of BT recurrence) the proposed approach is to use the spread model to test which level of low level circulation can be reached in a population of domestic ruminants under different scenarios. For the low level circulation in wildlife a draft spread model was presented, but this was criticised due to the absence of a baseline model of BT dynamics in wildlife. It was agreed to provide a detailed documentation of the model and its parameterisation to panel members and to further discuss this topic with the WG.

For TOR 1.3 (assessment of the suitability of the provisions on surveillance laid down in Regulation (EC) No 1266/2007) the proposed approach is to use the spread model, to simulate what could be the lowest level of seroprevalence that can be reached and compared this to the ability of current surveillance scheme to detect it different surveillance schemes. The previous EFSA opinion on BT surveillance and monitoring will be also reviewed.

For TOR 2 (protection from maternal antibodies and vaccination as options for safe trade applicable to movements of live animals from restricted zones) assessment questions were presented and agreed as defined in Prometheus protocol. Data will be collected through procurement, and provided by end of September.

For ToR 3 (protection from BTV vectors) the first sub-question is to review and update previous opinions as regards vectors ecology, in order to have more accurate and applicable criteria for the determination of the vector-free period. The proposed

approach is to attempt to correlate vector abundance with BTV circulation data in selected areas of countries for which data is available (case studies and data from IT).

For TOR 3.2 (over-wintering mechanisms in hosts and vectors), considering the scarcity of new available evidence, the approach is to update the previous EFSA opinion with recent literature and expert knowledge.

For TOR 3.3 (appropriateness of the use of insecticides and repellents against Culicoides) the approach is to update the previous opinion with new evidence, specifically, literature collected in the frame of the VBD mandate, ECHA's data on active substances efficacy, and data on products authorised by national authorities.

- **Scientific opinion on animal welfare aspects in respect of the slaughter or killing of pregnant livestock animals (cattle, pigs, sheep, goats, horses) (EFSA-Q-2015-00477)**

A short update on the state of art of this scientific opinion was presented. Particular focus was given to the outcomes for ToR3 (the assessment of the capacity of foetuses to feel pain) since one point of discussion was whether to go ahead with the last 2 ToRs of the mandate - ToR4 (methods for stunning and killing of foetuses) and ToR5 (methods for establishing gestational age at slaughter) – which are conditional depending on the results of ToR3, namely if foetuses are capable of feeling pain. The decision will be taken by the Requestors of the mandate (4 Member States), but the Panel did agree to go ahead.

For providing an answer to ToR3, the WG has done 2 activities: a literature review and an EKE exercise with 10 relevant experts from human and veterinary fields. However, it was not possible to derive a clear yes or no answer and the WG needs to do one more step to express the uncertainty around each conclusion by comparing the information resulted from the EKE with the information extracted from literature. The scientific opinion will be tabled for an in-depth discussion by the AHAW Panel at the October plenary meeting and be tabled for adoption of the first three ToRs at the November AHAW Panel plenary meeting.

- **Scientific opinion concerning the use of low atmosphere pressure system (LAPS) for stunning poultry (EFSA-Q-2016-00327)**

The Panel was informed that the scientific documents submitted fulfil the eligibility criteria for intervention and outcome description laid down in the EFSA guidance on the assessment criteria for studies evaluating the effectiveness of stunning interventions regarding animal protection at the time of killing. In a next step, the reporting and methodological quality will be assessed. It was agreed that the WG will send some questions for clarifications to the company through the EC following the assessment of reporting and methodological quality, if these also have a positive outcome. Feedback from the company regarding the confidentiality request had not yet been provided.

9. Other scientific topics for information and/or discussion

- **Art 31 mandate on ASF – progress update**

The Panel was updated about the outcomes of the workshop on ASF that was held in Latvia with affected MS on 28-29 June, and the progress of data reporting and analysis was presented. It was noted that the methodological approaches used should be explained in details in the scientific report. It was suggested to assess the importance of between-farm spread as this pathway is the most relevant for currently not affected

countries, and to carefully assess if a differential treatment of data from MS and non-EU MS is needed in the analysis.

Any other business

None