European Food Safety Authority

ANIMAL HEALTH AND WELFARE UNIT

MINUTES OF THE 54th PLENARY MEETING OF THE PANEL ON ANIMAL HEALTH AND WELFARE

01-02 December, 2010, Parma

1. PARTICIPANTS

AHAW PANEL MEMBERS

Anette Bøtner, Don Broom, Mariano Domingo, Jörg Hartung, Frank Koenen (Dec. 2), Simon More, David Morton, Pascal Oltenacu (Dec. 1), Fulvio Salati, Mo Salman, Moez Sanaa, Mike Sharp, Jan Arend Stegeman, Endre Szücs, Hans-Hermann Thulke, Philippe Vannier, J. Webster, and Martin Wierup.

AHAW UNIT

Scientific officers: Ana Afonso, Franck Berthe, Sandra Correia Rodeia, Milen Georgiev, Andrea Gervelmeyer, Tomasz Grudnik, Per Have, Oriol Ribó, Jordi Tarrés-Call, Sofie Dhollander.

Administrative assistant: E. Franchi.

EUROPEAN COMMISSION (DG SANCO)

Marina Marini (Unit 03, Science and Stakeholders), Laurence Bonafos (Unit D5, Animal Welfare - agenda item 6.1), Francisco Reviriego-Gordejo and Maria Pittman (Unit D1, Animal Health-agenda item 6.2 via teleconference).

2. OPENING, APOLOGIES AND AGENDA

The Chairman welcomed the Panel members and other attendants.

Apologies were received from Albert Osterhaus, Marcus Doherr, and Linda Keeling.

The agenda was adopted.

The date of the May plenary meeting was changed to May 4-5 in order to ensure timely adoption of the two bluetongue opinions (see agenda item 7.5) and follow-up actions by Commission.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests (DoI), EFSA screened the Annual and Specific Declaration of Interest (SDoI) provided by the Panel Members for the present meeting. No new interests were declared in the SDoIs submitted in relation to the

current agenda. The previously declared interests were still considered valid for this plenary[1]. The Panel Members confirmed that no further declarations of interests were to be made in the context of the adopted agenda.

4. PREVIOUS MINUTES ADOPTED BY WRITTEN PROCEDURE

The minutes of the 53rd plenary meeting of the AHAW Panel were unanimously adopted by written procedure and published on the EFSA web (http://www.efsa.europa.eu).

5. NEW MANDATES

5.1. Scientific advice on risk posed by Epizootic Ulcerative Syndrome (EUS)

The Commission intends to submit a new mandate to get scientific advice on EUS.

Epizootic ulcerative syndrome (EUS) is an infection by the oomycete, *Aphanomyces invadans* that affects wild and farmed freshwater and estuarine fish. The disease is listed by the OIE[2] Part II to Annex IV to Directive 2006/88/EC includes a list of diseases for which the import, placing on the market and control rules applies. Epizootic ulcerative syndrome (EUS) is included in the above list as an exotic disease. Relevant previous work by the AHAW Panel in relation to EUS: in 2008, the AHAW Panel published an opinion on aquatic species susceptible[3] to diseases listed in Council Directive 2006/88/EC in which EUS is discussed. In 2007, the AHAW Panel published an opinion on possible vector species[4] for certain fish diseases. A systematic literature review was also performed in 2009 through an article 36 contract.

The mandate: To assess: 1) the risk of introduction of EUS in the EU by means of import from third countries 2) the risk of EUS to spread and persist within the EU and the possible significance and impact in the European Aquaculture taking account of the epidemiology, the available diagnostic methods, the susceptible species range, and the relevant environmental conditions.

6. OPINIONS SUBMITTED FOR ADOPTION

6.1. Welfare of Animals during transport (EFSA-Q-2010-00053)

The mandate: the most recent scientific information available on the welfare of animals during transport (after 2004), concerning the main farm species as follows: horses, pigs, sheep, goats, cattle, poultry and rabbits should be assessed. Risks for the welfare of the

[1] In the SDoI filled for the January plenary meeting of the AHAW Panel, Prof. A. Osterhaus declared the following interest: pandemic influenza virus. In accordance with EFSA's Policy on declarations of interests and implementing documents thereof, the interest was deemed to represent a potential conflict of interest. Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest point C.III.b, the said expert should not chair discussions related to pandemic influenza virus.

[2] http://www.oie.int/eng/normes/fmanual/2.3.02_EUS.pdf

[3] http://www.efsa.europa.eu/en/scdocs/scdoc/808.htm

[4] http://www.efsa.europa.eu/en/scdocs/scdoc/584.htm

transported animals should presented according to the following sections of Annex 1 of the Regulation (EC) No 1/2005: a) fitness for transport; b) means of transport; c) transport practices; c) watering and feeding interval, journey times and resting periods; d) additional provisions for long journeys; e) space allowances. Only outcome-based welfare indicators (i.e. based on the observations of the animals) which can be used by transporters and veterinary inspectors under commercial conditions should be detailed here.

The approach a kick-off meeting was organised with the Commission to discuss and clarify the ToRs in January 2010. A WG was constituted on March 2010 to bring ad hoc expertise. The opinion proceeds with a bibliographic review of recently published evidence. The risk assessment focuses on hazards covered by the annex 1 of the 2005 Regulation. In cooperation with JRC, a chapter was developed on methods of monitoring animal transport.

A Technical Meeting with stakeholders was attended by 22 organisations, including transport industry, livestock breeders, and animal welfare NGOs. A representative of the Animal Welfare Unit (DG Sanco, D5) and the Chair of the WG also attended the meeting. Discussions were focused on the mandate from the Commission and the AHAW approach to address it. Participants also presented new evidence and scientific and technical data on the issue of welfare of animals during transport. It was concluded that different levels of implementation and enforcement of Regulation 1/2005 occur within the EU Member States. The meeting also recognised that this issue falls outside the remits of EFSA. The discussions clarified that the AHAW Scientific Opinion will concentrate on new evidence (since 2004), related to Annex I of Regulation 1/2005. Animal-based measurable indicators which may be used in practice for veterinarians and inspectors should be also developed. The meeting highlighted that stakeholders may have information and data relevant to the question; EFSA called for such information and data being submitted for further review and assessment by the WG.

The draft opinion was presented to the Panel for possible adoption.

Discussions were mainly focused on the conclusions and recommendations, which were amended accordingly. Where no scientific evidence was found to support a conclusion it was deleted. The methodology followed to rank the hazards with highest impact on the welfare of animals during transport was also discussed as concerns were raised about the model used. The Panel agreed to take out the model from the assessment and place the list of highest ranked hazards based on the expert opinion, in the appendix.

The Scientific Opinion was adopted on 2nd December.

6.2. Monitoring for emergence of possible new pandemic influenza strains (EFSA-Q-2009-00983)

The mandate: following the global spread of pandemic H1N1 in 2009 risk managers will require a better scientific understanding of influenza viruses and in particular of the underlying factors that most strongly contribute to the emergence on influenza viruses with pandemic potential. It is also necessary to develop better methods and criteria to asses the risk such viruses may pose to people and animals.

The terms of reference address the most important factors to be monitored in animals that would suggest a risk of emergence of a new pandemic influenza strain and options of

monitoring in different animal populations for the presence of the most important factors that would suggest a risk of emergence of viruses with pandemic potential.

The approach: Two WG tele-meetings have been held to discuss the approach to the ToR and distribution of tasks. A draft report has been prepared by the WG. The opinion will be submitted for adoption.

The draft opinion was presented for discussion and possible adoption at the plenary meeting of the AHAW Panel on December 1. A number of specific comments were made to the text and conclusions and recommendations.

During this discussion it became clear that certain aspects of the scientific evidence would need to be addressed further in order to respond more precisely to the terms of reference and to draw appropriate conclusions and recommendations.

The AHAW Panel therefore did not adopt the opinion and requested further information from the working group. In order to give sufficient time to complete this, it was suggested that the deadline for this mandate, initially agreed to December 31, 2010, be extended to February 28, 2011. A letter requesting this will be sent to the Commission in due course.

7. PROGRESS REPORTS AND DISCUSSION OF CURRENT MANDATES

7.1. Development of Animal Welfare Risk Assessment Guidelines (EFSA-Q-2007-168)

The mandate: The EFSA Scientific Colloquium on "Principles of Risk Assessment of Food Producing Animals" held in Parma in December 2005 concluded that no specific standardized methodology and international guidelines exists in the field of the Animal Welfare Risk Benefit Assessment". Therefore, EFSA launched in 2007 a self-mandate with the following terms of reference: 1) To define a comprehensive harmonised methodology to evaluate risks and benefits in animal welfare, taking into consideration the various procedures, management and housing systems and the different animal welfare issues, with reference to the methodologies followed in the previous EFSA Opinions on various species; 2) the defined methodology for assessing risks and benefits in animal welfare should take into account and adapt current risk assessment methodologies, for example those for animal diseases and food safety, and also the complex range of measurable welfare outcomes; 3) the guidance document should concisely define the generic approach for working groups addressing specific areas of assessment of risks and benefits in animal welfare.

The approach the original mandate was amended in 2009 and a WG formed from Panel members. The main contents of the guidelines have been agreed by the WG.

The Panel agreed to organise a Technical Hearing on the draft document in the first quarter of 2011.

The document will be submitted to the Panel for adoption in March 2011.

7.2. Use of animal-based measures to assess the welfare of dairy cows

The mandate requested to give an independent scientific view on the use of animal- based welfare measures to assess the welfare of dairy cows, considering the parameters included in

the welfare assessment protocols of the Welfare Quality® (WQ) Project and the conclusions and recommendations of the EFSA scientific opinions on the Welfare of Dairy Cows. In particular it is requested to: 1) identify how animal-based measures could be used to ensure the fulfilment of the recommendations of EFSA scientific opinions on the welfare of dairy cows; 2) identify how the WQ assessment protocols cover the main hazards identified in EFSA scientific opinions (and vice-versa); 3) identify which relevant animal welfare issues cannot be assessed using animal-based measures for dairy cows and what kind of alternative solutions are available to improve the situation; and 4) list main factors in the various husbandry systems which have been scientifically proven to have negative effects on the welfare of dairy cows. Deadline of the Mandate is June 2011.

The approach was discussed with the Commission at a kick-off meeting in July. The WG is formed from Panel members. WG meeting was held on 25-26 October to discus approach and methods and also ToR were disused and clarified with Commission. An outline of the structure of the report has been prepared and agreed by the WG.

EFSA is procuring "Review of methodologies applicable to the validation of animal based indicators of welfare", that will be available for WG by end of February 2011.

7.3. Request for a scientific opinion and technical assistance on the public health hazards to be covered by inspection of meat

The mandate: the Commission requests a scientific opinion and technical assistance on the public health hazards to be covered by inspection of meat. The scope of this mandate is to evaluate meat inspection in a public health context; however it is specifically requested that any change suggested to current inspection methods should not jeopardize the capacity to detect certain animal diseases nor compliance with regulation on animal welfare. The animal species or groups of species to be covered are: domestic swine; poultry; bovine animals (over and under 6 weeks old); domestic sheep and goats; farmed game and domestic solipeds.

The approach The AHAW Panel will ensure that any change to current inspection does not jeopardize the capacity to detect animal diseases nor compliance with the animal welfare regulation; it is essential to determine the importance and integration of meat inspection in the EU animal health surveillance and monitoring. Interlinks with the work of other EFSA Units involved in the mandate are identified as crucial. Overarching meeting was held on 12 October and AHAW WG meeting was on 29 October. The ongoing work is focused on identification of initial list of diseases/conditions of AHAW interest and then choose a subset for further modelling based on agreed criteria. Preliminary generic model and frame of necessary data were drafted.

The work is ongoing and organised in the following main steps:

Step1: Defining diseases/conditions of interest

There was detailed discussion on the development of criteria to identify an initial list of diseases/conditions of AHAW interest. Additional criteria from points of meat inspection importance and possibilities for detection during the meat inspection were proposed and further discussed. A hierarchical system was suggested to enable diseases/conditions to be grouped. The focus of the work should primarily be on probability of detection. Welfare

indicators measured at slaughter level have the potential to provide very useful information on events on-farm and during transport.

Step 2: Modelling the impact of proposed changes to the current meat inspection system

A preliminary generic model was completed and presented. Data should be collected on: prevalence, relative risks, ante-mortem inspection SE, post-mortem Se, specific tests Se. Prevalence should be the one corresponding to the population going to slaughter. The draft model and anticipated changes were shared with BIOHAZ WG.

The WG discussed some possible directions and anticipated possible changes. From AHAW perspective, there are several key areas where the WG feel that changes could be made, to maximise effectiveness and efficiency of the meat inspection process. These include:

- Changes in the number/type of animals being inspected, based on the risk profile of the batch, farm, region or country. For example, BIOHAZ could recommend a move from 'census' sampling (that is, all animals inspected) to either representative sampling (an unbiased subset of all these animals) or risk-based sampling (focusing on those animals considered at highest risk of the public health condition of interest).
- Changes to the inspection methods, among those animals that are inspected. This might include eliminating or reducing the intensity of some inspection methods, introducing new interventions, or modifying existing interventions (for example, using less sensitive tests with a greater number of animals, using more sensitive tests with a small number of animals, using multiple tests).

Step 3: Modelling the impact of proposed changes to the current meat inspection system on the overall monitoring and surveillance system

Those likely to be most adversely impacted from the recommended changes to meat inspection. The WG anticipate including of the following:

- Those diseases/conditions where gross inspection at post-mortem is particularly important, and
- Those diseases/conditions with a strong animal welfare component (and where farmer-based reporting is most unlikely).

7.4. Development of a Guidance on health and welfare aspects of GM-Animals (EFSA-Q-2010-698)

The mandate: in March 2010, the European Commission sent a mandate requesting EFSA to develop guidance on animal health and welfare aspects of GM animals in addition to the guidance on safety assessment of GM animal-derived food and feed. This mandate had been presented by Sebastien Goux (DG SANCO) during the April plenary meeting (web-meeting). EFSA has accepted the mandate, proposing a deadline of December 31, 2011 which was agreed by the Commission. In accordance with its policy on transparency, EFSA will organise a public consultation on the draft guidance of animal health and animal welfare aspects of GM animals. The consultation is planned for the first quarter of 2011.

The approach The guidance will be developed in close cooperation with the guidance on the safety assessment of genetically modified animal-derived food and feed being developed by

the GMO Panel. The two guidance documents will form a comprehensive package to be published simultaneously.

A first WG tele-meeting has been held where aims and scope of the guidance and scientific approach and assessment principles were discussed. The aim is to prepare guidance for applicants on what data to provide on animal health and animal welfare. The format of this guidance should allow both the GMO and AHAW Panels to make a joint evaluation of dossiers given the overlap between animal health and welfare, consumer concerns including health and environmental aspects. The required level of detail of the guidance was discussed. It was noted that the GMO guidance is not a cook-book but the objectives would be to provide the principles and aims of the assessments and the kind of information needed at a general level, plus examples.

The chairman of the WG gave a short update on the work so far including an outline of the proposed structure and table of contents of the report.

7.5. Bluetongue (EFSA-Q-2010-01238 and EFSA-Q-2010-01237)

The mandate: On 27 October 2010, EFSA received a request from the European Commission for a scientific opinion on: 1) the possible additional risk posed by bluetongue serotype 8 compared to other serotypes. In addition EFSA was requested to provide recommendations on: 2) epidemiological parameters, such as the expected prevalence under different circumstances and the size of a geographical relevant area for the purpose of monitoring and surveillance programmes. Since the two terms of reference included in the request are not directly connected, two scientific opinions will be delivered, separately addressing the questions. The scientific opinions will presented to the AHAW Panel for possible adoption on 4-5 May 2011, so the outcomes may be eventually included in the proposal for new amendments to EC Regulation 1266/2007 that are planned for the first half if 2011.

The approach:

A kick-off meeting was held on 17 Nov. 2010 to clarify the terms of reference (TOR). Two working groups were created, each of which will deal with one of the two terms of reference:

1 Working Group on bluetongue serotype 8:

1.1 To answer the first part of the question, a systematic literature review (SLR) on BTV8 will be carried out to update conclusions concerning BTV8 of previous EFSA opinions. The second part of the question can be answered by a SLR focussing on transplacental transmission and transmission through insemination and embryo transfer of BTV 8 and other BTV serotypes.

1.2 To assess the impact on the epidemiology of the potential higher risk for BTV-8 for transplacental transmission (or the impact of any other special feature of this serotype) a realistic approach should be chosen by the working group within the timeframe (probably a simple qualitative risk assessment or a more descriptive approach-to be updated).

1.3 To assess the effectiveness, suitability and proportionality of risk mitigating measures based on restrictions of the movement of pregnant animals it was suggested that there is

no risk assessment needed, but that we could just evaluate the effectiveness of the mitigation measure based on the biological knowledge provided by the SRL in 1.1.

2 **Working Group on bluetongue monitoring and surveillance:**

2.1 Literature search for studies into the prevalence of BTV; analyse results of the BT monitoring and surveillance in the EU MS to define observed prevalences in different circumstances (for "circumstances" where we have insufficient data a simple modelling exercise to estimate the design prevalence will be carried out); finally provide guidance on how to best determine the design prevalence for the difference scenarios.

2.2 Analysis of the variation between the observed prevalences in adjacent epidemiological units can tell us to which extent the current epidemiological areas behave similarly and from those results we can know whether and to which size these area's can be extended and how this will depend on the specific circumstances given above.

8. OTHER ISSUES

8.1. Visit of MEP M. Paulsen to EFSA

Ms. Marit Paulsen is Member of the European Parliament and prepared the Evaluation Report of the Community Action Plan on the protection and welfare of animals (2006-2010). She visited EFSA on December 2010 and gave an address on "The EU and the Animals: new perspectives", followed by a session of questions and answers to which participated members of the Panel.