

ANIMAL HEALTH AND WELFARE UNIT

MINUTES OF THE 60th PLENARY MEETING OF THE PANEL ON ANIMAL HEALTH AND WELFARE (AHAW)

19-20 October 2011, Parma

1. PARTICIPANTS

AHAW PANEL MEMBERS

Anette Bøtner, Don Broom, Marcus Doherr, Mariano Domingo, Jörg Hartung, Linda Keeling, Frank Koenen, Simon More, David Morton, Pascal Oltenacu, 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

Franck Berthe, Denise Candiani, Sandra Correia, Sofie Dhollander, Milen Georgiev, Andrea Gervelmeyer, Tomasz Grudnik, Karen MacKay, and Oriol Ribó.

SAS UNIT

Gabriele Zancanaro

EUROPEAN COMMISSION

Marina Marini (DG Sanco, Unit 03, Science and Stakeholders).

OTHER PARTICIPANTS

Nadege Leboucq (OIE).

2. OPENING, APOLOGIES AND AGENDA

Philippe Vannier welcomed the Panel members and other participants to the meeting.

The agenda was adopted.

Franck Berthe updated the Panel on EFSA's policy on independence. He explained the nature and importance of the declarations of interest. He clarified that independence is also related to how working groups are formed, how experts are selected, as well as how scientific information and data are retrieved, appraised, and included in risk assessments.

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 Panel Members confirmed that no further declarations of interests were to be made in the context of the adopted agenda.

4. MINUTES FROM THE PREVIOUS PLENARY MEETING

The minutes of the 59th 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

Franck Berthe presented the internal mandate (self-mandate) prepared by the BIOMO Unit and requesting the AHAW Panel to review the EU summary report on zoonoses. The review should address non-food-borne zoonoses (e.g. brucellosis, echinococcosis, rabies, tuberculosis). Mo Salman was nominated chairman of the working group to be formed.

6. DRAFT OPINIONS SUBMITTED FOR ADOPTION

6.1. Guidance on Risk Assessment for Animal Welfare

In 2007, EFSA launched a self-mandate to develop a guidance document on risk assessment for animal welfare. The request was to define comprehensive and harmonised methodology to assess risks in animal welfare, taking into consideration slaughter, transport, and various husbandry systems (housing and management), and different animal welfare issues. The guidance should refer to the methodological approaches followed in previous EFSA scientific opinions on animal welfare. The guidance should also take into account and adapt current risk assessment methods and practices, e.g. for animal diseases and food safety, and also the complex range of measurable welfare outcomes. It was requested that the guidance also concisely define a generic approach for conducting risk assessment in animal welfare.

The original mandate was amended in 2009 to include considerations for benefit assessment. However, during the 2011 February plenary meeting, the Panel recognised that risk and benefit analysis in the context of animal welfare would require further conceptual and methodological refinement. It was also recognised that previous opinions of the AHAW Panel were only rarely consider benefits or positive effects for animal welfare. The Panel proposed that it concentrates the guidance on risk assessment aspects as a main priority. The Panel also recommended that benefit analysis be considered for further work and possible future inclusion in its methodological framework.

The draft guidance was endorsed by the Panel in April 2011 for public consultation from May 4 to July 1. The feedback from this public consultation was considered by the Panel and its working group. EFSA is currently preparing a report from this public consultation, to be published with the guidance.

In May 2011, the draft guidance was also the subject of a workshop with members of the AHAW Scientific Network. The outcomes of this workshop were presented at the May plenary meeting of the Panel.

The draft guidance was discussed during the September plenary and amended accordingly to this discussion. Although the draft document was submitted for adoption, the Panel preferred not to adopt in order to clarify the text.

The Panel requested clarification of the document with regard to benefits and positive impact. The concept of balancing welfare impacts or integrating them within an overall welfare assessment as a synthesis of indicators covering the four welfare principles (good feeding, good housing, good health and appropriate behaviour) was also discussed at length. The Panel also requested that the definition of target population be revised so that it does not overlap with the one of exposure scenario. It was agreed that the document should provide a practical step-wise approach to risk assessment, with annexes providing detailed information on selected issues.

The Panel requested a new version of the working document be submitted in November for possible adoption in December.

7. DRAFT OPINIONS SUBMITTED FOR DISCUSSION

7.1. Guidance on health and welfare aspects of GM-Animals

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. The aim is to provide guidance for applicants on what data to submit on animal health and animal welfare aspects. 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 deadline is end of December 2011.

The guidance has been developed by a working group of the AHAW Panel, in close cooperation with working group of the GMO Panel on the safety assessment of genetically modified animal-derived food and feed. On request from the Commission, the two working documents will form a single and comprehensive guidance document.

The draft guidance on GM animals was submitted to public consultation and comments received were considered by the working group of the Panel. A report from the public consultation and submitted comments will be published. The relevant comments were presented to EFSA Panels together with the subsequent modification to the guidance. Such comments mostly related to the post market monitoring, to the stages and to the general principles for health and welfare assessment.

The text was also revised following a feedback from the Commission about the several references to research legislation which should be avoided. It was also agreed to take recommendations out of the guidance. Since the Working Group addressed most of the comments during a meeting held on the day before the Plenary, the Panel did not have the possibility to check through the revised version of the guidance. The guidance will therefore be resubmitted to the Panel in November.

The draft guidance will be tabled for endorsement by the Panel at the November plenary prior to be submitted to the GMO Panel for adoption in December. When adopted by the GMO Panel, the draft guidance will be submitted to the AHAW Panel for adoption either at its December plenary meeting, either by written procedure.

The Panel also noted that the GMO Panel is currently developing guidance on environment risk assessment and that several members of the AHAW Panel participate to the working group of the GMO Panel. The Panel welcome the idea of the draft guidance being submitted for comments before it is adopted by the GMO Panel.

8. PROGRESS REPORTS AND DISCUSSION OF CURRENT MANDATES

8.1. Electrical requirements for waterbath stunning of poultry

The mandate: in June 2011, EFSA received a mandate on electrical requirements for waterbath stunning of poultry. The Commission had received information from British and Dutch authorities that might justify amending the electrical requirements for waterbath stunning of poultry laid down in Table 2 of Chapter II of Annex I to Regulation (EC) No 1099/2009. EFSA is tasked to review relevant new scientific references on electrical stunning of poultry and in particular the ones provided by the British and Dutch authorities and to recommend, if necessary, new electrical requirements applicable for waterbath stunning equipment laid down in Table 2 of Chapter II of Annex I to Regulation (EC) No 1099/2009.

The approach: a technical hearing has been held on September 23 2011, at which British and Dutch scientists explained their findings that led to the requests of their authorities. A systematic review of scientific references on waterbath stunning of poultry is being carried out to collate the scientific evidence for electrical requirements of waterbath stunning of poultry in line with requirements of Article 4, Regulation (EC) No 1099/2009 by EFSA staff. The search yielded 709 results, of which 49 were found to be relevant. Currently over half of the full text relevant papers have been obtained, from which data, on methodological issues and the parameters relevant to the mandate, are being extracted. It was proposed to discuss the draft opinion at the plenary meeting in December 2011 with view of a possible adoption in February 2012.

8.2. Foot and Mouth Disease (FMD)

Gabriele Zancanaro joined the meeting for this discussion.

The mandate: after request from Bulgaria BFSA-RAC and Commission on FMD and in application of Regulations 178/2002 and 1304/2003 concerning requests from different parties on an issue, EFSA proposed to address the questions in one single opinion. The two requests were discussed in a tri-partite meeting with a view to allow for a coordinated approach and response to questions arising from the current situation in the Balkans. It was agreed that mandate should address the following terms of reference:

1. The relative significance of -and the role played by- wild and feral bi-ungulates, notably wild boar and deer species in the epidemiology of foot and mouth disease

(FMD) in Thrace (Bulgaria, Turkey and Greece), taking into account the different FMD virus strains circulating in the region.

2. The risk factors and other relevant epidemiological features, in particular for the different FMD virus strains circulating in Thrace (Bulgaria, Turkey and Greece) which must be taken into account for the design of surveillance systems (including estimation of advantages and disadvantages), that could be implemented for the early detection of any FMD virus incursion in the territory of Thrace (Bulgaria, Turkey and Greece).
3. The relevance and significance of epidemiological data and genetic characteristics for the different FMD strains recently isolated in Bulgaria and Turkey, with regards to the hypothesis of single versus multiple introductions to Bulgaria.

The approach: Answering TOR1 will require, inter alia, running a simulation model adapted to multiple hosts, using information that is provided by a systematic literature review, serosurvey data and expert opinion. It was suggested to use the Classical Swine Fever Control - Individual-Based Model (SwiFCoIBM) for that purpose, which was developed by the Ecological Epidemiology Unit of the Helmholtz Centre for Environmental Research (Leipzig). The model was presented to the Panel. Some limitation of the model was discussed, i.e. that it will only address the duration of FMDV circulation in the wildlife populations which have no interaction with livestock populations. To address the potential interaction between wildlife and livestock, a spatial analysis of the potential contact between livestock and wildlife species could be carried out, provided that data are available on the spatial distribution of the different livestock and wildlife populations (including information on the husbandry systems). The 'relative' significance of -and the role played by- wild and feral bi-ungulates in the epidemiology of FMD in Thrace compared to that of domestic animals will not be addressed by the model. It was suggested that this aspect will be addressed in a narrative discussion. The panel agreed with this approach to TOR1.

For the second question (ToR2), Gabriele Zancanaro gave a presentation of a simulation-based estimation of the prevalence of FMD overtime, which should enable the estimation of the relative impact of the different risk factors on the responsiveness of the surveillance system in terms of time. The outcome should allow for a ranking of the most important risk factors for the different surveillance strategies. This approach would need to be discussed first with the working group and will be presented at the next plenary meeting of the Panel, in November.

It was agreed that TOR3 will be addressed by a narrative discussion.

8.3. Swine Vesicular Disease (SVD) and Vesicular Stomatitis (VS)

Gabriele Zancanaro joined the meeting for this discussion.

The mandate: in June 2010, the European Commission sent a mandate requesting EFSA to develop an opinion concerning Swine Vesicular Disease (SVD) and Vesicular Stomatitis (VS). A initial meeting was requested to DG SANCO for clarification of the mandate and its ToRs

was held in July). The Commission explained the background and main purpose of this mandate. Given that current diagnostic methods allow for a rapid differentiation between FMD and SVD and VS, the Commission would like to reassess appropriate and proportionate surveillance/ control measures for these diseases. The impact of these two diseases will be assessed initially. The deadline requested is March 31, 2012.

The approach: The approach was presented to the Panel. Information on the impact of the diseases on animal health, animal production and the spread of the diseases will be collected through a systematic literature review and a questionnaire for affected countries. Questionnaires on the impact of SVD have been sent to selected EU MS (Portugal, Netherlands, Italy, Spain, UK) and countries affected by VS in the Americas (USA, Colombia, Costa Rica, El Salvador) and Panaphthosa. Data gathered by these means will be fed into a spread model and scenario tree (risk of introduction). Currently, the protocols for the systematic literature reviews are being prepared (support from the SAS unit). For the spread model, it was proposed to outsource the adaptation of an existing model developed in the frame of a FP7 research project (agreement 227003). The SAS unit of EFSA will assist in assessing the risk of introduction.

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

The mandate: The request is 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 assessment protocols suggested by the Welfare Quality® project 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.

The approach: The WG is mainly formed from Panel members with assistance of 3 hearing experts.

The approach for TOR1: a list of all recommendations from the EFSA scientific opinion was made and for each recommendation any animal-based measures considered useful to measure the hazard underlying that recommendation was listed. For recommendations referring directly to resources and management, resource-base measures were considered. A special note was made for animal-based measure proposed in the Welfare Quality protocol.

For TOR 2: another table was developed based on the main factors (hazards) in the EFSA dairy cattle welfare risk assessments (previous opinion). These factors were ranked according to the risk scores linked to the lists of animal-based measures identified when addressing the TOR 1.

Using the above tables it quickly became obvious when a hazard or a recommendation existed in the EFSA opinion for which there was no corresponding animal-based measure in

the Welfare Quality protocols or in the general animal welfare literature. We tried to group these 'gaps' to identify any common features with a view to determining whether there were similarities. In this way we could address question which asks whether there are animal welfare issues that cannot be assessed using animal-based measures (TOR3).

TOR 4 asks for a list of factors in husbandry systems that have been shown to have a negative effect on the welfare of dairy cows and the extent to which such negative effects can be prevented by management. Using the table developed to answer TOR 2 (listing the main factors (hazards) affecting dairy cattle welfare) experts in the working group were asked to assess the extent to which the negative effects could be prevented by management. Following standard Delphi methodology scores were reviewed.

As a final stage in addressing the four different TORs in this opinion, experts from outside the working group with expertise in dairy cow welfare and or implementation of animal welfare legislation were invited to review the approach taken by the working group. Any new insights gained from this consultation were added the report.

EFSA outsourced a "review of methodologies applicable to the validation of animal based indicators of welfare". The final report was published on the EFSA website¹.

EFSA also outsourced report 'Relationships between animal welfare hazards and animal-based welfare indicators' with objectives to integrate of different data sources generated from welfare assessment protocols, to identify and quantify of associations between welfare hazards identified by the 2009 EFSA scientific opinion and animal based welfare indicators and to identify an optimal set of indicators for the assessment of specific welfare aspects of dairy cows. The draft final report of this study was presented to the working group, and discussed. The outcomes of this work are proposed to be incorporate to the scientific option.

In agreement with the Commission, the deadline is for adoption is December 2011.

The draft opinion is open to Public Consultation until November 11, 2011. The document and the comments received during the Public Consultation will be presented at the plenary meeting of the Panel in November.

The Panel noted that the title of the mandate (and consecutive mandates on pigs, and broilers) is about "the use of animal based measures to assess the welfare of ...". The use of the word measure was debated again. It was reminded that this issue had already been discussed and clarified by the Commission during the September plenary meeting of the Panel. For the Commission, the words "animal based measures" is clear and Commission requested these words not to be changed. Additionally, it was reminded that in order to keep the consistency among the different opinions on animal based measures same title should be used.

¹ <http://www.efsa.europa.eu/en/supporting/pub/171e.htm>

The Panel also noted that the main term of reference of the mandate are dealt with in an appendix of the opinion and questioned the format and organisation of the document. It was agreed that EFSA will propose a common approach to the opinions on dairy cows and pigs.

The draft opinion will be submitted to the Panel for discussion at its November meeting, in view of possible adoption in December.

8.5. Use of animal-based measures to assess the welfare of pigs

The mandate: The official mandate was sent by SANCO on 25/03/2011 and accepted by EFSA. The deadline for the request is December 2011. The request is 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 pigs 2) identify how the assessment protocols suggested by the Welfare Quality® project 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 pigs 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 pigs.

The approach: A preparatory work has been outsourced for the update of the previous opinions on pig welfare (EFSA, 2007). The final external report, including recent literature and suggestions for new or amended conclusions and recommendations, was published on EFSA's website in the end of June.

The working group created a table responding to TOR1, listing all recommendations from the EFSA scientific opinions and linking them to the corresponding animal-based measures proposed in the Welfare Quality protocol. When possible, a non animal-based measure is also indicated. Another table was developed for addressing TOR2, based on the main factors (hazards) in the EFSA pig welfare risk assessments (previous opinions of 2007). The hazards will be cross-linked to the animal-based measures proposed by the Welfare Quality protocol. The methodology is supposed to identify the animal-based measures which cover the main hazards identified in EFSA scientific opinions (and vice-versa). A Delphi exercise is currently being run for responding to ToR3.

8.6. Use of animal-based measures to assess the welfare of broilers

The mandate: The mandate was sent by SANCO in June 2011 and accepted by EFSA. The deadline for the request is March 2012. The request is to 1) identify how animal-based measures could be used to ensure the fulfilment of the recommendations of a previous scientific opinion from SCAHAW (2000) on the welfare of broilers 2) identify how the assessment protocols suggested by the Welfare Quality® project cover the main hazards for broilers (and vice-versa); 3) identify which relevant animal welfare issues cannot be assessed using animal-based measures for broilers 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 broilers.

The approach: Overall, the approach for this mandate will be identical to the ones of mandates on dairy cows and pigs. A preparatory work for the update of previous opinions on broiler welfare (SCAHAW, 2000) is being outsourced. This preparatory work will include recent literature and suggestions for amendments of the conclusions and recommendations of the SCAHAW opinion. In addition, and since hazards for broilers were only identified in two scientific opinions on different aspects related to genetic selection of broilers (EFSA, 2010^{2 3}), the final external report will also propose a full list of hazards for the welfare of broilers. The deadline for the completion of the external report is January 2012.

8.7. Update the scientific opinions on the welfare of beef cattle and the welfare of intensive calf farming systems

The mandate: in March 2011, EFSA received a mandate to update the scientific opinions concerning the welfare of beef cattle and calves. In particular to consider if the conclusions and recommendations of the two previous scientific opinions on the "Welfare of cattle kept for beef production" (SCHAW, 2001) and "The risks of poor welfare in intensive calf farming systems" (EFSA, 2006) are still valid. Only the animal categories of these previous scientific opinions should be considered in the update.

The approach: A comprehensive scientific review of bibliographic references on the welfare of beef cattle and calves was outsourced (NP/EFSA/AHAW/2011/04) and its results circulated to the working group. Separate risk assessments will be performed for beef cattle and calves. In calves, hazards and animal categories from the previous scientific opinion will be considered as starting point. The update shall contain only new data (from 2000 in beef cattle and from 2005 in calves) not included in the above mentioned scientific opinions and new conclusions and recommendations from these data. The validity of the previous conclusions and recommendations should be also considered. The draft opinion should be discussed at the plenary meeting in February 2012 and submitted for possible adoption in March 2012.

8.8. Public health hazards to be covered by inspection of meat

The mandate: The Commission requested 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. The following species or groups of species should be considered: domestic swine (deadline September 2011), poultry (deadline June 2012), bovine animals over six weeks old, bovine animals under six weeks old (deadline June 2013), domestic sheep and goats (deadline June 2013), farmed game (deadline June 2013) and domestic solipeds (deadline June 2013).

² <http://www.efsa.europa.eu/en/efsajournal/pub/1666.htm>

³ <http://www.efsa.europa.eu/en/efsajournal/pub/1667.htm>

The approach: The AHAW Panel ensures whether any change in current inspection does not jeopardize the capacity to detect animal diseases nor compliance with the animal welfare regulation. For this, it is essential to determine the importance and integration of meat inspection in the EU animal health surveillance and monitoring. Two methodologies (qualitative and quantitative) are in use to assess the quality of both the current and proposed modified meat inspection systems. The former relied on expert opinion and a review of the literature, and the latter used a three stage modelling approach.

Poultry (EFSA-Q-2011-00019). The work is ongoing. The diseases/conditions of AHAW interest were defined and transferred to a contractor (CFT/EFSA/AHAW/2010/01) for modelling contribution of meat inspection on animal health surveillance. Report of the contractor and indications for changes in meat inspection poultry from BIOHAZ and CONTAM are expected in November. Assessment on the impact, in AHAW perspective, of proposed changes to the current meat inspection system would be possible in the spring 2012.

Bovine (EFSA-Q-2011-00324). The work is ongoing. The diseases/conditions of AHAW interest were defined and transferred to a contractor (CFT/EFSA/AHAW/2010/01) for modelling contribution of meat inspection on animal health surveillance. Possible 'what if' scenarios in the modelling were discussed between WG and contractor. Report of the contractor is expected in May 2012. Assessment on the impact, in AHAW perspective, of proposed changes to the current meat inspection system would be possible in the autumn 2012 – spring 2013.

Domestic sheep and goats (EFSA-Q-2011-01036), farmed game (EFSA-Q-2011-01037) and solipeds (EFSA-Q-2011-01038). The work is following the approach of former species, defining diseases/conditions of AHAW interest, including topic consultation with experts in specific animal species, further modelling and assessment of potential impact on AHAW of changes proposed in public health context. Report of the contractor CFT/EFSA/AHAW/2010/01 is expected in May 2012. Assessment on the impact, in AHAW perspective, of proposed changes to the current meat inspection system would be possible in the autumn 2012 – spring 2013.

9. OTHER ISSUES

9.1. Statistical significance and biological relevance

Gabriele Zancanaro (SAS Unit) presented the scientific opinion adopted by the Scientific Committee and clarifying definitions and concepts related to statistical significance and biological relevance (EFSA, 2011⁴).

⁴ <http://www.efsa.europa.eu/en/efsajournal/pub/2372.htm>