MINUTES OF THE XXXIV PLENARY MEETING OF THE PANEL ON ANIMAL HEALTH AND WELFARE

6-7 MAY 2008

PARTICIPANTS

B. Algers, P. Costa, Harry Blokhuis; Donald Broom, M. Domingo, Daniel Guemene, Joerg Hartung, Frank Koenen, David Morton, Christine Müller-Graf, Albert Osterhaus (7 May), Dirk Pfeiffer, (7 May), Mike Sharp, Mo Salman, Moez Sanaa, and Philippe Vannier.

EUROPEAN COMMISSION: S. Osaer, A. Gavinelli, and M. Ferrara **(DG SANCO),**

EFSA: E. Franchi, S. Mori, K. Plattner (administrative staff AHAW Unit), A. Afonso, S. Barbieri, F. Berthe, S. Correia Rodeia, F. De Massis, S. Dhollander, T. Grudnik, P. Have, M. Georgiev, O. Ribó and J. Serratosa (Scientific Coordination AHAW Unit).

1. WELCOME, APOLOGIES AND DECLARATIONS OF INTEREST

The Chairman welcomed the participants and no member declared any conflict of interest on the items on the agenda. Apologies were received from the panel members Ronald Roberts, Marion Wooldridge, Matthias Greiner and Martin Wierup, D. Candiani (EFSA), and observers from OIE and FAO.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. PREVIOUS MINUTES ADOPTED BY WRITTEN PROCEDURE

The minutes of the previous 33rd plenary meeting held in Parma on the 13-14 March 2008 were unanimously adopted by written procedure by Panel members on 11 April 2008 and published on the web (http://www.efsa.europa.eu).

4. COMMISSION SERVICES (CS) NEW MANDATES

4.1. Feedback from Commission representative on animal welfare

The Commission representative provided feedback on the animal welfare opinions that had been adopted in the past 2 years. In addition, there was an exchange of views on a number of issues, such as the interfacing between risk managers and risk assessors, a provision on the future mandates for this panel in line with the Community Action Plan on the Protection and Welfare of Animals 2006-2010, and possibly other tasks deriving from this. The panel was informed by the Commission representative that a separate unit dedicated to animal welfare has recently been established within DG SANCO.

5. OPINIONS AND REPORTS SUBMITTED FOR POSSIBLE ADOPTION/ ACCEPTANCE

5.1. Fish Welfare - Atlantic Salmon report

The Salmon Report, Draft 12, Rev 1, was sent with all track changes to the panel members on 25 April. The new revision addresses comments previously received and presents all data available for the various life stages considered in the risk assessment for each identified hazard. Deadline for comments by panel members was April 30. All comments received by EFSA secretariat were included into the draft prepared for discussion at the plenary. A summary of the main issues/comments was presented by EFSA secretariat. The report was also submitted to external review following EFSA quality control approach as done with other AHAW opinions.

The document could not be adopted due to disagreements regarding conclusions and recommendations. The discussion was postponed until the next plenary meeting. It was decided to organize an interim meeting with Panel experts and the WG chairman to address comments on

the current draft opinion before the next plenary. The objective of the meeting is to make proposals and facilitate the discussion at June plenary .

5.2. Avian Influenza - follow up:

EFSA received on October 16, 2007, a request for an opinion on AI from DG SANCO concerning an update and consolidation of conclusions and recommendations of the 5 previous opinions on avian influenza in the light of new scientific information, and scientific advice and assessment of risk factors for introducing and spread of AI in poultry holdings.
Three WG meetings were held on January 31, February 26 and March 27 as well as several teleconferences. The transversal meeting was held on 17 April. The fourth draft was submitted to the AHAW panel on 23 April for review and final comments. The Scientific Opinion was presented including all comments received from the panel members for possible adoption. After several amendments and editorial changes the SO was adopted by unanimity.

5.3. Statement on aquatic disease definitions

While developing its opinion on vectors of aquatic animal diseases (mandate EFSA-Q-2007-044), the AHAW Panel stated that the definitions used by the Commission, for “disease”, “susceptible species” and “vector” were different from those commonly used in the peer-reviewed papers of the scientific literature. These differences were identified as being a potential source of confusion in the process of risk assessment. Consequently, a working document was developed and presented to the members of the Panel for discussion. This document proposes a synopsis of the different definitions in use in the EC Directive (2006/88), the OIE Terrestrial and Aquatic Codes, as well as current working definitions for the AHAW panel. This document was adopted by unanimity and it was proposed that it be published as an annex to these minutes.

5.4. Fish Welfare-Trout:

A transversal meeting was held on the 14 of April. The Trout welfare report, Draft 9 Rev 1, with all track changes was sent out to the panel members on 24 April. The new revision addresses comments previously received and presents all data available for the various life stages considered in the risk assessment for each identified hazard. Deadline for comments by panel and WG members was 30 April. All comments received by EFSA secretariat up until 30 April were included into the draft prepared for the plenary. The report was also submitted for external review following EFSA quality control approach as previously done with other AHAW opinions. The discussion was postponed until the next plenary due to lack of time. It was agreed to follow the same methodological approach as for Salmon .

5.5. Scientific Report: Fish welfare-Carp:

The last meeting of the Carp welfare WG was on the 15 March. The Scientific Report with draft conclusions and recommendations was sent out to the Panel on the 30 April for comments during the Plenary Meeting, in the view of its submission and possible adoption at the next AHAW plenary meeting. An updated document (in light of discussions on salmon welfare) will be distributed to the panel in preparation of the June plenary meeting.

5.6. Scientific Report and Opinion on Bluetongue:

Three meetings have been organized on 26-27 March, 8-10 April and 14-15 April. A Transversal meeting is scheduled for 20-21 May and on next May 8 the Draft 5 Rev 0 will be posted in the EFSA Extranet webspace with the comments still pending. The WG and Panel Members that expressed their interest in attending the Transversal Meeting will be requested to comment the draft. The Opinion is expected to be finalized for May 30 in order to be presented for possible adoption during the 17-18 June Plenary.

6. WRITTEN COMMENTS ON THE STATE OF PLAY OF THE SCIENTIFIC OPINIONS AND REPORTS

6.1. Fish welfare-Sea bass and gilthead sea bream:

The second WG Meeting was held on 29-30 April. Next meeting focused on the Risk Assessment was held on 15th April and last WG Meeting will be held 29-30 May in order to able to submit the SO for possible adoption during the Plenary Meeting next 17-18 June.

6.2. Fish welfare-European eel:

The second WG Meeting was held on 28-29 April. Next meeting focused on the Risk Assessment will be held 16 April and the last WG Meeting will be held 27-28 May in order to able to submit the SR and SO for possible adoption during the Plenary Meeting 17-18 June.

6.3. Fish: susceptible species

The letter of acceptance of the mandate was sent to the Commission on April 14. The second WG Meeting was held on 24-25 April. The Transversal WG meeting will be held in Parma 8 May. There is the intention to complete the Report by June in order to be able to submit the SO for adoption at the September Plenary Meeting.

6.4. Welfare of Dairy Cows

In line with the decision taken at the last plenary meeting and at the last WG meeting (24-25 April) about splitting the mandate into 5 scientific opinions, a letter was sent to DG SANCO on 30 April (a hard copy has been distributed to AHAW Panel Members). According to the letter, four separate RAs (walking problems, udder problems, reproductive and metabolic disorders, and behavioural problems) will be carried out and Conclusions and Recommendations from each RA will be submitted as 4 separate SOs. The 5th SO will be an overall Dairy Cow Welfare Assessment that will integrate the outcomes of the 4 RAs as well as other welfare aspects presented in the S. Report.
Next WG meeting will be held next 18-20 June. The first 1.5 days will be focused on the Risk Assessment (4 sub WGs working on hazard characterization) whereas the second 1.5 days will be dedicated to draft Con&Rec from the Scientific Report.
The 4 opinions should be reinforced by specific experts in order to increase the scientific input. EFSA will propose to the chairman new experts and CVs for that purpose.

6.5. Classical Swine Fever

Data on the hunting practices and vaccination of wild boar in the MS will be collected through an online questionnaire. Data on the current CSF vaccines will also be collected through another questionnaire. Both have been sent to EFSA focal points on the 30 April and the deadline to reply is 30 May. The second will also be distributed through the IFAH. A meeting was held on the 18 and 19 March and on the 22 and 23April. The next will be on the 15 and 16 May.

For scientific and administrative reasons the work and opinion concerning CSF will be divided in two parts according to the 2 ToR of the mandate. The first group of experts will reply to the 1st ToR (efficacy of the available surveillance, hunting and vaccination measures to control and eradicate CSF in feral pig populations) and the second group of experts to the 2nd ToR (*safety* of fresh meat derived from vaccinated pigs for animal health).

6.6. Self-mandate Animal Welfare

The EFSA self-mandate on the development of the RA Guidelines for AW will be partly carried out through grants under Article 36. The AW issues to be considered in the Guidelines have been divided in three main categories: stunning and killing, transport, housing and management.

Following these categories, a grant under Article 36 was awarded last December 2007 in order to develop the AW RA Guidelines for stunning and killing. As requested by the project participants AHAW secretariat was present in some of the project meetings.
A second call for the development of the Transport part of the Guidelines was published on the EFSA Web last 10 April. Deadline for proposals is 6 June 2008.

6.7. Discussion on the document on modelling

The draft document "white paper on use of models" presented during the last meeting was not be discussed due to time constrains. Discussion was postponed for the next Plenary.

6.8. Feeding stuff & Salmonella (BIOHAZ)

The last meeting of this WG will be held on the 23rd May. The scientific opinion will be presented for possible adoption to the BIOHAZ Panel on the 4, 5th June.

6.9. MRSA (BIOHAZ)

BIOHAZ Panel is still contacting the experts that will participate in the WG. Three AHAW Panel members will support the tasks of the WG in terms of animal health and welfare aspects. The first WG meeting is planned for the 5, 6 June.

7. MISCELLANEOUS

7.1. Preparation of the meeting in June with COM official on Animal diseases.

EFSA invited SANCO officials responsible for animal diseases to give feed-back to the Panel on the opinions requested by SANCO and to exchange of points of view between risk assessors and risk managers. Therefore EFSA/AHAW secretariat would like to launch a written request to all panel members to prepare a questionnaire to be forwarded to the Commission officials for the meeting foreseen in June.

7.2. EXTRANET follow up.

AHAW workspace has recently expanded. The panel members were requested to express their comments on the current system of communications.

7.3. Art. 36 Grants for 2008 Follow up.

Under the Art. 36 framework, two calls of proposals were published April 10. Deadline to submit proposals is 6 June 2008. Copy of the calls for proposals was included in the CD distributed to the Panel Members. Titles of the call and web links are as follows:
- Call for proposals for the development of AW RA Guidelines for Animal Transport (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178699683470.htm).
- Call for proposals to make a scientific review and develop a database on the Epidemiology of different agents causing disease in aquatic animals (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178699683470.htm)

7.4. Advisory Forum meeting on Animal health 27-28 May in Parma

EFSA secretariat explained the preparatory work for this meeting. Two members of the Panel members and the chairman will attend.

7.5. Information on Rules of procedure including WG minutes in EFSA web.

As agreed in the previous plenary meeting EFSA/AHAW secretariat has circulated a new version of the Rules of procedure including the recent rules including the new format of the WG minutes to be included in the EFSA web for possible discussion at the next plenary meeting in June .

7.6. Next Plenary Meeting. extension for the -19 June

In order to be able to discuss for possible adoption the opinions on fish welfare and Bluetongue the next plenary meeting will take place in Parma on the **17-18** June (from 09.00 to 18.00h) and on the **19** June (from **08.30 to 15.30h)**. .

ANNEX

Statement of the AHAW Panel on the Usage of Definitions for "Disease", "Susceptible Species" and "Vector" and Related Issues in Aquaculture

Background

The Council of the European Union adopted on 24 October 2006 a new Directive on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain infectious diseases in aquatic animals (Council Directive 2006/88/EC). The Directive lays down harmonised animal health provisions for placing on the market of aquaculture animals and products thereof.

Article 17 of the Directive regulates the introduction of live aquaculture animals of vector species into disease-free areas. More specifically, Article 17 (2) requires that a list of vector species is drawn up. In accordance with Article 29 of Regulation (EC) 178/2002, the Commission asked EFSA to give scientific advice on which species may be responsible for the transmission of a specific disease by acting as a vector for diseases listed in Annex IV Part II to Directive 2006/88/EC.

In accepting the mandate (EFSA-Q-2007-044), the AHAW Panel noted that the definitions provided, as part of the Mandate by the Commission, for "disease", "susceptible species" and "vector" are not the same as those commonly used in the peer-reviewed papers of the scientific literature. The usage of different sets of definitions was indicated to be a potential source for confusion with regards to the understanding of the approach and outcomes of the risk assessment. Therefore, this document is intended to identify and analyse existing inconsistencies among the definitions currently applied. In this prospect and in the light of the WTO-SPS agreement, reference is made also to the OIE standards in order to facilitate alignment of the risk assessment framework.

Current status

Tables 1, 2 and 3 present the different definitions as used for "disease", "susceptible species" and "vector" in *i*) the annex of the Council Directive 2006/88/EC, *ii*) the OIE Terrestrial Code, *iii*) the OIE Aquatic Code, and *iv*) those commonly used by scientific terminology according to the AHAW panel. These AHAW panel scientific definitions were elaborated on the basis of the Webster definitions[1], in order to clarify the understanding of these terms as they are used in the risk assessment process.

[1] http://www.websters-online-dictionary.org/

Table 1: Definitions for *disease* in the OIE Terrestrial and Aquatic Codes, and Council Directive 2006/88/EC

AHAW working definition: *disease* is a pathological condition of an animal, resulting from one or several causes, such as infection and infestation, toxins or other poisons, development or growth disorder, a genetic defect, and environmental stressors and characterized by a set of pathological changes that may be accompanied by clinical signs.		
OIE Terrestrial Code[2]	**OIE Aquatic Code**[3]	**Council Directive 2006/88/EC**[4]
the clinical and/or pathological manifestation of infection.	clinical or non clinical infection or infestation with one or more of the aetiological agents of the diseases referred to in the Aquatic Code.	a clinical or non-clinical infection with one or more aetiological agents in aquatic animals

Disease is generally understood as an unbalanced physiological state of an organism that can be caused by infectious or non infectious factors. Diseases are usually characterized by an identifiable set of signs. The FAO glossary for aquaculture[5] defines disease as a deviation from the state of complete physical or social well-being of an organism involving a well-defined set of symptoms and aetiology, and leading to an impairment of its normal function. It may be inherited or caused by parasites, dietary deficiencies, or by physical and chemical factors in the environment. It should be stressed here that symptoms do not apply to animals. Also, diseases may have a not well defined aetiology; hence idiopathic conditions.

The OIE Terrestrial Code definition for disease is based on clinical or pathological manifestation of an infection (see Table 1). This definition, along with ones of the OIE Aquatic Code and Council Directive 2006/88/EC, restricts disease to infectious diseases. In the Aquatic Code and CD 2006/88/EC, disease is synonymous for (clinical or non clinical) infection. The aquatic definitions put emphasis on the presence of the pathogen in the host (infection or infestation) with no specific reference to any manifestation of the infection. As a matter of fact, the pattern of clinical expression in aquatic animals is highly variable and often dependant on environmental conditions.

Susceptible species are not defined in the OIE Terrestrial Code. The OIE Aquatic Code and CD 2006/88/EC both provide definitions for this term (Table 2). These definitions are very similar and mainly emphasise the way by which experimental demonstration is achieved. Such a way should mimic natural infection route. The underlying assumption of those definitions is that what constitutes the natural infection pathway for the pathogens under consideration is known. However, this is not the case for most of the listed diseases of aquatic animals. A possible consequence of this approach is that experimental data that fall outside the current understanding of

[2] http://www.oie.int/eng/normes/mcode/en_sommaire.htm
[3] http://www.oie.int/eng/normes/fcode/en_sommaire.htm
[4] http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_328/l_32820061124en00140056.pdf
[5] http://www.fao.org/fi/glossary/aquaculture/

pathogenic processes are discarded; still such data may provide valuable information on potential susceptibility of a host species**.**

While susceptibility appears as a natural underlying concept of the term susceptible species, there is no reference to any clinical or pathological manifestations of infection in the aquatic definitions. One should note in this context that a susceptible species, according to the definitions in the OIE Aquatic Code and CD 2006/88/EC, may be a healthy carrier or a biological vector both representing equivalent risk of pathogen introduction and spreading.

Table 2: Definitions for *susceptible species* in the OIE Terrestrial and Aquatic Codes, and Council Directive 2006/88/EC

AHAW working definition: a *susceptible species* is a species in which an agent can replicate; sometimes this may lead to development of disease. A *carrier species* is capable to maintain and transmit infectious agent without showing clinical signs.		
OIE Terrestrial Code[6]	**OIE Aquatic Code**[7]	**Council Directive 2006/88/EC**[8]
-	means a species of aquatic animal in which infection or infestation has been demonstrated by natural cases or by experimental exposures to the disease agent that mimics the natural pathways for infection or infestation. Each disease chapter in the Aquatic Manual contains a list of currently known susceptible species.	any species in which infection by a disease agent has been demonstrated by natural cases or by experimental infection that mimics the natural pathways.

Classically, the scientific definition of vectors (Table 3) recognises existence of mechanical vectors as opposed to biological vectors. Vectors are only defined in Council Directive 2006/88/EC. There is no definition for vector in the OIE Codes. The Council Directive definition of vector applies to species that are not susceptible to a disease. In application to the Council Directive definition for susceptible species, this excludes biological vectors as vectors by restricting the term to non susceptible species.

[6] http://www.oie.int/eng/normes/mcode/en_sommaire.htm
[7] http://www.oie.int/eng/normes/fcode/en_sommaire.htm
[8] http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_328/l_32820061124en00140056.pdf

Table 3: Definitions for *vector* in the OIE Terrestrial and Aquatic Codes, and Council Directive 2006/88/EC

AHAW working definition: a *vector* is an organism, a disease-producing organism, or a fomite, capable of transporting and transmitting a pathogen; examples of vectors include mosquitoes, aquatic invertebrates, molluscs, fish, birds, mammals, gears, particles, etc.		
OIE Terrestrial Code[9]	**OIE Aquatic Code**[10]	**Council Directive 2006/88/EC**[11]
-	-	species that is not susceptible to a disease but which is capable of spreading infection by conveying pathogens from one host to another.

Since, according to the risk manager, the purpose of the definition for susceptible species in the Directive 2006/88 is to identify those species that should be covered by the most stringent requirements for placing on the market and import, the broader scope of the term susceptible was deliberately applied. Furthermore, the term vector species was chosen to identify aquaculture animals, which are not covered by these stringent measures, but which still pose a risk of transmission for certain disease and therefore should be covered by some of the placing on the market requirements. For the same reason the risk manager limited the term "vector" to aquaculture animals.

The Table 4 presents the respective spans of vector and susceptible species according to scientific definitions and those provided in the Council Directive and OIE Codes. This table illustrates the potential impact of definitions on risk assessment.

Table 4. Respective span of susceptible species and vector according to sets of definitions in the Council Directive 2006/88/EC, the OIE Terrestrial and Aquatic Codes, and common scientific terminology.

<table>
<tr><th rowspan="2">Science</th><th rowspan="2">Susceptible species</th><th colspan="2">Vector</th></tr>
<tr><th>Biological vector</th><th>Mechanical vector</th></tr>
<tr><td>CD2006/88/EC</td><td colspan="2">Susceptible species</td><td>Vector</td></tr>
<tr><td>OIE Aquatic</td><td colspan="2">Susceptible species</td><td></td></tr>
<tr><td>OIE Terrestrial</td><td>Susceptible species</td><td colspan="2"></td></tr>
</table>

[9] http://www.oie.int/eng/normes/mcode/en_sommaire.htm
[10] http://www.oie.int/eng/normes/fcode/en_sommaire.htm
[11] http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_328/l_32820061124en00140056.pdf

Scientific definition of vector includes biological and mechanical vectors. The Council Directive definition excludes biological vectors. Consequently, in the assessment conducted under mandate EFSA-Q-2007-044, the risk associated with biological vectors was not addressed. In addition, it was observed that the lists of susceptible species would need to be more thoroughly and consistently established, based on robust criteria for susceptibility of host species and understanding of natural routes of infection. This has recently been addressed by submission of a new mandate to EFSA on the 15th of February 2008 (EFSA question 2008-074).

Finally, a list of mechanical vectors was identified along with a list of specific conditions by which these species may become mechanical vectors. Overall, the list of these conditions appears more significant than the list of vector species.

Conclusion

For risk management purpose, scientific definitions may not be always adapted to a particular context of application. The OIE and EU animal health standards and guidelines propose and use their own ad hoc definitions for specific terms, differing between aquatic and terrestrial standards. The variability of those definitions, and their respective span, may raise major difficulties when risk assessment is undertaken as explained in this document. Efforts should be made towards more clear, if possible harmonised definitions used in animal health standards and guidelines, with ad hoc definitions as close as possible to those commonly used by scientific terminology. The use of *on purpose* definitions in health standards should be limited to cases where the definition that is commonly used by scientific terminology does not provide the expected level of specificity or accuracy within the particular context of this standard. EFSA is willing to provide support to any actions further addressing these issues.