Organisation Mondiale de la Santé Animale
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Organización Mundial de Sanidad Animal

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REPORT OF THE MEETING
OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 13 – 17 February 2012

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A meeting of the OIE Scientific Commission for Animal Diseases (the Commission) was held at the OIE Headquarters in Paris, France from 13 to 17 February 2012.

1. Opening

The Commission was welcomed by Dr Bernard Vallat, Director General of the OIE, and Dr Kazuaki Miyagishima, Deputy Director General and Head of the OIE Scientific and Technical Department.

In his address to the Commission, Dr Vallat reiterated his support for the important task of the Commission. He clarified the relationship between the Specialist Commissions and Working Groups following the adoption of the revised *Basic Texts* of the OIE at the 79th General Session and confirmed that all relevant Specialist Commissions should be involved in the preparation of the agenda of the Working Groups. Requests to any Working Group could originate from any Specialist Commission. The Animal Welfare and Food Safety Working Groups report on their proposals and conclusions to the Terrestrial Animal Health Standards Commission (Code Commission), and the Working Group on Wildlife to the Scientific Commission. Dr Vallat also expressed his views on the possibility of shortening the usual two-year cycle process for the drafting through to adoption of revisions to the *Terrestrial Code* chapters in cases where these could go for adoption without necessarily having to go through a second round of Member Country comments provided that the first round comments had thoroughly been addressed by the responsible *ad hoc* Group and consensus had been reached between the Code and Scientific Commissions. Dr Vallat nevertheless reminded the Commission that the current two-year cycle allowed Member Countries to comment on the subsequent changes to draft texts before their final adoption at the General Session had been put in place in reply to a request from Member Countries some years ago. Finally, Dr Vallat reiterated that any amendments or updating of scientific content or rationale in the *Terrestrial Code* chapters should first be dealt with by the Scientific Commission. In this context and to facilitate prompt communication between the Code and Scientific Commissions, these consultations could take place electronically as appropriate.

Dr Kazuaki Miyagishima reminded the Commission that, in accordance with the revised General Rules of the OIE, experts were requested to submit to the Secretariat the Confidentiality Undertaking and the Declaration of Interests forms. The latter form in particular was intended to properly prevent potential conflicts of interest thereby ensuring neutrality and objectivity in the discussions and decisions of Specialist Commissions and *ad hoc* Groups. The Declaration of Interests form should be signed at least once during the terms of office of Members of the Commissions, while the Confidentiality Undertaking was valid for lifetime once it had been signed off.

2. Adoption of the draft agenda

The proposed agenda was adopted by the Commission as its agenda. The meeting was chaired by Dr Gideon Brückner, President of the Scientific Commission. The secretariat was ensured by Dr Marta Martinez Aviles, assisted by Dr Laure Weber-Vintzel of the Scientific and Technical Department, who acted as rapporteur.

The agenda and the list of participants are attached as Appendices I and II.

3. Feedback on issues raised during the meeting of the Scientific Commission for Animal Diseases of 29 August to 2 September 2011

The Commission reviewed salient points from the report of its previous meeting. The President of the Commission expressed his gratitude to the staff of the Scientific and Technical Department of the OIE for their hard work during the past year and for preparing detailed working documents for the current meeting. The Commission acknowledged with thanks that actions had been taken to alleviate the staff shortage in the Scientific and Technical Department. The following issues emanating from and related to the previous meeting were discussed:

3.1. Guide on Terrestrial Animal Health Surveillance

The Commission was updated on the progress being made with the Guide including the assistance received from CIRAD on the first draft of the Guide. To expedite the finalisation of the Guide, the Commission recommended that the document be submitted for discussion by the *ad hoc* Group on Epidemiology at its next meeting in March 2012 and a representative of CIRAD to advise on the final process to be followed. The Commission confirmed that it was not advisable to abandon the project and reiterated its wish that the work should now be completed.

3.2. Revision of BSE surveillance model

The Commission was informed that the authors of the BSE surveillance model had been contacted and a reply obtained with an opinion on the proposals for surveillance strategies that would take account of the situation faced by those Member Countries that could not meet all the surveillance requirements as required in the *Terrestrial Code* due to a smaller cattle population. The Commission requested that the Scientific and Technical Department forward the response from the authors to the *ad hoc* Group on BSE with a view to electronic discussion to obtain an overview of the matter before the 80th General Session in May 2012.

3.3. Livestock-wildlife interface policy

The Commission postponed discussion on this matter following a joint discussion with the Code Commission on this matter (see Agenda Item 5.10).

3.4. Information on recent personnel transfer in the Scientific and Technical Department of the OIE

Dr Miyagishima introduced the new staff members of the Scientific and Technical Department and indicated that the shortage of personnel identified during the previous meetings of the Commission was now mostly resolved.

4. OIE Collaborating Centres

The Commission was informed on the new OIE policy and procedure to designate Collaborating Centres (CCs), in line with the revised Basic Texts of the OIE adopted in May 2011. Whenever an institution requested to become a CC, the application should first be evaluated by the relevant Specialist Commission and by the relevant Regional Commission before proposals be forwarded to the OIE Council. The Scientific Commission was now responsible for evaluating applications related to risk analysis, epidemiology, wildlife, disease control and the animal-human-ecosystem interface. The final proposals from the OIE Council would be submitted to the World Assembly of Delegates for adoption in the form of a Resolution. It was also indicated that in future a CC would be designated for one specific specialty, instead of encompassing several specialties. Annual reports of CCs would also be reviewed by the relevant Specialist Commission.

4.1. Requests from Member Countries for designation of Collaborating Centres

The Commission considered the requests submitted to the OIE for the designation as OIE Collaborating Centres. After careful study, the Commission recommended that the following applications be approved by the OIE Council:

a) Italy

The application was for the official request from the existing Collaborating Centre *Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G. Caporale'* in Teramo, Italy to be split into and recognised for 4 distinct disciplines (Veterinary Training, Epidemiology, Animal Welfare and Food Safety) in accordance with the new policy of the OIE. The Commission considered the request that the Institute also be recognised as a Collaborating Centre for Training but agreed that training *per se* was an inherent function of all Collaborating Centres as outlined in their generic terms of reference and that there was no need to designate any Collaborating Centre specifically for a generic function such as training. The Commission, noting that the applications for Animal Welfare and for Food Safety were being dealt with by the Code Commission, recommended that the *Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G. Caporale'* be recognised as OIE Collaborating Centre for the following functional discipline:

- OIE Collaborating Centre for Epidemiology[1]

b) People's Republic of China

The Commission evaluated the request from the Delegate of China and recommended the establishment of the following Collaborating Centre:

- OIE Collaborating Centre for Zoonosis in Asia-Pacific[2]

c) OIE Collaborating Centre for Wildlife Disease Surveillance and Monitoring, Epidemiology and Management, Canada

The Commission considered and approved a proposal from the Delegate of Canada to create a consortium with a similar institution in the USA to avoid having two Collaborating Centres on Wildlife in the same region and to comply with the OIE policy. The Commission noted that the new Centre located in two sites would have one single focal point that would rotate between the two institutes.

A revised application from Cuba seeking the confirmation of the provisionally approved CC for Epidemiology and Diagnosis of Emerging, Re-emerging and Transboundary Diseases in the Caribbean and Central America as the CC for Diagnosis and Risk Management of Biological Disasters in Animals was examined by the Commission. The Commission decided to put the application on hold while requesting more information from the Delegate to enable an informed decision by the Commission at its next meeting, while maintaining the previous designation.

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1 The OIE Council, which met from 28 February to 1 March 2012, recommended that if the application was approved by the OIE Regional Commission for Europe, the application be put on hold until the evaluation of the two other applications from the same institution for animal welfare and for food safety had been concluded.

2 The OIE Council, which met from 28 February to 1 March 2012, recommended that if the application was approved by the OIE Regional Commission for Asia, the title of the proposed CC be amended as "OIE Collaborating Centre for Zoonoses from Asia-Pacific" to clarify that the CC would deal with those zoonoses endemic in Asia-Pacific and would provide services to all OIE Member Countries in the world.

5. Issues referred to the Scientific Commission by the Code Commission

5.1. Comments received from the Code Commission on the "Generic Checklist on the Practical Application of Compartmentalisation"

The Scientific Commission reviewed and endorsed the comments received from the Code Commission on the 'Generic Checklist on the Practical Application of Compartmentalisation' that had been developed by the Scientific Commission with the assistance of the *ad hoc* Group on Epidemiology. Minor amendments to the text related to the notification of disease outbreaks and emergency response were made and conveyed to the Code Commission. The text would shortly be placed on the OIE website as a guideline for the benefit of Member Countries.

5.2. Review of documents transferred from the Code Commission with comments from Member Countries:

The Scientific Commission reviewed draft or existing several Chapters of the *Terrestrial Code* for which Member Country comments had been received. The comments of the Scientific Commission were added to the following Chapters for further consideration by the Code Commission:

Chapter 1.2: *Criteria for listing of diseases:* Discussed between the two Commissions. Chapter forwarded to the Code Commission for further processing and possible adoption during the 80th General Session.

Chapter 6.9: *Antimicrobial resistance:* The Scientific Commission did not discuss this chapter with the Code Commission but endorsed the report of the *ad hoc* Group. The Commission could not address the additional comments received from Member Countries after the *ad hoc* Group meeting due to lack of time. The Commission therefore suggested addressing the scientific comments electronically; otherwise the comments could be addressed at the next *ad hoc* Group meeting in June 2012. Chapter 6.10 on risk assessment was referred to the Code Commission for circulation to Member Countries.

Chapters 8.10, 5.11: *Rabies:* Discussed between the two Commissions. Chapter forwarded to the Code Commission for further processing. Both Commissions agreed that the amended chapter be presented for adoption during the 80th General Session.

Chapter 8.12: *Rinderpest:* Discussed between the two Commissions. Member Country comments on the revised text of Chapter 8.12 would be reviewed with a view to adoption at the 80th General Session. Both Commissions noted that further action was dependent on progress and information especially on the procedures and guidelines for the sequestration of rinderpest virus from the Joint OIE/FAO Advisory Committee on Rinderpest.

Chapter 11.3: *Brucellosis:* Discussed between the two Commissions. Both Commissions took note of the apparent difficulties experienced by Member Countries in applying the concept of a pathogen approach for *Terrestrial Code* chapters if more than one pathogen was involved or when different pathogens in a multi-species disease (such as Brucellosis) needed to be considered for disease control and for the purposes of declaring disease freedom. It was agreed that these concerns be outlined in a separate summarised document to assist the *ad hoc* Group to revise the chapter in accordance with Member Country comments and in accordance with guidance on the recommended approach to be followed that would be provided following a discussion between the two Commissions in conjunction with their meeting in September 2012.

Chapters 12.1 and 1.1.6 (bis): *African horse sickness:* Comments of the Commission forwarded to the Code Commission with the request that the chapter be presented for adoption at the 80th General Session.

Chapter 14.8: *Peste des petits ruminants (PPR):* The Commissions discussed Member Country comments on the chapter. Concern was raised on the proposed inclusion of cattle and camels and the possible trade implications as well as financial implications of the surveillance to demonstrate freedom from disease. The Commissions agreed that further convincing scientific information would help to make an informed decision – also in respect of the safe trade in commodities from PPR infected countries.

The Scientific Commission was updated on the status of the *Terrestrial Manual* chapter on PPR. The diagnostic section of the chapter had been updated by the *ad hoc* Group and circulated for Member Country comments. The section on vaccines for PPR was still under study.

The Scientific Commission reiterated its previous recommendation that once the amended chapter for the *Terrestrial Code* had been adopted, PPR should be proposed for consideration by the OIE Council for official disease status recognition to enable the possible establishment of a global eradication programme for PPR.

Chapter 14.9: *Atypical scrapie:* Both Commissions discussed the request from the *International Embryo Transfer Society* (IETS) to consider adding atypical scrapie to the OIE listed diseases. Both Commissions reiterated their previous view that scientific evidence was insufficient to justify the request of the IETS.

5.3. Swine Vesicular Disease

The Commission reiterated its previous decision that further work on the revision of the chapter would depend on whether the disease would be retained on the OIE Listed Diseases following the adoption of the revised listing criteria for OIE Listed Diseases (Joint discussions with Code Commission).

5.4. Bluetongue

The Commission was in agreement with the comment from a Member Country that the criteria for vector-protected establishments for vector-borne diseases needed to be re-evaluated.

5.5. Foot and mouth disease

See comments under Agenda Item 11.

5.6. Echinococcosis/Hydatidosis

The Commission took note of the work of an *ad hoc* Group reporting to the Code Commission on this issue.

5.7. Explanation of "epidemiological important" in *Terrestrial Code* Chapters

Joint discussions with Code Commission.

5.8. Classical Swine Fever (CSF) and African Swine Fever (ASF)

In reply to comments from a Member Country, the Commission indicated that CSF and ASF were two distinct diseases each with a distinct epidemiology and it could not be implied that the control measures proposed for one disease would have a negative effect on the control of the other disease.

5.9. Tuberculosis

The Commission reiterated its previous decision that a review of the current chapter and the chapter on Tuberculosis of Cervidae was a priority once the revised chapter on Brucellosis had been adopted**.**

5.10. Joint discussion with the Code Commission (Described in detail in the report of the Code Commission)

6. Review of reports of *ad hoc* Group meetings

6.1. Report of the *ad hoc* Group on Epidemiology: 20 – 22 September 2011

The Commission acknowledged with appreciation the work conducted by the *ad hoc* Group.

The Commission discussed comments received from an external review on the draft guidelines for *General Principles for Disease Control* developed by the *ad hoc* Group and decided to refer these comments back to the Group with the request to amend the text accordingly and also to include an additional section on animal disease contingency planning. The draft text proposed by the *ad hoc* Group for possible consideration for inclusion in the *Terrestrial Code* should be amended accordingly following the review of the draft guidelines.

With regard to the proposal from the *ad hoc* Group for a possible inclusion in the Glossary of the *Terrestrial Code* of amended text for surveillance, the Commission considered that such a step would have major implications on several *Terrestrial Code* chapters. The *ad hoc* Group was therefore requested to first test the proposed new definitions against existing text in chapters in the *Terrestrial Code* to see whether a change in the existing text would not be better or easier for Member Countries to apply. The Commission also requested that the *ad hoc* Group appreciate that definitions in the Glossary of the *Terrestrial Code* were meant to be in support of the existing text in the Chapters and not of the text not yet developed that might need additional definitions.

The Commission noted the suggestion of the *ad hoc* Group for an international OIE Conference on animal health decision-making. The Commission recalled that the OIE had launched several initiatives in this regard following the Resolution adopted at the 77th General Session after a presentation of a Technical Item on Animal Disease Modelling - such as dedicating an entire volume of the OIE Scientific and Technical Review to this subject. The Commission recommended that the *ad hoc* Group should liaise with other interest groups on this topic and also participate in relevant workshops on the subject that were already announced to take place during 2012.

The draft agenda for the meeting of the *ad hoc* Group scheduled for March 2012 was reviewed to ensure that priority issues identified by the Commission were addressed and was approved by the Commission.

The Commission adopted the report of the *ad hoc* Group. The report is attached as Appendix III.

6.2. Report of the *ad hoc* Group on the Evaluation of the FMD status of Member Countries: 22 – 24 November 2011

The Commission acknowledged with appreciation the work done by the *ad hoc* Group. The *ad hoc* Group had received and evaluated dossiers for disease status recognition from 4 Member Countries, the recovery of status of one Member Country that experienced an outbreak of FMD and dossiers to be evaluated for the endorsement of official control programmes for FMD from 3 Member Countries. The *ad hoc* Group had evaluated all the dossiers in detail but had not been able to reach a final recommendation on all of them and had suggested that the Scientific and Technical Department obtained additional information from some of the applicant Member Countries to enable an informed decision by the *ad hoc* Group at its next meeting scheduled for February 2012.

On a request of the Scientific Commission, the *ad hoc* Group evaluated additional information submitted by a Member Country on the suspension of status following an outbreak of FMD and recommended further appropriate action by the Commission.

a) Evaluation of the request from three Member Countries for the establishment of a zone free from FMD where vaccination is not practised

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of 3 Member Countries for the establishment of a FMD free zone where vaccination is not practised. The application of one Member Country was not approved by the Commission and referred back to the applicant Member Country to consider the provisions provided in Article 8.5.2.

In the case of the second application, the Commission concluded that the zone without vaccination in a portion of the Macro-region of the Altiplano of Bolivia fulfilled the conditions to be considered a FMD free zone without vaccination in accordance with Article 8.5.4. of the *Terrestrial Code.*

In the case of the third application, the Commission, after discussions with the Director General, decided to apply the provisions of Resolution XXII of the 76th General Session and requested the Director General to despatch an expert mission to the country to enable the Commission to make an informed decision, taking into account the findings of the mission.

b) Evaluation of the request from a Member Country for the establishment of a zone free from FMD where vaccination is practised

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of a Member Country for the establishment of a FMD free zone where vaccination is practised. The application of the Member Country was not approved by the Commission and was referred back to the applicant Member Country to consider the provisions provided in Article 8.5.2

The Commission adopted the report of the *ad hoc* Group. The report is attached as Appendix IV.

6.3. Report of the *ad hoc* Group on the Evaluation of the FMD status of Member Countries: 31 January – 3 February 2012

This special meeting of the *ad hoc* Group was requested by the Commission to review Chapter 8.5 (Foot and mouth disease) of the *Terrestrial Code* and to complete the evaluation of Member Country applications for recognition of disease status and endorsement of official control programs for FMD, which had been left over from the November 2011 meeting, in the light of additional information provided by the applicant Member Countries.

a) OIE endorsed official control programme for FMD

The Commission took note of the observations of the *ad hoc* Group that the format of the existing questionnaire in Article 1.6.7 of the *Terrestrial Code* focused mainly on information on the status of the disease the *status quo* of the disease in a country but might not be clear enough in respect of information required from Member Countries on the future programme and plans for FMD control. The Commission considered and endorsed the proposal for an amendment of Article 1.6.7 of the *Terrestrial Code* and requested the Code Commission to circulate the amended Article for Member Country comments and possible adoption at the 80th General Session in May 2012.

The Commission considered and endorsed the recommendations of the *ad hoc* Group that the World Assembly of Delegates endorse the official control programmes for FMD for the following countries:

- Algeria, Morocco and Tunisia.

b) Evaluation of the request from a Member Country for recovery of FMD free country status where vaccination is not practised

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of one Member Country for the recovery of a FMD free country status where vaccination is not practised. The application of the Member Country was not approved by the Commission and was referred back to the applicant Member Country to consider the provisions provided in Article 8.5.2.

c) Revision of Chapter 8.5 (Foot and mouth disease)

The Commission noted with appreciation the progress made by the *ad hoc* Group in reviewing Chapter 8.5 of the *Terrestrial Code*. As the work was still on-going, the amendments already made were not discussed. The Commission reiterated its earlier decision that completion of the task was of high priority. The Director General was therefore requested to convene an additional meeting of the *ad hoc* Group in July 2012 to enable the Commission to evaluate the amended Chapter during its meeting in August 2012.

The Commission also proposed and submitted for consideration of the Council amendments to Resolution XXII (76th General Session, May 2008) to provide for national official control programmes for FMD and also to provide more clarity on the control measures that need to be applied by Member Countries having within their territory adjacent free zones with the same sanitary status.

The Commission adopted the report of the *ad hoc* Group. The report is attached as Appendix V.

6.4. Report of the *ad hoc* Group on the Evaluation of BSE Risk Status of Member Countries: 29 November – 2 December 2011

The Commission noted with appreciation the work of the *ad hoc* Group.

a) Evaluation of requests from Member Countries

The Commission considered and supported all of the recommendations of the *ad hoc* Group on the evaluation of 10 Member Countries for the evaluation of their BSE risk status and agreed to recommend the following Member Countries for adoption as having negligible risk for BSE by the OIE World Assembly of Delegates at the 80th General Session:

- Austria, Belgium, Brazil and Colombia.

The Commission agreed to recommend the following Member Countries for adoption as having a controlled risk for BSE by the OIE World Assembly of Delegates at the 80th General Session:

- Croatia and Nicaragua.

For the remaining 4 Member Countries, the applications were not approved and referred back to the applicant Member Countries with suggestions to the Member Countries on actions that needed to be taken to comply with the requirements of Chapter 11.5 of the *Terrestrial Code*.

b) Annual reconfirmation of BSE risk status

The Commission endorsed the minor changes proposed by the *ad hoc* Group to simplify the format for the annual reconfirmation of status in response to the comments raised by a Member Country. The amended annual reconfirmation form would be posted on the OIE website after the 80th General Session.

c) Evaluation of the BSurv surveillance model for BSE risk status

As stated under point E2, the Commission considered the response received from the authors of the BSurv model for surveillance of BSE risk status and recommended that the response be evaluated electronically by the *ad hoc* Group to provide feedback to the Commission prior to the 80th General Session.

The Commission adopted the report of the *ad hoc* Group. The report is attached as Appendix VI.

6.5. Report of the *ad hoc* Group on the Official Disease Status Recognition for Classical Swine Fever: 5 –7 December 2011

The Commission discussed in detail the report including the amended Chapter 15.2 and draft questionnaire prepared by the *ad hoc* Group on Classical swine fever (CSF) to make provision for Official Disease Status recognition of CSF. The proposal of the *ad hoc* Group to include diagrams with the different pathways for the recovery of status as well as on the different tests in the *Terrestrial Code* Chapter was positively considered by the Commission and confirmed by the President of the Code Commission who accepted the possibility of incorporating such diagrams at the end of the Chapter (similarly to the diagram that appeared in the FMD and avian influenza chapters).

The Commission adopted the report of the *ad hoc* Group with the understanding that another meeting of the *ad hoc* Group would be arranged to address any pending issues including Member Country comments so far received and the comments to be provided by the Code Commission. The report is attached as Appendix VII.

6.6. Report of the OIE Expert Meeting: Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive: 30 November – 1 December 2011

The Commission took, with appreciation, note of the work done by the Expert Meeting and recommended that the draft guidelines for assessing the risk of non-native animals becoming invasive, developed by the Expert Meeting, be published on the OIE website for the benefit of Member Countries.

The Commission adopted the report of the Expert Meeting. The report is attached as Appendix VIII.

6.7. Report of the *ad hoc* Group on Antimicrobial Resistance: 12 – 14 December 2011

The Commission could not address the additional comments received from Member Countries after the *ad hoc* Group meeting due to lack of time. The Commission suggested that the *ad hoc* Group electronically address the scientific comments received; otherwise the comments could be addressed at its next meeting in June 2012.

The chapter 6.10 on risk assessment was referred to the Code Commission for circulation to Member Countries.

The Commission endorsed the report of the *ad hoc* Group. The report is attached as Appendix IX.

6.8 Report of the *ad hoc* Group on Honey Bee Diseases: 31 January– 2 February 2012

The Commission was briefed on the work of the *ad hoc* Group and the outcomes of its recent meeting. The Commission congratulated the Group for the work done on the seven *Terrestrial Code* chapters on honey bee diseases.

The Commission supported a request for another meeting of the Group during June-July 2012 to finalize chapters after Member Country comments and to take into account the new criteria for listing disease chapter.

The Commission endorsed the report of the *ad hoc* Group. The report is attached as Appendix X.

6.9 Report of the *ad hoc* Group on Schmallenberg Virus: 9 February 2012

The Commission took, with appreciation, note of the meeting of experts convened by the Director General to discuss the emergence of this disease/syndrome in Europe.

The Commission was provided with information and an update on outbreaks of Schmallenberg Virus (SBV) in Germany by Dr. Mettenleiter, Head of Friedrich-Loeffler-Institut Germany. The Scientific Commission expressed its gratitude to the FLI, for providing a complete and transparent update as well as for sharing PCR for diagnosis with other laboratories in Europe.

The Scientific Commission, while mindful of the limitation in the knowledge so far available on the disease, reviewed and endorsed the recommendations of the *ad hoc* Group with minor amendments to the information on zones around outbreaks, as follows:

– The safe distance from outbreaks to be used for applying control measures could not yet be determined;

– The *Terrestrial Code* chapter on Bluetongue (BT) could be used as a model to provide guidance on measures for vector control, but taking into account that the infective periods of the two agents were different (1 week for SBV vs. 60 days for BT virus);

– It was essential to maintain vigilance as more clinical cases could be observed in the next calving/lambing season, given that based on the experiences so far, infection probably happened during periods of vector activity between 3-6 months before clinical signs in offspring were observed;

– The risk of disease spread from milk and meat was negligible.

On a request of the Director General, the Commission assisted in finalising an OIE press release on SBV which was subsequently also posted on the website of the OIE.

The Commission recommended that the *ad hoc* Group reconvene when more information became available and that Member Countries be given an update on the disease during the presentation of the Scientific Commission at the General Session in May 2012.

The Commission adopted the report of the *ad hoc* Group. The report is attached as Appendix XI.

7. Issues referred to the Scientific Commission by the Biological Standards Commission

7.1 Feedback on scientific partnership for Collaborating Centres and References Laboratories: guidelines on laboratory networking and ring tests

The Commission was informed and took note of the new Terms of Reference for networks of OIE Reference Laboratories designated for the same disease.

7.2 Development of DIVA tests for tuberculosis

The Commission took note of an application that was received for the evaluation of DIVA tests for tuberculosis vaccination. As vaccination of cattle against tuberculosis was not officially endorsed by the OIE, the Commission recommended that this issue be discussed in detail by the experts would be asked to review the chapters on tuberculosis in the *Terrestrial Code*.

7.3 Update on the progress of disease-specific chapters of the *Terrestrial Manual* under revision

Peste des Petits Ruminants – discussed under Agenda Item E above.

8. Update on 'One Health' activities

The Commission was informed by the Scientific and Technical Department on the events and activities of the OIE on "One Health".

8.1. Follow up to the 2010 Stone Mountain meeting process

The Commission noted the recent activities under the umbrella of the Stone Mountain meeting working groups in which the OIE participated. One of the working groups proposed a self-assessment process that could be either complimentary or included within the OIE PVS Pathway and the World Health Organisation (WHO)/International Health Regulations Implementation framework. A closer alignment of the efforts of the working group with the ongoing work by the Tripartite (OIE/WHO/FAO) had been proposed.

A second Stone Mountain-related meeting, that of the One Health Global Network working group, took place in November 2011, in which the OIE participated. A report was made available to the Commission members. The Commission noted that the OIE would continue engaging in the ongoing dialogue within this working group, looking at how best to fill an expressed need of networking between the various One Health efforts occurring globally while not attempting to create a burdensome governance structure.

8.2. Mexico "High-Level Technical Meeting" – 15-17 November 2011

The Commission was updated by the Scientific and Technical Department on the summary of the Mexico meeting. A provisional summary report of the meeting was available on the OIE website while a more detailed report was forthcoming. The Director General had expressed strong commitment to continue to expand the work of the OIE, together with FAO and WHO, on the three areas that were presented at the Mexico meeting as entry points for inter-sectorial collaboration (rabies, antimicrobial resistance and animal influenza).

8.3. Annual FAO/OIE/WHO Tripartite Meeting – 1-2 February 2012

The Commission was informed by the Scientific and Technical Department of the on-going efforts to better coordinate activities between FAO/OIE/WHO. The Commission noted that there was substantial discussion on issues related to One Health, and there was the need to continue to expand the Tripartite efforts to promote inter-sectorial collaboration through concrete actions. Among the recommendations of the meeting a specific commitment had been included to follow up on the main findings of the Mexico High-level Technical Meeting and other collaborative global conferences (such as the OIE Global Conference on Rabies of September 2011 and the OIE Global Conference on Wildlife Animal Health and Biodiversity of February 2011).

8.4. Planning for Prince Mahidol Award Conference 24-27 January 2013

The Commission was informed by the Scientific and Technical Department that there were an increasing number of One Health meetings scheduled. The Global Risk Forum's One Health Summit would take place at Davos, Switzerland, on 19-23 February 2012 with high level OIE participation. The Prince Mahidol Award Conference was planned for 24-27 January 2013 in Thailand.

8.5. 80th General Session Technical Item #1 (with questionnaire)

The Commission took note that the analysis on responses to the questionnaire was currently underway. A total of 114 responses (64%) had been received from Member Countries.

8.6. Report of the Working Group on Wildlife Diseases: 7 – 10 November 2011

The Commission discussed the report of the Working Group on Wildlife Diseases (hereafter the Working Group) and noted with appreciation the excellent work done by the Working Group in support of the objectives of the Commission and the OIE. An update on the OIE activities of the training of national Focal Points for Wildlife was provided by the Scientific and Technical Department.

The Chairman of the Working Group, who joined the Commission for discussions on the programme of the Working Group and priority issues identified by the Commission, provided an overview on the activities of the Working Group as reflected in the report. A brief update was provided on relevant activities including the development of a wildlife component in the PVS tool.

The Commission supported the initiative to work on guidelines on baseline surveillance in wild animals which would be sustainable at minimum costs. The Commission recommended that OFFLU provide a first draft to be discussed by the *ad hoc* Group in Epidemiology in collaboration with the Working Group. The Commission expressed its support for the publication by the OIE of the detailed document on the risk analysis of wildlife diseases that was being developed in collaboration with IUCN.

Following discussion with the Code Commission on the wildlife-livestock interface policy and on surveillance in wildlife, the Working Group was requested by the Commission to assist in the identification of epidemiologically important wildlife species in the *Terrestrial Code* chapters, taking care not to list every susceptible species but to propose the main ones where documented evidence indicated their role in the epidemiology of a disease that could compromise trade.

An update was provided by the OIE Animal Health Information Department on the progress being made with the WAHIS-Wild data capture system.

The Commission requested the Working Group to assist in providing guidance on the methodology for the collection of samples in wildlife which could best be promoted during the training workshops of Wildlife Focal points.

The Commission reiterated the importance of the involvement of members of the Working Group or other selected wildlife experts in selected *ad hoc* Groups dealing with diseases for which wildlife played a significant role in the epidemiology.

The report of the Working Group was adopted (80 SG/13 GT).

9. Evolution of emerging/other continuing epidemics

9.1. Glanders

The Commission was updated by the Animal Health Information Department on the current status of Glanders and its control in the Middle East. Note was taken that a regional conference on Glanders would take place in Dubai on 23-25 April 2012.

The Commission noted that a new diagnostic test for Glanders was now available that could pave the way to considering assessing country or zonal freedom from the disease in a future review of the *Terrestrial Code* chapter.

9.2. "Schmallenberg" virus outbreak in Europe – see Agenda Item F9 above

10. Scheduled or recently held scientific conferences relevant to the Scientific Commission

The Commission took note with appreciation of the conferences that had been or were being convened by the OIE or in collaboration with other international partners.

11. Foot and Mouth Disease (FMD)

11.1. General aspects related to the submission of dossiers for official recognition of status

The Commission took note of general administrative problems encountered with the processing and evaluations of dossiers received from Member Countries. It was reported that large-size files often got blocked within the email systems and implied significant costs and time for translation. The Commission recommended that a one-page executive summary stating briefly the aim and reasons for what a Member Country was applying for be submitted by Member Countries as an introduction to all applications. It was also proposed to limit the main application dossier to 50 pages with the possibility of adding appendices if the applicant country considered them as necessary. Due to administrative and translation problems encountered at the OIE Headquarters, the Commission agreed to a proposal from the Scientific and Technical Department to anticipate the deadline for submissions of dossiers to the OIE from 30 to 45 days before the date of the meeting of the relevant *ad hoc* Group. It was once again confirmed that dossiers should be sent prior to the meeting of the *ad hoc* Group to selected experts within the relevant *ad hoc* Group for preliminary reading, in order to evenly distribute the workload and to ensure detailed study and analysis of dossiers. The Commission agreed to request the Director General to make necessary arrangements so that all three official OIE languages could appropriately be handled in the work of the *ad hoc* Groups dealing with country status.

11.2. Planning of future OIE expert missions

The Commission re-iterated its previous decision to request the Director General to conduct an expert mission to the southern African region (Botswana, South Africa, Swaziland and Namibia) during July/August 2012 to assess the implementation and compliance with OIE standards for the maintenance of FMD free status.

11.3. OIE/FAO FMD Reference Laboratories Network

The Commission invited Dr Jef Hammond from the OIE/FAO FMD Reference Laboratory at Pirbright, UK, who was also managing the OIE/FAO FMD Reference Laboratories network and vaccine bank, to provide an overview on the current global status of FMD and on the activities of the network.

It was indicated that serotype O was still the dominant FMD virus (80% of the 2300 samples submitted and representing 38 countries) followed by serotype A (8.5%). During 2010 and 2011, serotypes C and SAT3 were not detected. Most of the samples received were from Afghanistan (292), Iran (91), Pakistan 130) and Turkey (68). Out of the total of 1041 samples received in 2011, 69 were positive for serotype Asia 1 and 338 for serotype O.

Vaccine matching tests had produced an acceptable result for serotype O but poor results for serotype Asia 1 (Shamir). Serotypes O, A and Asia 1 were regarded as the current most important threats for the global spread of FMD virus.

11.4. FMD network working group on post vaccination monitoring

A slide presentation given by a representative of FAO at a meeting of the OIE/FMD Reference Laboratory network's working group on post vaccination monitoring (PVM), held in India on 14 February 2012, was shared with the Commission.

It was explained that the objective of the initiative of the working group that had been established within the network was to produce guidelines on the assessment of effectiveness of FMD vaccination programmes, with main emphasis on post-vaccination monitoring. The working group also aimed to address issues on the assessment of vaccine quality, vaccine application efficacy, diagnostic tests and methods to establish herd immunity.

The Commission supported this initiative but cautioned against a too optimistic approach and recommended that the working group should first set clear priorities for its work. Emphasis should be on PVM and, if deemed necessary, include other aspects, such as vaccine quality at a later stage. The Commission was informed that the OIE had received several requests by international organisations to work on "certification" of vaccine manufacturers to facilitate the selection process after international tenders for vaccine purchase by these organisations. Currently, a possibility of adapting the *Pharmaceutical Inspection Scheme (PIC/S)*, a system used for human vaccine manufacturer inspection, to veterinary needs was being considered with a view to developing a reference document regarding GMP compliance of manufacturers. It was, however, acknowledged that this would be a lengthy process and that therefore, currently, the OIE was not in the position to assist with quality assessments of veterinary vaccine manufacturers. The Commission advised that this information should also be shared with the Biological Standards Commission which had the mandate within the Specialist Commissions to attend to this aspect.

The Commission encouraged active OIE participation in the working group on PVM. The Commission suggested using existing examples, such as that of Argentina and other countries that already proved to have successful PVM strategies, to draft the intended PVM guidelines. It was also essential that regional differences for planning of PVM strategies were well taken care of.

11.5. OIE expert mission to the Andean Region (Colombia, Ecuador, Peru)

The Commission was debriefed on the recent expert mission to the Andean region. Two members of the Scientific Commission, an invited expert of the OIE, and one representative each from PANAFTOSA, FAO and CAN constituted the mission. The main objective was to assess the possibilities for a regional approach for FMD control in the Andean region, more specifically between Colombia, Venezuela, Ecuador and Peru. The experts concluded that there were promising indications that such a regional approach was possible but that there were still critical elements that needed to be resolved such as the persistence of virus circulation in some areas and the need for closer cross-border control between the potential participating countries.

Due to unforeseen circumstances, the experts could not conduct a visit to Venezuela, although a brief discussion could be held with representatives of the Venezuelan Veterinary Services. A similar visit to Venezuela was scheduled to take place from 30 April to 4 May 2012. Although the expert team did not visit Bolivia, the general opinion was that especially the FMD control strategy in the western region of Bolivia should be included when considering a regional approach for FMD control in the Andean region.

The report of the visit and recommendations of the expert team was to be circulated by the Director General to the countries concerned for comments by April 2012.

11.6. Safety of casings for FMD virus

The Commission reviewed a document received from the Code Commission on the inactivation of casings for FMD, classical swine fever and African swine fever viruses. Although the Commission was in agreement with the recommendations in the document and in other similar publications by the same authors made available to the Commission, note was taken of a meeting on this issue by the European Food Safety Agency (EFSA) scheduled for February 2012. The Commission agreed that it would be advisable for the Code Commission to wait for the outcome of the EFSA meeting before a final decision on amendments to the *Terrestrial Code* on the inactivation of FMD virus was considered.

11.7. Global strategy for FMD control and Global FMD Conference (Thailand, 27-29 June 2012)

The Commission was briefed and took note of a draft document on the Global FMD Strategy that included the preliminary conclusions of a conference held at the OIE Headquarters in November 2011. The Commission agreed to provide comments on the document and also on the final version of the document that would be made available in April 2012.

An update was also provided on the progress made with the preparations for the second OIE/FAO Global FMD Conference, to be held in Bangkok, Thailand in June 2012.

11.8. Global FMD Research Alliance workshop (South Africa, 17 – 19 April 2012)

The Commission took note of the conference to be held in South Africa and supported this research initiative that would also include discussions on vaccine matching.

12. Bio-threat reduction

The Commission took note with appreciation of a document on Bio-threat Reduction developed by the OIE Scientific and Technical Department, which summarised existing OIE activities and tools contributing to minimising the risk of accidental and deliberate releases of animal pathogens.

Note was also taken of the on-going discussions to establish a new Joint OIE/FAO Advisory Committee on Rinderpest to oversee actions related to the sequestration and research of the rinderpest virus. The Commission, however, expressed its concern over the slow progress in establishing this Committee as any further progress, also in respect of the development of OIE standards, was dependent on the activities and participation of the committee.

13. Other matters discussed

- 'New' bluetongue serotypes - Following reports of possible additional circulating serotypes of the bluetongue virus, the Commission suggested that the OIE contact the authors of the reports to enquire whether or not the International Committee on Taxonomy of Virus (ICTV) had recognised the new bluetongue serotypes. Unless ICTV recognised the new classification of the bluetongue serotypes no further action was needed.

14. Update of the Work programme of Scientific Commission 2012/2013

The Commission identified the convening of the following *ad hoc* Groups and activities as priority for 2012/2013:

a) *Ad hoc* Group on Foot and mouth disease: Finalisation of the review of Chapter 8.5 of the *Terrestrial Code*

b) *Ad hoc* Group on Classical swine fever: Finalisation of amended Chapter

c) *Ad hoc* Group on Rift Valley fever: Review of the current Chapter in the *Terrestrial Code*

d) *Ad hoc* Group on Vector Surveillance: Review of the current Chapter to include provisions on arthropod vectors

e) *Ad hoc* Group to harmonise the *Terrestrial Code* chapters on viral diseases of pigs in respect of control measures relative to management practices

f) *Ad hoc* Group on Schmallenberg virus (second meeting): Updating conclusions and recommendations of the first meeting of the Group as necessary.

g) *Ad hoc* Group on Peste des petits ruminants: Revision of the current chapter to introduce provisions for safety of commodities, official status recognition and possibly global eradication.

15. Next meeting of the Scientific Commission for Animal Diseases

The next meeting of the Scientific Commission for Animal Diseases was scheduled to take place from 27 to 31 August 2012, pending confirmation.

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…/Appendices

Appendix I

MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 13 - 17 February 2012

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1. Opening

2. Adoption of the draft agenda

3. Feedback on issues raised during the meeting of the Scientific Commission for Animal Diseases of 29 August to 2 September 2011

3.1. Guide on Terrestrial Animal Health Surveillance
3.2. Revision of BSE surveillance model
3.3. Livestock-wildlife interface policy
3.4. Information on recent personnel transfer in the Scientific and Technical Department of the OIE

4. OIE Collaborating Centres

4.1. Requests from Member Countries for designation of Collaborating Centres
   a) Italy
   b) People's Republic of China
   c) OIE Collaborating Centre for Wildlife Disease Surveillance and Monitoring, Epidemiology and Management, Canada

5. Issues referred to the Scientific Commission by the Code Commission

5.1. Comments received from the Code Commission on the "Generic Checklist on the Practical Application of Compartmentalisation"
5.2. Review of documents transferred from the Code Commission with comments from Member Countries:
5.3. Swine Vesicular Disease
5.4. Bluetongue
5.5. Foot and mouth disease
5.6. Echinococcosis/Hydatidosis
5.7. Explanation of "epidemiological important" in *Terrestrial Code* Chapters
5.8. Classical Swine Fever (CSF) and African Swine Fever (ASF)
5.9. Tuberculosis
5.10. Joint discussion with the Code Commission

6. Review of reports of *ad hoc* Group meetings

6.1. Report of the *ad hoc* Group on Epidemiology: 20 – 22 September 2011
6.2. Report of the *ad hoc* Group on the Evaluation of the FMD status of Member Countries: 22 – 24 November 2011
   a) Evaluation of the request from three Member Countries for the establishment of a zone free from FMD where vaccination is not practised
   b) Evaluation of the request from a Member Country for the establishment of a zone free from FMD where vaccination is practised

6.3. Report of the *ad hoc* Group on the Evaluation of the FMD status of Member Countries: 31 January – 3 February 2012
   a) OIE endorsed official control programme for FMD
   b) Evaluation of the request from a Member Country for recovery of FMD free country status where vaccination is not practised
   c) Revision of Chapter 8.5 (Foot and mouth disease)

6.4. Report of the *ad hoc* Group on the Evaluation of BSE Risk Status of Member Countries: 29 November – 2 December 2011.
   a) Evaluation of requests from Member Countries
   b) Annual reconfirmation of BSE risk status
   c) Evaluation of the BSurv surveillance model for BSE risk status

6.5. Report of the *ad hoc* Group on the Official Disease Status Recognition for Classical Swine Fever: 5 –7 December 2011

6.6. Report of the *ad hoc* Group on Invasive Animal Species: 30 November – 1 December 2011

6.7. Report of the *ad hoc* Group on Antimicrobial Resistance: 12 – 14 December 2011

6.8 Report of the *ad hoc* Group on Honey Bee Diseases: 31 January– 2 February 2012

6.9 Report of the *ad hoc* Group on Schmallenberg Virus: 9 February 2012

7. Issues referred to the Scientific Commission by the Biological Standards Commission

7.1 Feedback on scientific partnership for Collaborating Centres and References Laboratories: guidelines on laboratory networking and ring tests

7.2 Development of DIVA tests for tuberculosis

7.3 Update on the progress of disease-specific chapters of the *Terrestrial Manual* under revision

8. Update on 'One Health' activities

8.1. Follow up to the 2010 Stone Mountain meeting process

8.2. Mexico "High-Level Technical Meeting" – 15-17 November 2011

8.3. Annual FAO/OIE/WHO Tripartite Meeting – 1-2 February 2012

8.4. Planning for Prince Mahidol Award Conference 24-27 January 2013

8.5. 80th General Session Technical Item #1 (with questionnaire)

8.6. Report of the Working Group on Wildlife Diseases: 7 – 10 November 2011

9. Evolution of emerging/other continuing epidemics

9.1. Glanders

9.2. "Schmallenberg" virus outbreak in Europe – see Agenda Item F9 above

10. Scheduled or recently held scientific conferences relevant to the Scientific Commission

11. Foot and Mouth Disease (FMD)

11.1. General aspects related to the submission of dossiers for official recognition of status

11.2. Planning of future OIE expert missions

11.3. OIE/FAO FMD Reference Laboratories Network

11.4. FMD network working group on post vaccination monitoring

11.5. OIE expert mission to the Andean Region (Colombia, Ecuador, Peru)

11.6. Safety of casings for FMD virus

11.7. Global strategy for FMD control and Global FMD Conference (Thailand, 27-29 June 2012)

11.8. Global FMD Research Alliance workshop (South Africa, 17 – 19 April 2012)

12. Bio-threat reduction

13. Other matters discussed

14. Update of the Work programme of Scientific Commission 2012/2013

15. Next meeting of the Scientific Commission for Animal Diseases

MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 13 – 17 February 2012

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Annexe III

Original: English
September 2011

MEETING OF THE OIE *AD HOC* GROUP ON EPIDEMIOLOGY

Fort Collins, USA, 20 – 22 September 2011

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The meeting of the OIE *ad hoc* Group on Epidemiology (hereafter the Group) was held at the OIE Collaborating Centre for Animal Health Surveillance, Risk Analysis and Modelling, in Fort Collins, Colorado, the United States of America. On behalf of the OIE, Dr Alessandro Ripani welcomed the participants and thanked the Collaborating Centre for hosting the meeting. He gave an overview on the main topics on the agenda.

1. Adoption of the agenda and appointment of a rapporteur

The meeting was chaired by Dr Cristóbal Zepeda and Dr Vitor Picao Goncalves was designated as rapporteur. The adopted agenda and list of participants are attached as Appendices I and II, respectively.

2. Feedback from the Scientific Commission meeting 29 August - 02 September 2011

Dr Alessandro Ripani provided information on the topic-specific discussions on the work of the *ad hoc* Group on Epidemiology that had taken place at the last meeting of the Scientific Commission for Animal Diseases (Scientific Commission), notably on the demand for finalising the document addressing the General Guidelines for Disease Control. He informed the Group that the Scientific Commission expected both a Chapter for the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) and an expanded version for inclusion on the OIE website. The Group was also asked to review the *Terrestrial Code* definitions regarding surveillance, including a critical analysis of the Draft Output of the pre-ICAHS Workshop on Animal Health Surveillance Terminology, held in May 2011, in Lyons, France.

3. Development of a *Terrestrial Code* Chapter on General Principles for Disease Control

At the request of the Scientific Commission, the Group reviewed the document on generic guidelines for disease control developed at the previous meeting, in March 2011, and worked on a new version to be included in the *Terrestrial Code* as a new horizontal Chapter. There was common understanding that such a Chapter should provide a set of principles to be taken into account by countries wishing to develop disease control policies. It should not be prescriptive and ought to make reference to other *Terrestrial Code* Chapters where appropriate. The title was changed, accordingly, to "General Principles for Disease Control". The Group considered that the content of the current version of the document was close to the format used in the *Terrestrial Code* but undertook a thorough revision of the text.

At the request of the Scientific Commission, the Group discussed the inclusion of sections on immediate action in case of disease outbreaks, and sample collection and shipping. The section on emergency preparedness and response was expanded and a section on outbreak investigation was added. The Group felt that sample collection and shipping was adequately covered in Chapter 1.1.1 of the OIE *Manual* and a reference thereto was inserted.

The Group expanded the text on economic and social issues to be considered in animal disease control. In addition, the Group discussed the importance of livestock production systems that were generally not included in commercial animal industries, such as backyard operations and pastoralist herders, and included a sentence highlighting the importance of taking the needs of such stakeholders into account.

The proposed *Code* Chapter is attached as Appendix III.

4. Development of a Web version of the General Principles for Disease Control

The Group used the proposed *Code* chapter as a basis for the expanded, web document. It added tables, figures and further explanatory text with a view to enhancing the clarity while maintaining the conciseness of the document.

The proposed web version document is attached as Appendix IV.

5. Surveillance definitions and analysis of the surveillance terminology issued from pre-ICAHS Workshop on Animal Health Surveillance Terminology held prior to the International Conference on Animal Health Surveillance (ICAHS), 17-20 May 2011

The Group discussed the Draft Output of the pre-ICAHS Workshop on Animal Health Surveillance Terminology, held in May 2011, in Lyon. It was noted that this document, as well as the ICAHS Conference, reflected the growing importance of animal health surveillance systems and represented an important contribution to the discussion at the global level. With regard to the surveillance definitions proposed by the pre-ICAHS workshop, the Group acknowledged the relevance of most of the concepts built in the definitions. However, the Group felt that the proposed terminology was too detailed and for the purposes of the *Terrestrial Code* more concise definitions were preferred.

The surveillance definitions that had been developed and previously proposed by the Group were reviewed, taking into account the recommendations of the pre-ICAHS workshop. In addition, the Group reviewed the *Terrestrial Code*'s definition on "surveillance system" in Chapter 1.4 and proposed to delete it. The Group felt that this definition was not needed in light of its proposed amended definition for surveillance.

The Group felt that the definition for surveillance was an umbrella term for different types of surveillance in use. Therefore, the Group proposed a broader definition for the term "surveillance" and, by doing so, also highlighted the importance of surveillance for early detection. The *Terrestrial Code* already included a definition for specific surveillance focused on a specific disease or infection and the Group proposed to rename it "pathogen-specific surveillance". In addition, the Group agreed that two other types of surveillance of growing importance warranted inclusion. To this end, the Group proposed to amend the current definitions for "surveillance" and "specific surveillance" and include new definitions for "risk-based surveillance" and "syndromic surveillance".

The proposed surveillance definitions are attached in Appendix V.

6. Other matters

Following the outcome on the proposed Chapter on Disease Control, the Group agreed to propose that the work on guidelines for contingency planning be initiated.

The meeting of the OIE *ad hoc* Group was preceded by an extra day of presentations by the OIE Collaborating Centre for Animal Health Surveillance, Risk Analysis and Modelling. Dr Larry Granger, the Director, welcomed the Group participants. The purpose of the presentations was to generate a discussion on the use of modelling and other epidemiological tools in disease control. The outline of presentations is given in Appendix VI.

The Group participants discussed the usefulness of tools and applications presented in decision making in animal health. Some of the issues that may warranted discussion were:

- Should the OIE continue to provide guidance on the use of models?
- Should the OIE expand its guidance to include other tools and approaches in decision-making?
- Should the guidelines be on decision-making in animal health?
- Should the OIE organize a conference for CVO's on decision-making?
- What types of information do decision-makers need?
- What methods, techniques and models are available?
- What are the risks and benefits associated with each approach?

The Group suggested the OIE organize a conference on decision-making in animal health addressing the issues outlined above.

7. Next meeting of the *ad hoc* Group on Epidemiology

Of the proposed dates, the Group found the dates 6 to 8 March 2012 to be the most convenient for its next meeting.

8. Finalisation and adoption of the report

The *ad hoc* Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report captured the discussions but should be circulated to the entire Group for final comments.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON EPIDEMIOLOGY

Fort Collins, USA, 20 – 22 September 2011

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Agenda

1. Adoption of the agenda and appointment of a rapporteur
2. Feedback from the Scientific Commission meeting 29 August - 02 September 2011
3. Development of a *Terrestrial Code* Chapter on General Principles for Disease Control
4. Development of a Web version of the General Principles for Disease Control
5. Surveillance definitions and analysis of the surveillance terminology issued from pre-ICAHS Workshop on Animal Health Surveillance Terminology held prior to the International Conference on Animal Health Surveillance (ICAHS), 17-20 May 2011
6. Other matters
7. Next meeting of the *ad hoc* Group on Epidemiology
8. Adoption of the draft report

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON EPIDEMIOLOGY

Fort Collins, USA, 20 – 22 September 2011

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List of participants

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Appendix III

Chapter 4.x.

General Principles ~~Generic Guidelines~~ for Disease Control

Article 4.x.1

Introduction and objectives

The objective of ~~these generic guidelines~~ this chapter is to provide a framework for countries to establish disease control priorities, strategies and policies to achieve the desired goal of specific animal disease control programmes. ~~The guidelines are~~This chapter ~~not intended to be a prescriptive list but~~provides~~ rather~~ a conceptual framework that can be adapted to a particular national and epidemiological context.

~~These guidelines are~~The chapter is intended to help countries identify priorities, objectives and desired endpoints of disease control programmes. Disease control programmes are often established with the aim of eventual eradication of agents at a country, zone or compartment level. While this approach is desirable, the needs of stakeholders may require a broader range of outcomes. For some diseases, eradication may not be economically or practically feasible and options for sustained mitigation of disease impacts may be needed.

It is important to clearly formulate the programme goals and these may range from simple mitigation of impacts to disease control, progressive control or eradication of the disease. ~~These guidelines~~This chapter highlights the importance of economic assessment of disease intervention options in the design of programmes taking into consideration effectiveness, feasibility of implementation, as well as costs and benefits.

It is assumed that the country has determined its disease control priorities and ~~these guidelines~~this chapter should ~~are intended to~~ help Members in the development and implementation of a specific animal health programme that includes objectives, policies and strategies adapted to the full range of national needs. Specific outputs of this process will include the **rationale for establishing a disease control programme** ~~**a problem statement**~~, programme goals, a **control programme strategy** and an **implementation plan**.

~~B.~~ Article 4.x.2

Rationale for establishing a disease control programme ~~Problem statement~~

The country should clearly state the rationale for establishing a disease control programme. Consideration should be given to public health, food safety, food security, biodiversity and socioeconomic aspects.

The justification for the disease control programme should include a summary of the current knowledge about the epidemiological situation within the country detailing:

1. Description of the disease situation
2. Description of disease impacts (public health, food safety, food security and socioeconomic) and how these are distributed among stakeholders
3. Identification and level of interest ~~engagement~~ of stakeholders

Article 4.x.3

~~C.~~ Control programme ~~strategy~~ goals

The desired endpoint of a control programme should be defined from the outset. Although eradication has traditionally been the goal for many disease control programmes it may not always be achievable within a reasonable timeframe or at an acceptable cost. The epidemiology of the disease along with the availability of technical tools as well as social and economic considerations will dictate if eradication is achievable or if control at a certain prevalence level is adequate. For some diseases, or in certain situations, the emphasis of a programme should be on reducing the health and economic impact of the disease. Some of the factors to consider are listed below.

Biological factors	Availability of technical tools
– Species affected – Agent stability and diversity – Density of susceptible species – Wildlife reservoir – Vector transmission – Transmissibility – Current extent of disease – Survival in the environment – Carrier state – Ease of clinical recognition	– Diagnostic tests – Vaccines – Treatment – Disinfectants and insecticides ~~– Effectiveness of isolation/quarantine~~ ~~Disinfection~~
Control measures	**Socioeconomic considerations**
– Movement control – Stamping-out – Zoning/compartmentalization – Herd accreditation – Isolation and quarantine – Cleaning and disinfection – Vector and reservoir control – Treatment of products and by-products	– Cost and benefits of intervention – Availability of resources – Public health implications – Ease of implementation – Stakeholder engagement – Environmental impact – Political will

Article 4.x.4

~~D.~~ Strategic planning

The *Veterinary Authority* in collaboration with concerned stakeholders should develop ~~The development of~~ a strategic plan ~~should be~~ based on the choice of the endpoint of the programme. The choice of intervention options should be based on their biological effectiveness, ease and cost of implementation to fit the needs of the programme, as well as the benefits that are expected by reaching the objectives of the programme. Tools such as v~~V~~alue chain analysis may be used to help~~s~~ understand the role of different players within the production system, identify critical control points to target measures and provide an indication on the incentives for and feasibility of implementation of the programme. The decision on the most appropriate intervention options should take into account cost-benefit considerations, in conjunction with the likelihood of success of a particular set of disease control measures.

Institutional analysis examines the organizations involved in delivering services and the processes that govern their interaction. This type of analysis would be helpful to inform the strategic planning process and identify areas where a change would enable better programme implementation and facilitate effective collaboration.

The programme should include a continued review process to assess the effectiveness of the interventions that are being applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required.

The programme should take into consideration the distribution of costs and benefits among different stakeholders and understand the factors limiting stakeholder participation in programme activities. These factors can affect the optimal selection of interventions. Programme policies need to include incentives for engagement including, for example, additional services for the producer, appropriate compensation schemes, adding value to the final product and protecting public health. In addition, it may be necessary to include measures to raise awareness and ensure compliance including movement restrictions and fines.

In addition, disease control programmes should take into consideration non financial factors (social, cultural, religious, etc.) affecting the livelihoods and well-being of animal owners such as pastoralists, indigenous communities or small-scale backyard producers. These factors can be important incentives for participation or non compliance and ultimately impact the success of the programme.

Article 4.x.5

~~E.~~ Implementation plan

A disease control programme should be based on an efficient and effective veterinary service. Countries are encouraged to follow the provisions of Chapter 3.1 of the *Terrestrial Animal Health Code* (*Terrestrial Code*), as well as to undergo a Performance of Veterinary Services (PVS) evaluation and address the gaps that may be identified. In addition, the programme should have political support, and sustainable sources of funding including government and private stakeholder contributions.

The implementation plan should address the following:

1. Regulatory framework

The disease control programme should be supported by effective legislation at the primary and secondary levels. Countries are encouraged to follow the OIE Guidelines on Veterinary Legislation[1]. ~~(http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/A_Guidelines_VetLeg.pdf).~~ The disease should be notifiable throughout the country. The regulatory framework for the disease control programme should be flexible enough to be adapted to evolving programme needs.

2. Epidemiological situation

The implementation of the programme needs to take into consideration:

a. Distribution and density of susceptible species including wildlife
~~a.~~b. Knowledge of ~~livestock~~ animal production and marketing systems
~~b.~~c. Geographical and temporal distribution of disease
~~c.~~d. Zoonotic potential
~~d.~~e. Risk factors and critical control points
~~e.~~f. Vectors
~~f.~~g. Carriers
h. Reservoirs
i. Neighbouring specific disease situation where applicable
~~g.~~j. Evaluate the appropriateness and need for establishing disease zones or compartments

3. Disease surveillance

The underpinning of the disease control programme activities is an effective surveillance system that provides guidance on priorities and targets for the application of interventions. The surveillance system should consist of general surveillance activities reinforced by pathogen specific activities. A clear case definition and outbreak investigation and response procedures are required. The provisions of Chapters 1.1 on notification of disease and epidemiological information and 1.4 ~~of the *Terrestrial Code*~~ on animal health surveillance of the *Terrestrial Code* should be referred to.

4. Diagnostic capability

The programme needs to be supported by diagnostic facilities with adequate capacity. Samples for diagnosis should be collected and shipped in accordance to Chapter 1.1.1 of the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.* The choice of diagnostic tests applied should ensure detection and confirmation of the disease. The tests should follow the specific requirements in Chapter 1.1.4 on Principles of Validation of Diagnostic Assays for Infectious Diseases and the disease specific recommendations in the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. Diagnostic facilities, either official or accredited[2], should be under a quality assurance scheme coordinated by the designated national reference laboratory system ~~(ies)~~. The latter should establish communication with an OIE reference laboratory for the particular disease. National and sub-national laboratories need to ensure that diagnostic results are communicated to the national surveillance system, field veterinarians and producers. National laboratories are also needed to provide independent and impartial quality control of vaccines. ~~When advantageous,~~ When

[1] OIE Guidelines on Veterinary Legislation: http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/A_Guidelines_VetLeg.pdf

~~national~~appropriate, national laboratories are encouraged to submit samples to OIE reference laboratories for confirmation of findings and developing an understanding of the molecular epidemiology of the agent.

5. Traceability

An effective traceability system facilitates the identification of affected individual animals, herds or flocks. ~~The existing traceability system may need to be adapted to take into account the epidemiology of the disease particularly the length of the incubation period.~~ The design of the traceability system should follow the provisions of the *Terrestrial Code* in particular, Chapter 4.1 on General Principles on Identification and Traceability of Live Animals and 4.2 on Design and Implementation of Identification Systems to Achieve Animal Traceability.

6. Vaccination

a) Role of vaccination

Vaccination is an essential tool in the control of many diseases. However, vaccination on its own will not usually achieve the desired results unless the vaccination programme is part of an integrated control strategy. Depending on the epidemiological situation, the pattern of animal movements, population density and production systems within the country, targeted vaccination may be more effective than systematic mass vaccination. Where ~~appropriate~~possible, vaccination campaigns should be serologically monitored for their effectiveness to ensure that herd-level immunity objectives are being met.

b) Vaccine quality

A vaccine quality assurance programme ensures the purity, safety, potency of vaccines as well as measures their efficacy in relation to the circulating strains. Vaccines used within control programmes should be licensed under the authority of the official veterinary services in accordance to the provisions of the OIE *Manual of diagnostic tests and vaccines for terrestrial animals* ~~international standards~~ and preferably tested independently for safety and potency.

c) Vaccine delivery

Effective delivery of vaccine, including preservation of the cold chain and proper administration, is the cornerstone for reaching an adequate level of population immunity. Governmental and/or private schemes that include quality assurance controls can be established to ensure vaccine distribution at the local level.

d) Vaccine and antigen banks

Banks could be useful to ensure sufficient stocks are available if targeted vaccination is needed. Such banks may be held at national or regional levels and should comply with the provisions of Chapter 1.1.10 on Guidelines for international standards for vaccines banks of the OIE *Manual of diagnostic tests and vaccines for terrestrial animals*~~.~~

7. Emergency preparedness and response

Countries should develop emergency preparedness and response plans for immediate action ~~to be applied~~ in case of ~~a disease introduction~~an outbreak in~~to~~ a formerly free country or zone, or an unexpected increase in incidence in areas that have reached an appropriate level of control or in the case of disasters. These plans are especially important for rapidly spreading diseases. Plans should include detailed disease investigation procedures in case of a suspected outbreak to confirm or rule out disease as well as immediate measures to limit the spread of the disease and minimize impact. Emergency response plans should be up to date, tested in the real world setting and embedded in the legal framework. Emergency funds should be available to cover operational costs and indemnities. The chain of command and coordination with all key players, where necessary, including the police and armed forces, should be well established to ensure control efforts are executed rapidly and with success. Contingency plans need to be in place when immediate response is needed, including critical actions that need to be taken when a sudden outbreak of a disease is notified. Arrangements need to be in place to ensure rapid communication at all times. It is also important that these plans are coordinated on a regional level, particularly for transboundary animal diseases.

Following the confirmation of an outbreak, control areas may be established around the affected premises. The extent of these areas depends on a number of factors, in particular, the epidemiology of the disease in question. The measures imposed in these control areas will often include movement restrictions, intensified surveillance as well as specific measures applied to affected premises. In addition, for ease of management and for trade purposes, a larger area surrounding the control areas may be designated corresponding to administrative boundaries, ~~or~~ geographical or other appropriate features.

When the disease control measures applied have a significant economic impact, appropriate compensation mechanisms are needed to ensure cooperation by farmers. Funding is essential but is often lacking leading to non-compliance, if the disease occurs again. Partnerships between government and the private sector have proven effective to develop sustainable contingency funds in several parts of the world.

Information on disease confirmation should be immediately sent to other appropriate ministries, trading partners, stakeholders and made generally available general public. In addition, notification to the OIE should follow the provisions of Chapter 1.1 of the Terrestrial Animal Health Code.

8. Outbreak investigation

An outbreak investigation is a systematic procedure to help identify cause and source of cases of infection with a view to control and prevent possible future occurrence. Outbreak investigation is an important responsibility of the Veterinary Services to ensure that preventive and control measures are applied. Investigations also help recognize intervention strategy failures and successes, identify changes in the agent, environment or events that may be beyond the scope of a disease control programme. The main steps of the outbreak investigation may need to be adapted to the specific requirements of the control strategy. It is important to maintain records of outbreak investigations including those which were not confirmed as this will help demonstrate the effectiveness of the surveillance system.

9~~8~~. Regional integration

Many diseases are considered transboundary animal diseases and require a regional approach to disease control. Regional and inter-sectorial agreements, including the chief veterinary officers in each country and representatives from international and other relevant regional organizations should be established to ensure proper coordination. Where possible, member countries ~~should~~ act on a regional basis to ensure that~~regional~~ funds and resources are available ~~could be pooled to ensure a source is available~~ in an emergency and to protect the region from disease incursion and spread.

10~~9~~. Social participation

Communication, awareness programmes and programme ownership need to be in place. Stakeholders should be involved in the development, planning, implementation, ~~and~~ management and revision of the programme. This should be an on-going process.

11~~0~~. ~~Disease control measures~~ Programme management

Disease control measures to be applied in the programme can be implemented by the *Veterinary Authority*, or private or community entities or a combination of ~~both~~all. In any event, the overall responsibility for oversight of the programme remains with the *Veterinary Authority*. ~~The basic principles of a control programme and the measures to address them include:~~

~~a) Identification of foci of infection~~
~~Early detection and diagnosis~~
~~Disease reporting~~
~~Surveys~~
~~Abattoir surveillance~~
~~Epidemiological and outbreak investigation~~
~~b) Prevention of infection of susceptible hosts,~~
~~Vaccination~~
~~Quarantine~~
~~Animal movement control~~
~~Vector control~~
~~Public awareness and communication~~

~~c) Elimination of the infectious agent~~
~~Cleaning, disinfection and rest period~~
~~Animal treatments~~
~~Treatment of products and by-products~~
~~Test and isolation~~
~~Test and slaughter~~
~~Stamping-out~~

The management of the application the disease control measures should follow standard operating procedures including:

- Implementation, maintenance, monitoring of the measures
- Application of corrective actions
- Verification of the process
- Record keeping

~~11. Assessment of programmes~~

The programme should include a continued review process to assess the effectiveness of the interventions that are being applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required. This process should begin with the establishment of baseline data on the epidemiological, economic and social impact of the disease. The programme should collect data on process and impact indicators. This enables measurement of the effectiveness of interventions on epidemiological indicators such as incidence and prevalence, and identify areas needing strengthening.

~~12~~12. Role of research in support of disease control programmes

During the strategic planning and assessment of programmes certain areas needing further research may be identified. Communication with national and international research institutions should be established to address programme needs.

~~13~~13. Training and capacity building

Institutional capacity building is important in development of systems and infrastructure. The personnel in charge of implementing the measures within the programme need to be adequately trained and updated on the current knowledge on the disease. Veterinary accreditation schemes of private veterinarians and veterinary para-professionals can be a useful tool to increase the veterinary presence in the field, however training and supervision coordinated by the official veterinary service is required.

Appendix IV

General Principles for Disease Control

Introduction and objectives

The objective of these guidelines is to provide a framework for countries to establish disease control priorities, strategies and policies to achieve the desired goal of specific animal disease control programmes. These guidelines provide a conceptual framework that can be adapted to a particular national and epidemiological context.

The guidelines are intended to help countries identify priorities, objectives and desired endpoints of disease control programmes. Disease control programmes are often established with the aim of eventual eradication of agents at a country, zone or compartment level. While this approach is desirable, the needs of stakeholders may require a broader range of outcomes. For some diseases, eradication may not be economically or practically feasible and options for sustained mitigation of disease impacts may be needed. It is important to clearly formulate the programme goals and these may range from simple mitigation of impacts to disease control, progressive control or eradication of the disease. The guidelines highlight the importance of economic assessment of disease intervention options in the design of programmes taking into consideration effectiveness, feasibility of implementation, as well as costs and benefits.

It is assumed that the country has determined its disease control priorities and this chapter should help Members in the development and implementation of a specific animal health programme that includes objectives, policies and strategies adapted to the full range of national needs. Specific outputs of this process will include the rationale for establishing a disease control programme, programme goals, a control programme strategy and an implementation plan (Figure 1).

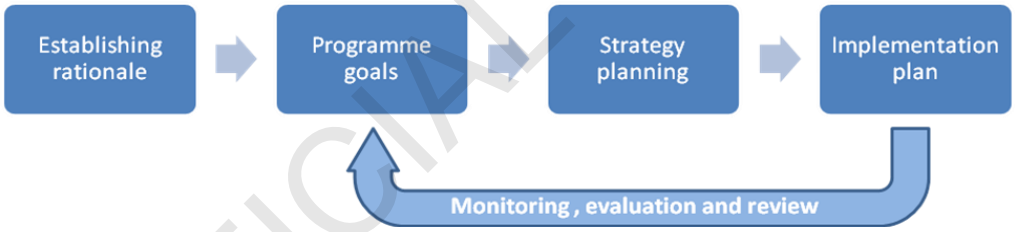

Figure 1 – Steps in establishing a disease control programme

Rationale for establishing a disease control programme

The country should clearly state the rationale for establishing a disease control programme. Consideration should be given to public health, food safety, food security, biodiversity and socioeconomic aspects.

The justification for the disease control programme should include a summary of the current knowledge about the epidemiological situation within the country detailing:

4. Description of the disease situation
5. Description of disease impacts (public health, food safety, food security and socioeconomic) and how these are distributed among stakeholders
6. Identification and level of interest of stakeholders

Control programme goals

The desired endpoint of a control programme should be defined from the outset. Although eradication has traditionally been the goal for many disease control programmes it may not always be achievable within a reasonable timeframe or at an acceptable cost. The epidemiology of the disease along with the availability of technical tools as well as social and economic considerations will dictate if eradication is achievable or if control at a certain prevalence level is adequate. For some diseases, or in certain situations, the emphasis of a programme

should be on reducing the health and economic impact of the disease. Some of the factors to consider are listed below (Table 1).

Table 1 – Factors to be considered in strategic planning for disease control

Biological factors	**Availability of technical tools**
– Species affected – Agent stability and diversity – Density of susceptible species – Wildlife reservoir – Vector transmission – Transmissibility – Current extent of disease – Survival in the environment – Carrier state – Ease of clinical recognition	– Diagnostic tests – Vaccines – Treatment – Disinfectants and insecticides
Control measures	**Socioeconomic considerations**
– Movement control – Stamping-out – Zoning/compartmentalization – Herd accreditation – Isolation and quarantine – Cleaning and disinfection – Vector and reservoir control – Treatment of products and by-products	– Cost and benefits of intervention – Availability of resources – Public health implications – Ease of implementation – Stakeholder engagement – Environmental impact – Political will

Strategic planning

The *Veterinary Authority* in collaboration with concerned stakeholders should develop a strategic plan based on the choice of the endpoint of the programme. The choice of intervention options should be based on their biological effectiveness, ease and cost of implementation to fit the needs of the programme, as well as the benefits that are expected by reaching the objectives of the programme. Tools such as value chain analysis may be used to help understand the role of different players within the production system, identify critical control points to target measures and provide an indication on the incentives for and feasibility of implementation of the programme. The decision on the most appropriate intervention options should take into account cost-benefit considerations, in conjunction with the likelihood of success of a particular set of disease control measures.

Institutional analysis examines the organizations involved in delivering services and the processes that govern their interaction. This type of analysis would be helpful to inform the strategic planning process and identify areas where a change would enable better programme implementation and facilitate effective collaboration (Figure 2).

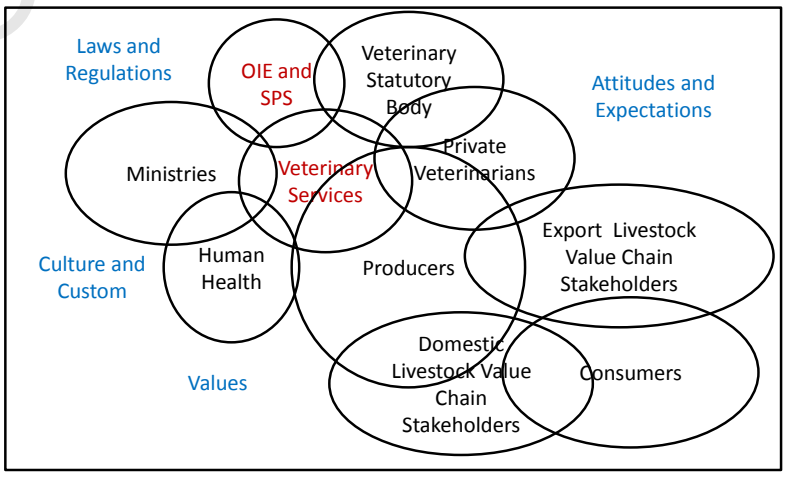

Figure 2 – An example of an institutional map concerning animal health

The programme should include a continued review process to assess the effectiveness of the interventions that are being applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required.

The programme should take into consideration the distribution of costs and benefits among different stakeholders and understand the factors limiting stakeholder participation in programme activities. These factors can affect the optimal selection of interventions. Programme policies need to include incentives for engagement including, additional services for the producer, appropriate compensation schemes, adding value to the final product and protecting public health. In addition, it may be necessary to include measures to raise awareness and ensure compliance including movement restrictions and fines.

In addition, disease control programmes should take into consideration non-financial factors (social, cultural, religious, etc.) affecting the livelihoods and well-being of animal owners such as pastoralists, indigenous communities or small-scale backyard producers. These factors can be important incentives for participation or non-compliance and ultimately impact the success of the programme.

Implementation plan

A disease control programme should be based on an efficient and effective veterinary service. Countries are encouraged to follow the provisions of Chapter 3.1 of the *Terrestrial Animal Health Code* (*Terrestrial Code*), as well as to undergo a Performance of Veterinary Services (PVS) evaluation and address the gaps that may be identified. In addition, the programme should have political support, and sustainable sources of funding including government and private stakeholder contributions.

The implementation plan should address the following:

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2. Epidemiological situation

The implementation of the programme needs to take into consideration:

- Distribution and density of susceptible species including wildlife
- Knowledge of animal production and marketing systems
- Geographical and temporal distribution of disease
- Zoonotic potential
- Risk factors and critical control points
- Vectors
- Carriers
- Reservoirs
- Specific disease situation in neighbouring country if applicable
- evaluate the appropriateness and need for establishing disease zones or compartments

3. Disease surveillance

The underpinning of the disease control programme activities is an effective surveillance system that provides guidance on priorities and targets for the application of interventions. The surveillance system should consist of general surveillance activities reinforced by pathogen specific activities. A clear case definition and outbreak investigation and response procedures are required. The provisions of Chapters 1.1 on notification of disease and epidemiological information and 1.4 on animal health surveillance of the *Terrestrial Code* should be referred to. The figure 3 below describes the main components of an effective surveillance system.

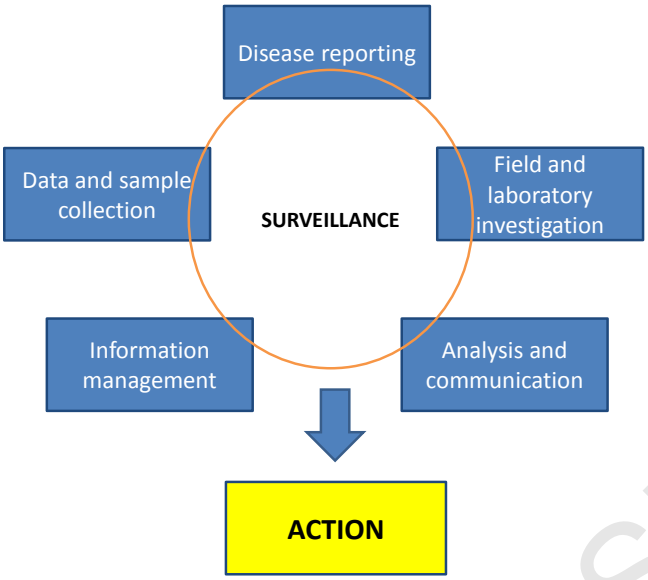

Figure 3 – Essential components of a surveillance system

4. Diagnostic capability

The programme needs to be supported by diagnostic facilities with adequate capacity. Samples for diagnosis should be collected and shipped in accordance to Chapter 1.1.1 of the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.* The choice of diagnostic tests applied should ensure detection and confirmation of the disease. The tests should follow the specific requirements in Chapter 1.1.4 on Principles of Validation of Diagnostic Assays for Infectious Diseases and the disease specific recommendations in the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. Diagnostic facilities, either official or accredited, should be under a quality assurance scheme coordinated by the designated national reference laboratory system. The latter should establish communication with an OIE reference laboratory for the particular disease. National and sub-national laboratories need to ensure that diagnostic results are communicated to the national surveillance system, field veterinarians and producers. National laboratories are also needed to provide independent and impartial quality control of vaccines. When appropriate, national laboratories are encouraged to submit samples to OIE reference laboratories for confirmation of findings and developing an understanding of the molecular epidemiology of the agent.

5. Traceability

An effective traceability system facilitates the identification of affected individual animals, herds or flocks. The design of the traceability system should follow the provisions of the *Terrestrial Code* in particular, Chapter 4.1 on General Principles on Identification and Traceability of Live Animals and 4.2 on Design and Implementation of Identification Systems to Achieve Animal Traceability.

6. Vaccination

a) Role of vaccination

Vaccination is an essential tool in the control of many diseases. However, vaccination on its own will not usually achieve the desired results unless the vaccination programme is part of an integrated control strategy. Depending on the epidemiological situation, the pattern of animal movements, population density and production systems within the country, targeted vaccination may be more effective than systematic mass vaccination. Where possible, vaccination campaigns should be serologically monitored for their effectiveness to ensure that herd-level immunity objectives are being met.

b) Vaccine quality

A vaccine quality assurance programme ensures the purity, safety, potency of vaccines as well as measures their efficacy in relation to the circulating strains. Vaccines used within control programmes should be licensed under the authority of the official veterinary services in accordance to the provisions of the OIE *Manual of diagnostic tests and vaccines for terrestrial animals* and preferably tested independently for safety and potency.

c) Vaccine delivery

Effective delivery of vaccine, including preservation of the cold chain and proper administration, is the cornerstone for reaching an adequate level of population immunity. Governmental and/or private schemes that include quality assurance controls can be established to ensure vaccine distribution at the local level.

d) Vaccine and antigen banks

Banks could be useful to ensure sufficient stocks are available if targeted vaccination is needed. Such banks may be held at national or regional levels and should comply with the provisions of Chapter 1.1.10 on Guidelines for international standards for vaccines banks of the OIE *Manual of diagnostic tests and vaccines for terrestrial animals*

7. Emergency preparedness and response

Countries should develop emergency preparedness and response plans for immediate action in case of an outbreak in a formerly free country or zone, or an unexpected increase in incidence in areas that have reached an appropriate level of control or in the case of disasters. These plans are especially important for rapidly spreading diseases. Plans should include detailed disease investigation procedures in case of a suspected outbreak to confirm or rule out disease as well as immediate measures to limit the spread of the disease and minimize impact. Emergency response plans should be up to date, tested in the real world setting and embedded in the legal framework. Emergency funds should be available to cover operational costs and indemnities. The chain of command and coordination with all key players, where necessary, including the police and armed forces, should be well established to ensure control efforts are executed rapidly and with success. Contingency plans need to be in place when immediate response is needed, including critical actions that need to be taken when a sudden outbreak of a disease is notified. Arrangements need to be in place to ensure rapid communication at all times. It is also important that these plans are coordinated on a regional level, particularly for transboundary animal diseases.

Following the confirmation of an outbreak, control areas may be established around the affected premises. The extent of these areas depends on a number of factors, in particular, the epidemiology of the disease in question. The measures imposed in these control areas will often include movement restrictions, intensified surveillance as well as specific measures applied to affected premises. In addition, for ease of management and for trade purposes, a larger area surrounding the control areas may be designated corresponding to administrative boundaries, geographical or other appropriate features (Figure 4).

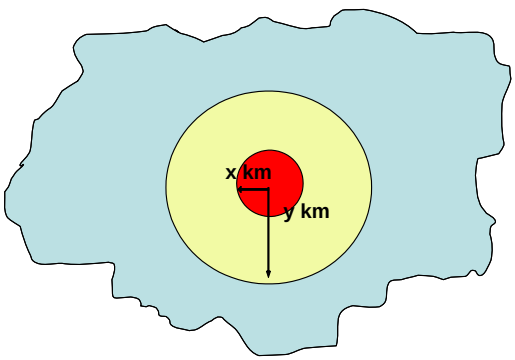

Figure 4 – Illustration of movement control areas centred on a disease outbreak indicating an infected zone around an outbreak

When the disease control measures applied have a significant economic impact, appropriate compensation mechanisms are needed to ensure cooperation by farmers. Funding is essential but is often lacking leading to non-compliance, if the disease occurs again. Partnerships between government and the private sector have proven effective to develop sustainable contingency funds in several parts of the world.

Information on disease confirmation should be immediately sent to other appropriate ministries, trading partners, stakeholders and made generally available general public. In addition, notification to the OIE should follow the provisions of Chapter 1.1 of the Terrestrial Animal Health Code.

8. Outbreak investigation

An outbreak investigation is a systematic procedure to help identify cause and source of cases of infection with a view to control and prevent possible future occurrence. Outbreak investigation is an important responsibility of the Veterinary Services to ensure that preventive and control measures are applied. Investigations also help recognize intervention strategy failures and successes, identify changes in the agent, environment or events that may be beyond the scope of a disease control programme. The main steps of the outbreak investigation process are outlined below and in Figure 5. These may need to be adapted to the specific requirements of the control strategy. It is important to maintain records of outbreak investigations including those which were not confirmed as this will help demonstrate the effectiveness of the surveillance system.

Basic steps of outbreak investigation include:

- preparation for field work
- establishment of the validity of the report triggering the investigation
- determination of the characteristics of the event in the affected population
- confirmation of diagnosis
- intensive follow-up and tracing
- collection and analysis of data
- implementation of control and preventive measures
- documentation and reporting

A field investigation often entails doing several of these steps simultaneously.

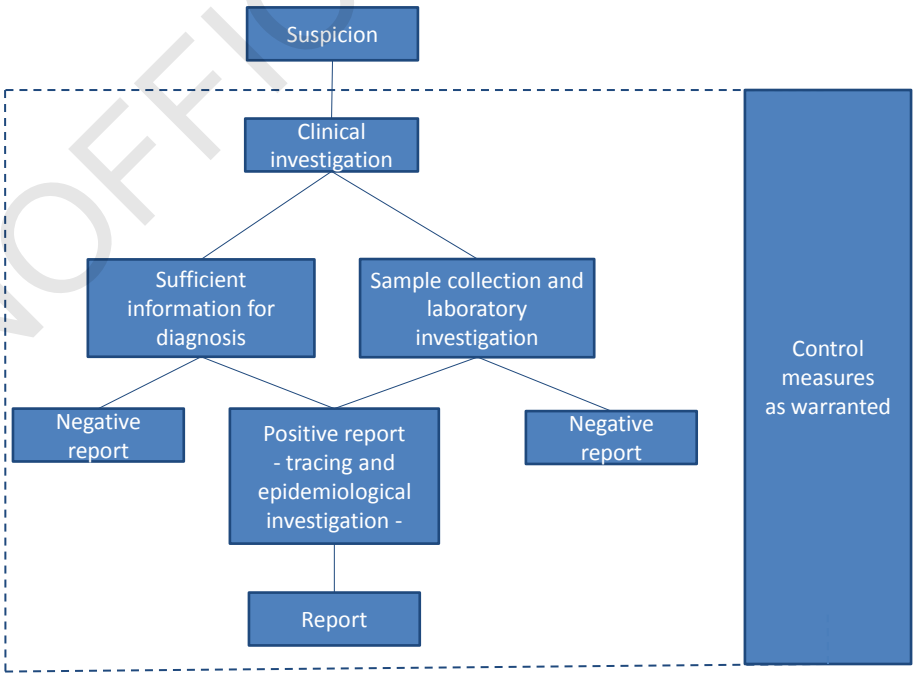

Figure 5 – Flowchart of the outbreak investigation process

9. Regional integration

Many diseases are considered transboundary animal diseases and require a regional approach to disease control. Regional and inter-sectorial agreements, including the chief veterinary officers in each country and representatives from international and other relevant regional organizations should be established to ensure proper coordination. Where possible, member countries should act on a regional basis to ensure that funds and resources are available in an emergency and to protect the region from disease incursion and spread.

10. Social participation

Communication, awareness programmes and programme ownership need to be in place. Stakeholders should be involved in the development, planning, implementation, management and revision of the programme. This should be an on-going process.

11. Programme management

Disease control measures to be applied in the programme can be implemented by the *Veterinary Authority*, or private or community entities or a combination of all. In any event, the overall responsibility for oversight of the programme remains with the *Veterinary Authority*.

The management of the application the disease control measures should follow standard operating procedures including:

- Implementation, maintenance, monitoring of the measures
- Application of corrective actions
- Verification of the process
- Record keeping

The programme should include a continued review process to assess the effectiveness of the interventions that are being applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required. This process should begin with the establishment of baseline data on the epidemiological, economic and social impact of the disease. The programme should collect data on process and impact indicators. This enables measurement of the effectiveness of interventions on epidemiological indicators such as incidence and prevalence, and identify areas needing strengthening.

12. Role of research in support of disease control programmes

During the strategic planning and assessment of programmes certain areas needing further research may be identified. Communication with national and international research institutions should be established to address programme needs.

13. Training and capacity building

Institutional capacity building is important in development of systems and infrastructure. The personnel in charge of implementing the measures within the programme need to be adequately trained and updated on the current knowledge on the disease. Veterinary accreditation schemes of private veterinarians and veterinary para-professionals can be a useful tool to increase the veterinary presence in the field, however training and supervision coordinated by the official veterinary service is required.

Appendix V

OIE AD HOC GROUP ON EPIDEMIOLOGY PROPOSED DEFINITIONS FOR SURVEILLANCE TERMINOLOGY

Proposed OIE definitions:

Surveillance (already in the *Terrestrial Code*)

Means the systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information ~~to those who need to know~~ so that action can be taken. A surveillance system may apply complementary approaches such as an *early detection system*, *risk-based surveillance*, *syndromic surveillance* and *pathogen specific surveillance*.

Risk-based surveillance (new)

Means the application of qualitative or quantitative methods to increase surveillance efficiency by directing surveillance activities to (1) ~~sampling~~ the population of interest based on exposure to factors that may predispose it to disease or infection, or (2) ~~sampling~~ subpopulations where, due to ~~inherent~~ host factors, the disease or infection is most likely to be found, or (3) prioritizing populations where the consequences of disease or infection could be severe.

Syndromic surveillance (new)

Means surveillance directed to detect a predefined set of clinical signs compatible with one or more diseases of interest. It may also ~~using~~ use health-related data (trends in the occurrence of clinical signs, production parameters or other data) that indicate sufficient probability of a change in the health of the population to warrant further investigation.

Pathogen specific surveillance (already in the *Terrestrial Code* as 'Specific Surveillance')

Means the surveillance targeted to a specific disease or infection.

Appendix VI

OIE AD HOC GROUP ON EPIDEMIOLOGY MEETING

AGENDA

Monday September 19, 2011

9:00-9:15	Welcome	Larry Granger
9:15-10:30	North American Disease Spread Model • General description • discussion on inputs for specific parameters	Kim Forde-Folle Marna Sinclair
10:30-10:45	Break	
10:45-11:30	TB modeling project	Steve Bengston Ken Forsythe
11:30-12:00	Proactive risk assessment work and role in food security and business continuity	Tim Clouse
12:00-1:30	Lunch	
1:30-2:00	Hot spot analysis for emergency planning and response	Barbara Corso
2:00-2:30	Animal movement modeling	Matt Farnsworth
2:30-2:45	Break	
2:45-3:30	NAHMS overview EHV response	Bruce Wagner Barbara Bishoff
3:30-4:30	Tool for the Assessment of Intervention Options (TAIO)	Cristóbal Zepeda
4:30-5:00	Discussion on the use of epidemiological models in animal health	Participants

Appendix IV

Original: English
November 2011

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES

Paris, 22 - 24 November 2011

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1. Opening

The meeting of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) status of Member Countries (hereafter the Group) was held at the OIE Headquarters, Paris, from 22 – 24 November 2011. Dr Kazuaki Miyagishima welcomed the Group on behalf of the Director General and thanked the experts for their dedication to the task of evaluating country dossiers. The Group was requested to evaluate the first three applications received from Member Countries for the endorsement of their official control programmes for FMD further to the adoption in May 2011 of the new Articles related to FMD of the *Terrestrial Animal Health Code* (Terrestrial Code). Dr Miyagishima stated that the Group could discuss, if necessary, the need to develop criteria for evaluating these and future applications to ensure the objectivity and consistency of the process whilst at the same time giving due considerations to countries' specific epidemiological situations. The Group was also asked to engage in an iterative process with the countries applying for the OIE endorsement of their control programme by providing technical feedback via the Scientific Commission for Animal Diseases (Scientific Commission) where necessary and appropriate. Due to concerns over the workload for the Group, the OIE and the President of the Scientific Commission decided to extend by one day the Group's meeting, to be held on 31 January - 3 February 2012.

Dr Miyagishima introduced to the Group Dr Laure Weber-Vintzel as part of the team in charge of official recognition of disease status, who moved to the Scientific and Technical Department from the OIE Animal Health Information Department. Dr Marta Martinez-Aviles would start in December 2011, who would deal with general matters related to the Scientific Commission. Dr Kiok Hong was also welcomed as new member of the Scientific and Technical Department, seconded from the Republic of Korea.

Dr Miyagishima reminded the Group that OIE had three official languages and countries were allowed to submit their dossiers in any of the OIE languages. The South American countries have a long standing agreement with the OIE that they would submit English translations of their application dossiers. On the contrary, no agreement exists with the French speaking countries. The three dossiers received from 3 North-African countries for the endorsement of their official control programmes for FMD were all in French and delays were experienced with their translation. The issue of countries submitting dossiers after the deadline was also raised and the Group was invited to make suggestions to overcome these problems.

The Group was reminded that the confidentiality form previously signed by the experts of the Group had unlimited validity and needed not to be signed for a second time. In addition, the Group was informed that there would be a new document on declaration of interest available in January 2012.

Dr Kris de Clercq, Vice-President of the Scientific Commission, attended the meeting to provide guidance to the Group as representative of the Scientific Commission.

2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group was chaired by Dr David Paton and Dr Wilna Vosloo acted as rapporteur. The Group endorsed the proposed agenda, with some changes on the order of the items to be addressed.

The Agenda and list of participants are presented as Appendices I and II of this report, respectively.

3. Evaluation of a pending dossier including additional information received from the applicant Member Country

The Group was informed that the OIE received a letter from Argentina on 20 October 2011 requesting the suspension of the evaluation of the current application 'Veranadas zone'. Consequently, the Group took no action of the application.

4. Evaluation of information received from Paraguay following the Scientific Commission request in order to monitor and assess the situation in the remaining FMD free zone (recognized in May 2011)

The Group was informed that on 27 October 2011, the OIE had sent a letter to the Delegate of Paraguay asking for information to enable the Scientific Commission to further monitor and analyse the situation in the remaining FMD free zone of Paraguay (recognized in May 2011), subsequent to the outbreak that occurred on 17 September 2011 in the village of Sargento Loma (department of San Pedro) and the suspension of FMD free status of the zone located at the centre of the country. As the source of the outbreak or the origin of infection was yet unknown or inconclusive, information had been sought on results of the epidemiological investigation, description and documented evidence of the animal health control measures applied, and surveillance results from the free zone for FMD and FMD virus infection/circulation.

At the request of the Scientific Commission, the Group was asked to evaluate the additional information provided by Paraguay following the letter sent by the OIE with particular attention to the following points:

- Clarity on the source of the outbreak
- Evidence for satisfactory vaccination programme
- Sufficient evidence that the free zone is safe
- Surveillance of free zone and whether the outer zone can maintain its status as free with vaccination

The Group reviewed the information provided by Paraguay in response to the letter sent by the OIE and requested, and received, further clarification from Paraguay during the meeting.

The Group noted that there was not sufficient documentation to follow the chronology of the recent outbreak and follow up actions. The origin of the outbreak remained unknown. The last reported movement onto the farm (5-6 months prior to the outbreak) was traced and two sources of animals were from the previous high surveillance zone. However, these animals were subsequently kept at a fair close to Asuncion. Paraguay indicated that the movements to and from this fair had not been traced. As the movements onto the outbreak farm occurred 5-6 months prior to the outbreak, it probably did not explain the origin of the outbreak. No other movements were mentioned in the dossier. The make-up of the farm in terms of differing epidemiological units and ages and their relationship to infected animals was provided. The infected animals were the ones resident on the farm and not the newly introduced ones.

The number of animals with lesions was not provided and neither was any estimate of the age of the lesions present. The 13 animals sero-positive to 3ABC and with high levels of antibodies to the structural proteins included the animal with a lesion from which virus was recovered. No other animals on the farm had been serologically tested; these data, if available, would have informed the Group on whether the disease had been on the farm for some time. Not all the animals that were destroyed were checked to exclude clinical signs of FMD.

In some documents it was mentioned that the outbreak could be due to 'products'. However, it was not mentioned whether pigs were present on any farms in addition to other species such as sheep. No information concerning investigations into the possible role of pigs or sheep in the outbreak was supplied.

Suspicious movement of animals from outside the country was considered to have increased significantly as could be seen by the increase in numbers of animals intercepted due to controls on illegal imports.

The slaughterhouse located in the Central Department where 315 animals from the outbreak farm were slaughtered in May to July 2011 performed proper ante- and post-mortem examination and no suspicious lesions were found.

The genetic relationships, based on 1D gene sequences, indicated that the outbreak virus was related to O viruses previously found in Paraguay, Bolivia and Argentina (specific eco-system). This might indicate that there was virus circulating in the region.

According to the information provided by Paraguay, vaccine brand Oleolada from Paraguay had been used on the farm where the outbreak occurred. It was considered that the vaccination had been performed by the livestock owner on the farm under SENACSA accreditation according to the regulations and protocols in force and the last visit for vaccination was on 10 September 2011. The outbreak was reported on 17 September 2011. The Group did not receive specific information on how often the animals on the farm had been vaccinated prior to the outbreak, except the statement that vaccination was performed twice per year (February and September). It was therefore difficult to explain how it was possible that vaccinated animals could be infected. In addition, it was mentioned in the dossier that all animals, regardless of age, were vaccinated during the two compulsory vaccination campaigns, and that all animals must be vaccinated before movement, therefore the animals that were moved onto the outbreak farm should have been immune.

The vaccine strain O1 Campos appeared to be suitable for protecting against the outbreak strain of virus. Some data were provided on the results of monitoring for population immunity in the frontier zone in 2010, but not for the rest of the country or in 2011. It was not clear whether these data on herd immunity were based only on vaccinated animals, or, the younger animals included some unvaccinated animals. The Group asked clarification on the serological results presented on pages 15-16 of the document "Report related to the item 3 of the letter AR/SB 30.533 submitted by the OIE'. The tables indicated the same results for all 3 serotypes in terms of numbers protected and non-protected. In the experience of all members of the Group, such perfect correspondence of numbers would not be expected for all the serotypes tested. No reply was received on this issue.

The conclusion of the Group was that based on the information supplied, there had not been a comprehensive investigation into the outbreak after the entire central part of the country had lost its free status. Sero-surveillance for virus circulation had been completed in a small zone surrounding the outbreak but not elsewhere. The Group considered that in order to maintain disease freedom of two adjacent zones with same status, such as two zones free with vaccination, there had to be strict movement control between the two zones. There was evidence that such movement control was instituted after the outbreak occurred but not before.

Since the origin of the infection had not been determined and sero-surveillance to demonstrate freedom of virus circulation in the country as a whole had not been completed, there were insufficient grounds to conclude that either the central or frontier zone should be considered free of infection. The Group, therefore, agreed to recommend that the FMD free status of the frontier zone be suspended.

5. Evaluation of requests from Member Countries for recognition of an FMD free zone where vaccination is not practised

The Group assessed the request of three Member Countries for recognition of zones without vaccination which did not meet the requirements, the dossiers were referred back to the corresponding Member Countries.

6. Evaluation of the request from a Member country for recognition of an FMD free zone where vaccination is practised

The Group assessed the request of a Member Country for recognition of a zone with vaccination which did not meet the requirements, the dossier was referred back to the corresponding Member Country.

7. Evaluation of requests from Member Countries for recognition of an OIE endorsed official control programme for FMD

Dr Antonio Petrini from the OIE Sub-regional Representation for North Africa provided the Group with background on the process that led to the submission of three dossiers by Algeria, Morocco and Tunisia for the endorsement of their official control programme for FMD. The representatives from the three countries met in 2009 and decided to apply for disease free status (with and without vaccination depending on the country) since FMD had not been found in any of the countries since 1999. The Delegates of the three countries decided to work together by sharing information with the aim to submit dossiers to the OIE. These countries decided to use the new provisions laid out in the *Terrestrial Code* adopted in May 2011 for the endorsement of the control programme for FMD before preparing the submission to apply for FMD free status. During the preparation of these dossiers, working groups were formed that included various role players from the laboratories, epidemiologists and veterinary services. Some guidance from the OIE Sub-regional Representation for North Africa was also provided but the dossiers were prepared by the countries themselves.

The Group decided to follow Article 8.5.48 as criteria to evaluate the dossiers. The Group congratulated all three Member Countries for submitting a comprehensive set of information. The Group noted that these dossiers, prepared following the provisions of Article 1.6.7 of the *Terrestrial Code* and presented this time, were very long and voluminous but did not include a succinct plan identifying priorities, timelines and performance indicators for implementing the programme. Based on the evaluation of these first three dossiers, the Group held the view that the current questionnaire did not sufficiently emphasise the importance of addressing future plans as well as history and current status. The Group agreed that the three countries could be asked to provide feedback on the questionnaire in order for the OIE to identify areas for future improvements.

7.1. Algeria

The Group reviewed the dossier submitted by Algeria for the endorsement of its official control programme for FMD.

Considering the expressed wish to apply for an FMD free status in the future, the Group noted the following points:

- The history of FMD in the country and measures to prevent infection was provided in the dossier. It seemed to be difficult to control all movement of animals and the Authorities leant also on control at market level. The movement patterns were presented qualitatively and not quantitatively. Movement of sheep was important but not well described. In a future dossier, the possible illegal movement could also be mentioned.

  It was recommended that Algeria provide a summary of suspicious cases with laboratory results.

- Vaccination coverage was not good because the country had been disease-free for a long period of time. Given the recent events in neighbouring countries, the Veterinary Services were focusing vaccination efforts in high risk areas such as the borders with Tunisia and Libya. As Morocco was free of FMD, Algeria did not vaccinate along the border with Morocco. The Group suggested that Algeria submit more information on where vaccination was done and what numbers were covered per area. This should be developed into a programme on how and where vaccination would be used. Vaccination was performed only once per year in animals over 6 months of age. The efficacy of such an approach was questionable. It would be necessary to ensure the use of vaccines that enable a DIVA approach in future.

- Algeria initially decided to cease vaccination, but due to the risk situation on its borders, decided to continue with mass vaccination of bovine animals except the 3 wilayas (districts of Algeria) in the south that were in the Sahara desert with few animals, humans and veterinarians. Movement from the south of the country to other regions was forbidden and the unvaccinated animals in that area were used as sentinels for the southern borders with endemically infected countries. Serological samples were regularly taken and sent to the central laboratory for testing. Algeria had official veterinary offices to better control movement and diseases. The dossier did not have indicators of future plans for disease control. Performance indicators could be included such as: "complete the PVS process analysis (including Gap Analysis)", "implement the animal identification system", "control national borders", "perform sero-surveys", "continue to do laboratory investigations of suspicions", and "participate in ring trials".

- The performance of Veterinary Services seemed to be acceptable, but with few veterinarians in the south of the country.

- The laboratories seemed to be sufficient and the central laboratory participated in proficiency rounds before. Algeria was encouraged to continue to participate in proficiency rounds also including the decentralised laboratories in ring tests.

- There was an updated contingency plan (2010) and operational manual. These were organised in a modular way so parts could be updated.

- Algeria had a PVS evaluation and was in a process of applying for a PVS Gap Analysis that would be performed in the next months.

- Algeria was encouraged to provide a timeline for their intentions to become eligible for disease free status with vaccination and to provide performance indicators such as plans for the vaccination, sero-surveys, and clinical surveys.

The Group recommended that Algeria would submit the programme outlining the plan of action with performance indicators and additional minor points of clarification in light of the comments above by early January 2012 for re-evaluation in accordance with Article 8.5.48 supported by the Article 1.6.7 at the next meeting of the Group scheduled for 31 January - 3 February 2012. The Group decided to keep the present application pending until the programme and an update of the relevant points of the dossier were provided.

7.2. Morocco

The Group reviewed the dossier submitted by Morocco for the endorsement of their official control programme for FMD.

The dossier provided information on the capacity of Morocco's Veterinary Services. Following the PVS performed in 2007, Morocco had restructured its Veterinary Services and was in the process of asking for a PVS Gap Analysis in 2012.

Considering the expressed wish to apply for an FMD free status in the future, the Group noted the following points:

- The dossier described the general epidemiology in the country and highlighted the current knowledge and gaps, the measures to prevent introduction of infection, and main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country. Details on the future plans for disease control were missing. A statement of intent on when Morocco planned to apply for freedom without vaccination and performance indicators could be included such as: "complete the PVS process analysis (including Gap Analysis)", "implement the animal identification system", "control national borders in the south of the country", "perform sero-surveys", "continue to do laboratory investigations of suspicions", and "participate in ring trials."

- The emergency preparedness plan was submitted as part of the dossier and appeared sufficient.

- Vaccination was not part of the current control programme, but in the country there was a vaccine bank from a company that supplied NSP free antigen and procedures were put in place on its use.

- Although it seemed to the Group that the official control program was applicable to the entire country, the geographic distribution of the veterinarians was uneven and could be problematic for disease and cross border movement control in the southern part of the country as most of the veterinarians were in the urban areas.

- Morocco had a record of regular and prompt animal disease reporting borne out by the number of suspicious cases investigated during the last two years. However, the Group agreed to recommend that the details of the laboratory testing of suspicious cases be included in the dossier.

- With reference to diagnostic capability and procedures, the Group was satisfied that Morocco had sufficient capacity but would recommend participation in ring trials and proficiency panels.

- The Group agreed to suggest to Morocco to provide more up to date data on animal markets. In the current dossier, the data of 2004 were presented. For future disease control, it would be important to have current information on animal markets.

- According to the dossier, live animals were only allowed to enter into Morocco from countries free of FMD where no vaccination is practised. However, Algeria and Tunisia also applied for OIE endorsement of official control programmes and both countries were using vaccination; the Moroccan legislation should therefore prevent, in principle, live imports from these neighbouring countries. Therefore, special requirements were needed for land crossings.

The Group recommended that Morocco submit the programme outlining the plan of action with performance indicators and additional minor points of clarification in light of the comments above by early January 2012 for re-evaluation in accordance with Article 8.5.48 supported by the Article 1.6.7 at the next meeting of the Group scheduled for 31 January - 3 February 2012. The Group agreed to keep the application pending until the programme and an update of the relevant points of the dossier were provided.

7.3. Tunisia

The Group reviewed the dossier submitted by Tunisia for the endorsement of their official control programme for FMD.

Considering the expressed wish to apply for an FMD free status in the future, the Group noted the following points:

- The dossier provided a good summary of past outbreaks but no information was given on possible routes of introduction of FMD virus. The animal movement patterns were well understood which could be used in risk analysis.

- More information would be needed on the vaccination strategy such as numbers of animals vaccinated and in which part of the country. This information would be necessary to identify possible risk areas with insufficient vaccination coverage.

- The contingency plan was considered to be acceptable.

- Due to the political situation in Libya there was major movement of people and animals into Tunisia. The Tunisian Veterinary Services made efforts to vaccinate all animals entering Tunisia. Information about this vaccination campaign should be added to the dossier as it would indicate the ability of the Veterinary Services to cope with emergencies.

- The dossier should include an outline of the programme with performance indicators such as "work to better understand the FMDV strains circulating in the region", "understand the role of wildlife", "complete the PVS evaluation (including Gap Analysis)", "implement the animal identification system", "control national borders", "perform sero-surveys", "continue to do laboratory investigations of suspicious cases", and "participate in ring trials."

- Tunisia should use existing tools such as PVS Gap Analysis for adapting the control programme and to establish clear objectives and priorities. The recent problem with PPR in sheep indicated problems with animal movement/imports. The presence of PPR also would make the differential diagnosis of FMD more challenging and highlighted the need for a robust surveillance plan.

The Group recommended that Tunisia submit the programme outlining the plan of action with performance indicators and additional minor points of clarification in light of the comments above by early January 2012 for re-evaluation in accordance with Article 8.5.48 supported by the Article 1.6.7 at the next meeting of the Group scheduled for 31 January - 3 February 2012. The Group decided to keep the application pending until the programme and an update of the relevant points of the dossier were provided.

8. Evaluation of a request from Member Country for recovery of FMD free status without vaccination

The Group did not review the dossier submitted by Bulgaria due to lack of time and the timing of the submission of the dossier. The Group agreed to refer the matter to the Scientific Commission for advice and the steps to be taken.

9. Opinion on the case where vaccination of zoo animals is applied to protect valuable genetic material within a country free of FMD without vaccination without endangering the free status of the country

This item was not discussed due to lack of time and was deferred to the next meeting of the Group.

10. Opinion on the need for a possible review of Article 8.5.9 of the *Terrestrial Code* (recovery of status) to make a provision for countries that had been free without vaccination prior to an outbreak and that apply for an FMD free status with vaccination after successful containment of the outbreak.

This item was not discussed due to lack of time and was deferred to the next meeting of the Group.

11. Other matters

The Group suggested that the deadline for submitting an application for official recognition of disease status and for the endorsement of an official control programme for FMD should be increased from 30 to 45 days prior to the meeting of the Group to allow timely translation of dossiers. Countries that would submit the application after the deadline should be informed that their dossiers would not be evaluated by the Group. For this meeting, the three dossiers from North Africa (Algeria, Morocco and Tunisia) arrived in time but the English translations by the OIE took time and did not provide the members of the Group to fully study the dossiers prior to its meeting. The dossier from Bulgaria arrived the day before the meeting started and it was agreed that it could be evaluated only if time permitted.

The Group discussed the desirability to increase the number of experts serving on the Group by including two Spanish-speaking and two French-speaking FMD experts to address the challenges posed by the languages in which the dossiers were submitted. They could be formal members or invited consultants, depending on the number and nature of submitted or expected dossiers.

The Group also suggested adopting an internal working arrangement whereby the dossiers would be sent to the experts prior to the meeting who would conduct in-depth reading of assigned dossier and report their findings to the other experts for further discussion.

The Group recommended that in future each dossier both for recognition of official status and for OIE endorsed national control programme for FMD be prefaced by a one-page executive summary to state clearly what the Member Country was applying for, how it addressed the various requirements set out by the *Terrestrial Code* and what information was provided in the dossier. The Group stressed the importance of obtaining the description of effective control measures put in place (e.g. animal movement controls between the two zones next to each other) in the application when the applicant country decided to keep separate two adjoining zones with the same status in order to ensure the differentiation of the subpopulations.

The Group proposed to limit the core document of each application to 50 pages with unlimited appendices. The expert in charge of making the preliminary reading and analysis would advise the OIE to translate the appendices or relevant parts of them.

12. Finalisation and adoption of the report

The Group reviewed and amended the preliminary draft report provided by the rapporteur. The Group agreed that the report would be subject to a short period of circulation to the Group for comments and adoption.

The next meeting of the *ad hoc* Group was scheduled for 31 January - 3 February 2012.

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…/Appendices

Appendix I

MEETING OF THE *OIE AD HOC* GROUP ON EVALUATION OF FOOT AND MOUTH DISEASE STATUS OF MEMBERS

Paris, 22 - 24 November 2011

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Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Evaluation of a pending dossier including additional information received from the applicant Member Country
4. Evaluation of information received from Paraguay following the Scientific Commission request in order to monitor and assess the situation in the remaining FMD free zone (recognized in May 2011).
5. Evaluation of requests from Member Countries for recognition of an FMD free zone where vaccination is not practised
6. Evaluation of the request from a Member Country for recognition of an FMD free zone where vaccination is practised
7. Evaluation of requests from Member Countries for recognition of an OIE endorsed official control programme for FMD:
8. Evaluation of a request from a Member Country for recovery of FMD free status without vaccination:
9. Opinion on the case where vaccination of zoo animals is applied to protect valuable genetic material within a country free of FMD without vaccination without endangering the free status of the country
10. Opinion on the need for a possible review of Article 8.5.9 of the Terrestrial Code (recovery of status) to make a provision for countries that had been free without vaccination prior to an outbreak and that apply for an FMD free status with vaccination after successful containment of the outbreak.
11. Other matters
12. Finalisation and adoption of the report

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON EVALUATION
OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES
Paris, 22 - 24 November 2011

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Appendix V

Original: English
January/February 2012

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES

Paris, 31 January – 3 February 2012

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1. Opening

A meeting of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) Status of Member Countries (hereafter the Group) was held at the OIE Headquarters, Paris, from 31 January – 3 February 2012. Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department, welcomed the Group on behalf of Dr Bernard Vallat, Director General of the OIE and thanked them for attending this additional meeting called mainly to address the urgent need to redraft Chapter 8.5 in the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*). The Group was reminded that in accordance with the revised General Rules of the OIE, experts were requested to submit to the secretariat the Confidentiality Undertaking and the Declaration of Interests forms. Especially the latter form was intended to properly manage potential conflicts of interest thereby ensuring neutrality and objectivity in the Group's work.

Dr Gideon Brückner conveyed the views of the Scientific Commission for Animal Diseases (Scientific Commission) on the review of the current Chapter 8.5 in the *Terrestrial Code* on foot and mouth disease (FMD) and indicated that the approach recently applied during the review of the *Terrestrial Code* chapter on classical swine fever (CSF) could consistently be used when reviewing the *Terrestrial Code* chapter on FMD. For this reason Dr Cristobal Zepeda was invited to assist with the redrafting of Chapter 8.5 as he was a member of the *ad hoc* Group that reviewed the Code chapter on CSF. Dr Brückner reminded the Group on behalf of the Scientific Commission that a number of important issues needed to be considered in the redrafting of Chapter 8.5:

- The wildlife-livestock interface was an important issue to be considered following recent developments where wild boar that could not be separated from domestic livestock seemed to have been involved in outbreaks.

- The protection of valuable animals such as zoo animals using vaccination in a FMD free country or zone needed to be discussed.

- A new article was needed that would allow Member Countries free of FMD where vaccination is not practiced to gain FMD free status with vaccination after outbreaks have occurred.

- The interpretation of protection zones needed to be clarified as there was some confusion among Member Countries on the use of such zones and the rules that apply in relation with other zones with a disease status. The misperception may partly be due to the use of the term high surveillance zone applied in the MERCOSUR countries based on a specific agreement between the OIE and these countries.

- The provisions of containment zones needed revision and Member Countries needed to be made more aware of their advantages when used as a management option during FMD outbreaks.

- Some Member Countries seemed to consider that having two zones with equal disease status provided some advantage. However, the Member Country would lose its disease status in both zones if there was no control of the movements across the zones prior to the outbreak.

- Wildlife surveillance needed to be addressed either by expanding Chapter 1.4. (Animal Health Surveillance) or including more information in Chapter 8.5.

2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group was chaired by Dr Alf-Eckbert Füssel and Dr Wilna Vosloo acted as rapporteur. The Group endorsed the proposed agenda, with some additions such as feedback from Drs Brückner and De Clercq after their recent visit to the Andean region.

The Agenda and list of participants are presented as Appendices I and II, respectively.

3. Evaluation of pending country applications (OIE endorsed official control programme for FMD) including additional information received from the applicant Member Countries

The dossiers submitted by three Member Countries for the December 2011 meeting were of high standard, but a plan for the future that indicated a timeline and key indicators was lacking. The OIE had sent a request, after the December 2011 meeting of the Group and on its request, to the three applicant countries to submit more information where the Group had identified information gaps. Additional information was received by the OIE prior to the present meeting of the Group.

Since all three Member Countries applied for endorsement of their own national official control programmes by favouring a regional approach, the Group agreed that the message to be sent from the OIE to these Member Countries after deliberations at the Scientific Commission should highlight the advantages of pursuing such a regional approach while attending to specific aspects for each country. The Group recommended endorsement of the national control programmes, but requested that the outstanding points should be addressed and documented in the forthcoming annual reconfirmation which the countries would submit.

3.1. Algeria

The Group appreciated the additional information provided by Algeria. However, the requested plan with a clear indication of where they aimed to go was not provided.

The decision to stop using serotype A in the vaccine did not seem to be risk-based and the Group recommended Algeria to consider this decision only after a proper risk assessment including assessment of the serotypes circulating in the region was performed. The future plan should include when Algeria planned to use only NSP free vaccines. The Group strongly recommended the use of NSP free vaccines if Algeria wished to apply for disease freedom as outlined in the *Terrestrial Code*. The country should focus more on vaccinating animals in the high risk areas and not as it was currently the practice to vaccinate animals in several clusters of areas but with a low coverage rate. Algeria should also consider the timeline and requirements of the *Terrestrial Code*. If Algeria continued to vaccinate until 2014, they would have to wait another 12 months for obtaining FMD free status without vaccination (Article 8.5.2).

Algeria was encouraged to use all opportunities for disease surveillance and enhance investigations to rule out any suspect cases of FMD. Laboratory diagnosis should be performed to exclude FMD, even where another disease such as bluetongue, epizootic haemorrhagic disease or Peste des petits ruminants had been suspected.

The Group recommended that Algeria review the design of the planned sero-survey as the inclusion of sheep only might not provide a true indication of FMD virus circulation. Other important species such as cattle should also be included. Although the Group noted the intent to use sheep as 'sentinels' as they were not vaccinated, there was no guarantee that they serve the purpose of detecting virus circulation as transmission of the disease was complex and involved many factors.

The Group recommended endorsement of the control programme. The Member Country should be invited to address the observations made in this report and indicate actions taken for improvement when sending a reconfirmation to the OIE in the following year.

3.2. Morocco

The Group appreciated the additional information provided by Morocco. However, the requested plan with a clear indication of future planning was not provided.

The Group recommended that Morocco make it clear when the country intended to apply for disease freedom and whether the country intended to obtain FMD free status with or without vaccination. In addition, indicators such as improvement of surveillance, traceability, more clarity on veterinary supervision in the south of the country with timelines should be developed. Animal movement from the south of the country could still be a problem and indicated the need to have strong veterinary services in the southern part of the country. Animal movement from neighbouring countries was not addressed in the additional information received and updated information on animal movement to and from markets should be indicated in the annual reconfirmation the country would be sending to the OIE.

The additional information provided indicated that Morocco's procedure for FMD confirmation was the use of serological assays only. Morocco should be advised that it was usual practice to use the Non-Structural Protein (NSP) tests as screening and in the absence of vaccination, use the liquid-phase blocking ELISA as confirmation, the latter being a more sensitive test. There should also be a clear indication of a principle that samples be sent to a reference laboratory for confirmation using tests detecting virus, antigen or nucleic acid. In addition, when dealing with a suspect sample, further sampling, including probing, in the field was essential.

The Group recommended endorsement of the control programme. The Member Country should be invited to address the observations made in this report and indicate actions taken for improvement when sending a reconfirmation to the OIE in the following year.

3.3. Tunisia

The Group expressed its compliments to Tunisia, which had provided additional information and details that addressed all the concerns expressed by the Group at its previous meeting. The Group noted that all necessary regulations were in place as well as a clearly defined plan with timelines for the next 24 months. However, it was not clear what disease free status Tunisia would apply for once their plans for disease control had been successfully implemented.

The Group recommended endorsement of the control programme.

4. Evaluation of the request from a Member Country for the recognition of an FMD free zone where vaccination is not practised

The Group reiterated their recommendations to the Scientific Commission as made at the November 2011 meeting after being briefed on the outcome of an expert mission to a Member Country that had applied for the recognition of an FMD free zone where vaccination is not practised.

5. Evaluation of the request from a Member Country for recovery of FMD free country status where vaccination is not practised

The Group assessed the request of a Member Country for recovery of FMD free country status where vaccination is not practised which did not meet the requirements and was referred back to the applicant Member Country to consider the provisions in Article 8.5.2 of the *Terrestrial Code*.

6. Revision of Chapter 8.5 with the objective of improving internal consistency further to the comments received from Member Countries.

The Group started the process of reviewing the Chapter that would require an additional meeting for finalisation. The Group requested the secretariat to keep track of the present and future revision in order to keep records of all comments together as the revision work would progress. Only a limited number of items were addressed at this meeting further to a specific request of the Scientific Commission. The Group revised the Article 8.5.48. to clarify the requirements in relation to the evaluation and endorsement of a national control programme for FMD.

7. Revision of Article 1.6.7. Questionnaire for endorsement of an official control programme for FMD

The Scientific Commission had requested that the Group revise the questionnaire for a Member Country with an OIE endorsed official control programme for FMD. Through the evaluation of the first three dossiers for endorsement of national control programmes, it was observed that Member Countries tended to focus only on the current status and did not provide sufficient information on the future plans. For this reason the questionnaire was updated by adding an additional paragraph to clearly indicate the need for a plan for FMD control with timelines and indicators as part of an application dossier. The Group reviewed the rest of the questionnaire to ensure all references to future plans were collated to the new point. The proposed revised questionnaire is attached as (see Code Commission Report).

8. Development of a form for the annual reconfirmation of an OIE endorsed official control programme for FMD

The Group drafted an annual reconfirmation form for the OIE endorsed official programme for FMD using the existing format for annual reconfirmation and complying with the requirements of Article 8.5.48 of the *Terrestrial Code* (see Appendix III).

9. Other matters

Dr Domenech informed the Group on the progress with the Global FMD Control Strategy under development, to be presented at the OIE/FAO Global Conference on FMD to be held in Bangkok, Thailand, 27 -29 June 2012.

10. Adoption of report

The Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report would be subject to a short period of circulation to the Group for comments and adoption.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES

Paris, 31 January – 3 February 2012

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Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Evaluation of pending country applications (OIE endorsed official control programme for FMD) including additional information received from the applicant Member Countries
    a. Algeria
    b. Morocco
    c. Tunisia
4. Evaluation of the request from a Member Country for the recognition of an FMD free zone where vaccination is not practised
5. Evaluation of the request from a Member Country for recovery of FMD free status where vaccination is not practiced:
6. Revision of Chapter 8.5. with the objective of improving internal consistency further to the comments received from Member Countries
7. Revisions of Article 1.6.7. Questionnaire for endorsement of an official control programme for FMD
8. Development of annual reconfirmation form as to OIE endorsed official control programme for FMD
9. Other matters
10. Adoption of report

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES

Paris, 31 January – 3 February 2012

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List of participants

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Appendix III

Form for the annual reconfirmation of the endorsement of the official control programme for FMD of OIE Members

(submit during the month of November each year)

Countries with an endorsed official control programme for FMD

QUESTION	YES	NO
Is your country on the official list of countries with an endorsed official control programme for FMD of OIE?		
Is there effective FMD surveillance in place?		
Has there been any outbreak of FMD during the past 12 months? If yes, please attach a brief report.		
Have the timelines and performance indicators outlined in the endorsed official control programme been met? Please provide a brief report.		
Have any changes in the epidemiological situation or other significant events regarding FMD occurred during the past 12 months? If yes, please attach a brief report.		
Date: Signature of Delegate :		

Appendix VI

Original: English
November 2011

MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) RISK STATUS EVALUATION OF MEMBER COUNTRIES

Paris, 29 November - 2 December 2011

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A meeting of the *ad hoc* Group on Bovine Spongiform Encephalopathy (BSE) Risk Status Evaluation of Member Countries (hereafter the Group) was held at OIE Headquarters from 29 November - 2 December 2011, to evaluate Member Countries submissions to assess compliance with the chapter on BSE of the *Terrestrial Animal Health Code* 2011 (*Terrestrial Code*).

1. Opening comments, adoption of agenda and appointment of chairperson and rapporteur

The members of the Group were welcomed by Dr Kazuaki Miyagishima, Head of the Scientific and Technical Department. He emphasized the importance for the Group to continue to operate objectively and independently from undue biases and to recommend, if deemed necessary, the Scientific Commission for Animal Diseases (hereafter the Scientific Commission) to consider deploying in-country audits in instances in which assessments could not be determined solely on the basis of the submitted dossier. Dr Miyagishima also described the renewed emphasis placed on annual reconfirmations from Member Countries with an official BSE risk status, as announced during the General Session of 2011. In addition, Standard Operating Procedures had been published on the OIE website, clarifying how the experts from applicant Member Countries could provide their input to the assessment of their dossiers. The Group was reminded of the new OIE policy concerning declaration of interest and confidentiality of information statements, noting that the members of the Group had already signed and were bound by confidentiality undertaking. Dr Miyagishima regretted the absence of two members of the Group, despite the fact that one member contributed to the assessments by correspondence. A commitment was made by the OIE secretariat to give as much advance notice as possible regarding the dates of the next meeting in order to avoid conflicts in schedule.

The meeting was chaired by Dr John Kellar and Dr Armando Giovannini was appointed rapporteur.

The agenda and list of participants are provided as Appendices I and II, respectively.

2. Evaluation of requests from Member Countries for the evaluation of BSE risk status

Experts of the Group, in pairs, had accepted to conduct a preliminary analysis of the dossiers of individual applicant Member Countries (as allocated by the OIE Headquarters) prior to the meeting. The experts presented their key findings to the plenary meeting of the Group, which proceeded with in-depth discussion, application by application, on the applicant Member Country's compliance with the provisions on BSE risk status of the *Terrestrial Code*. Where necessary, messages were sent electronically to the applicants requesting missing information. All contacted Member Countries provided requested information to the Group.

2.1. Austria

The Group recalled that in July 2007 the OIE received a dossier from Austria to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that Austria should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. Austria had been listed as a Member Country having a 'controlled BSE risk' status since May 2008.

In May 2011 Austria submitted a new dossier seeking a negligible BSE risk status and an update in October 2011. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Austria during the interval covered by the assessment was not negligible.

- *Risk of recycling and amplification of the BSE agent*

  The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in the country's cattle population during the interval covered by the assessment.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 1998 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

  The Group determined that the arrangements for laboratory examination met the requirements of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter the *Terrestrial Manual).*

- *Appropriate level of control and audit of the feed ban*

  The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country:

The Group noted that Austria had so far detected 8 BSE cases. The youngest birth cohort reported as affected by BSE was June 2000, meaning that all indigenous cases were born more than 11 years preceding the application. Therefore, Austria had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided, the Group recommended that Austria be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    Negligible BSE risk

2.2. Belgium

The Group recalled that in July 2007 the OIE received a dossier from Belgium to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that Belgium should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. Belgium had been listed as a Member Country having a 'controlled BSE risk' status since May 2008.

In November 2010 Belgium submitted a new dossier seeking a negligible BSE risk status and an update in August 2011. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Belgium during the interval covered by the assessment was not negligible.

- *Risk of recycling and amplification of the BSE agent*

  The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in the country's cattle population during the interval covered by the assessment.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 1998 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

  The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual*.

- *Appropriate level of control and audit of the feed ban*

  The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country:

The Group noted that Belgium had so far 133 cases of BSE. The youngest birth cohort reported as affected by BSE was November 1998, meaning that all indigenous cases were born more than 11 years preceding the submission of the dossier. Therefore, Belgium had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided, the Group recommended that Belgium be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    Negligible BSE risk

2.3. Brazil

The Group recalled that in 2006 the OIE received a dossier from Brazil to evaluate the BSE risk status of the cattle population of Brazil in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that Brazil should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. Brazil had been listed as a Member Country having a 'controlled BSE risk' status since May 2007.

In November 2010 Brazil submitted a new dossier seeking a negligible BSE risk status and an update in October 2011. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

a) Section 1: Risk Assessment — Article 11.5.2. point 1

The Group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 11.5.2. point 1.

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that there was a negligible risk that the BSE agent could have entered Brazil during the interval covered by the assessment.

- *Risk of recycling and amplification of the BSE agent*

  The Group noted that the rates of cross-contamination had dropped based on exit testing results from feed mills at 6.1% in 2008 and 3.9% in 2009 and 1.8% in 2010, based on a random sampling plan with mid-programme transition from mass spectrometry to microscopy claiming analytic sensitivity to a 0.10% cross-contamination level. Since 2005, SRM not destined to human consumption had been destroyed. Only a small percentage of beef and dairy cattle continued to experience potential exposure to MBM. Based on these elements, the Group considered, in its exposure assessment, that there was a decreasing risk of recycling and amplification of the BSE agent if it were present in the country's cattle population.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken met the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group concluded that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 1997 and concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

  The Group concluded that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual*.

- *Appropriate level of control and audit of the feed ban*

  Notwithstanding SRM removal, the documented progress being achieved and the complete transparency shared by Brazil in respect of its livestock demographics and its diagnostic approach, parameters and levels, the Group concluded that it could not be demonstrated that for at least eight years no meat-and-bone meal or greaves had been fed to ruminants.

d) BSE history in the country:

No BSE case had been recorded in Brazil.

e) Compliance with conditions for 'negligible BSE risk' status — Article 11.5.3.

Based on the information provided, the Group concluded that Brazil met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director-General*

  - Status

    The Group recommended that Brazil be regarded as having met the requirements for recognition as complying with the *Terrestrial Code* as 'negligible BSE risk'.

  - Annual update — specific requirements

    Provide documentation on the continuous progress in reduction of potential cross-contamination in feed mills.

2.4. Colombia

The Group recalled that in February 2009 the OIE received a dossier from Colombia to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that Colombia should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. Colombia had been listed as a Member Country having a 'controlled BSE risk' status since May 2009.

In February 2011 Colombia submitted a new dossier seeking a negligible BSE risk status and an update in November. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that there was a negligible risk that the BSE agent could have entered Colombia during the interval covered by the assessment.

- *Risk of recycling and amplification of the BSE agent*

  The Group considered that the conclusion of the exposure assessment was that, given the absence of SRM removal, the risk of recycling and amplification of the BSE agent if it were present in the country's cattle population during the interval covered by the assessment could not be considered negligible.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken exceeded the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*. The group noted that Colombia maintained a level of surveillance meeting the requirements for type A surveillance even upon having achieved the status of controlled BSE risk.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group determined that the awareness programme started in 2002 and it met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 2001 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

  The Group determined that the arrangements for laboratory examination were based on immuno-histopathology since 1998. ELISA, Western blot and immunohistochemistry have been introduced since 2002 and met the requirements of the *Terrestrial Manual*.

- *Appropriate level of control and audit of the feed ban*

  The Group noted that the appropriate legislation for control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country:

No case of BSE had been recorded in Colombia.

e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.

Based on the information provided, the Group recommended that Colombia be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    Negligible BSE risk

2.5. Croatia

The Group noted that in March 2011 Croatia submitted a dossier seeking a 'negligible or controlled BSE risk status' and an update in October 2011. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Croatia during the interval covered by the assessment was not negligible, due to imported cattle from countries of undetermined BSE status.

- *Risk of recycling and amplification of the BSE agent*

  The Group considered that the conclusion of the exposure assessment was that the risk of recycling and amplification of the BSE agent if it were present in the country's cattle population during the interval covered by the assessment was not negligible.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken met the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 1997 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

  The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual*.

- *Appropriate level of control and audit of the feed ban*

  The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

d) BSE history in the country:

BSE had never been recorded in Croatia

e) Compliance with conditions for 'controlled BSE risk' status - Article 11.5.4.

Based on the information provided, the Group recommended that Croatia be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    Controlled BSE risk

2.6. Nicaragua

The Group noted that in September 2011 Nicaragua submitted a dossier seeking a negligible or controlled BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries seeking a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code.*

a) Section 1: Risk Assessment — Article 11.5.2. point 1

- *Risk assessment for introduction of the BSE agent*

  The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Nicaragua during the interval covered by the assessment, although very low, could not be considered negligible due to the import of cattle from non-qualified countries.

- *Risk of recycling and amplification of the BSE agent*

  Although SRM removal started in 2004 as an effective mitigation measure and microscopic techniques were being put in place for feed mills, the Group considered that the conclusion of the exposure assessment was that the risk of recycling and amplification of the BSE agent if it were present in the country's cattle population during the interval covered by the assessment could not be considered negligible due to the presence of common lines in 7 of the 8 feed mills, the recent start of inspections in feed mills (2010) and the absence of testing to check for cross-contamination in past years.

b) Surveillance according to Articles 11.5.20.-11.5.22.

The Group noted that the surveillance undertaken fulfilled the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

c) Other requirements — Article 11.5.2. points 2–4

- *Awareness programme*

  The Group determined that the awareness programme started in 2004 and it met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 1998 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

  The Group determined that the arrangements for laboratory examination were mainly based on histopathology since 2004 and changed to immunohistochemistry in 2009, following the evolution of the *Terrestrial Manual*.

- *Appropriate level of control and audit of the feed ban*

  The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in place since 2004 and training of people for testing for cross-contamination was performed in 2010.

d) BSE history in the country:

In Nicaragua BSE had never been recorded.

e) Compliance with conditions for 'controlled BSE risk' status - Article 11.5.4.

Based on the information provided, the Group recommended that Nicaragua be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'.

f) Conclusions

- *Recommended message to be conveyed to the Member Country by the Director General*

  - Status

    Controlled BSE risk

    In the absence of a mammalian to ruminant feed-ban, Nicaragua should consider reinforcing the testing for cross-contamination by PCR or other tests able to distinguish the species of the MBM possibly cross-contaminating feed.

In summary, the Group recommended four Member Countries as having 'negligible BSE risk' and two other Member Countries as having 'controlled BSE risk' and agreed to forward these recommendations to the Scientific Commission for endorsement.

For the other four dossiers, the Group either rejected applications or assigned the same risk status as at present. The Group recommended that reasons for rejection be communicated to applicant Member countries from the Director General.

3. BSE surveillance: Revision of the BSurvE model

The Group was informed that the Director General of the OIE had sent a letter to the authors of the BSurvE model seeking their input towards revisions which might facilitate BSE surveillance points achievement by Member Countries with small bovine populations. This letter was sent on the request of the Scientific Commission following analysis of the Group's preceding report on the subject.

4. Other matters

- Annual update

On the basis of comments received from a Member Country, the Group modified table 2 of the annual reconfirmation form to clarify the fact that biological sampling was not required in rendering plants producing ruminant material (Appendix III). The Group agreed to emphasize that changes made in the submission document for annual update did not seek a broadening of content. The Group trusted that the change made to table 2 would clarify that position.

5. Finalization and adoption of the draft report

The Group reviewed and amended the preliminary draft report provided by the rapporteur. The Group agreed that the report would be subject to a short period of circulation to the Group for comments and adoption. The report was finalized by e-mail upon receipt of the additional information requested.

The Group tentatively identified the dates for the next meeting as 27 - 29 November 2012.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)
RISK STATUS EVALUATION OF MEMBER COUNTRIES

Paris, 29 November – 2 December 2011

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Agenda

1. Opening comments, adoption of agenda and appointment of chairperson and rapporteur

2. Evaluation of requests from Member Countries for the evaluation of BSE risk status

3. BSE surveillance: Revision of the BSurvE model

3.1 Letter dispatched by the OIE to the Authors of the BSurvE model

4. Other matters

4.1 BSE annual reconfirmation form: possible use of the previous form to collect data for 2011 and to discuss the questions raised by a Member Country on the revised form entered into force end of May 2011.

4.2 For information: Correspondence between Mexico and OIE concerning the objections received on the recognition of BSE risk status of some Member Countries before the 79th General Session.

4.3 For information: Correspondence between OIRSA and OIE concerning the concerning criteria for the recognition of BSE risk status

5. Finalization and adoption of the draft report

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) RISK STATUS EVALUATION OF MEMBER COUNTRIES

Paris, 29 November – 2 December 2011

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Appendix III

Form for the annual reconfirmation of the BSE risk status of OIE Members

ANNUAL UPDATE IN SUPPORT OF BSE STATUS RETENTION

YEAR _____	COUNTRY_____

Please answer the following questions and complete the following tables

Please provide documentation about relevant changes in BSE legislation, compared to the previous year

Table 1: Describe bovines and ruminant-derived MBM imports from all countries in this table

Country	Commodity and quantity			
	Cattle		MBM & products containing MBM	
	Number of head	Use	Amount	Type of commodity (+)

(+) Specify type and intended use of feedstuff and species composition of ingredients

Table 2: Complete this table on the audit findings in rendering plants (inspections and sampling, if applicable).

Type of rendering plants processing ruminant material	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
(A)	(B)			(C)	
For ruminants only				Not applicable	Not applicable
For multi- species					

Table 3: Complete this table on the audit findings in feed mills producing feed for ruminants (inspections and sampling, if applicable).

Type of plant	Number of plants	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
	(A)	(B)			(C)	
For ruminants only						
For multi-species						

Table 4: Complete this table for each plant in Tables 2 and 3 with infractions, specifying the type of infraction and corrective measures.

Type of plant	Plant ID	Nature of infraction	Corrective measures	Follow up
Rendering plant	ID 1			
	ID 2			
	ID 3 etc.			
Feed mill	ID 1			
	ID 2			
	ID 3 etc.			

Table 5: Record surveillance conducted since your last submission or update in this table (cover a period of 12 months).

SUMMARY TABLE FOR BSE SURVEILLANCE								
Surveillance subpopulations								
	Routine slaughter		Fallen stock		Casualty slaughter		Clinical suspect	
	Samples	Points	Samples	Points	Samples	Points	Samples	Points
≥2 and <4 years	**0**	0,1	**0**	0,2	**0**	0,4	**0**	260
≥4 and <7 years	**0**	0,2	**0**	0,9	**0**	1,6	**0**	750
≥7 and <9 years	**0**	0,1	**0**	0,4	**0**	0,7	**0**	220
≥9 years	**0**	0	**0**	0,1	**0**	0,2	**0**	45
Subtotals	**0**		**0**		**0**		**0**	
Total points	**0**		**0**		**0**		**0**	

Appendix VII

Original: English
December 2011

OIE *AD HOC* GROUP ON OFFICIAL DISEASE STATUS RECOGNITION OF CLASSICAL SWINE FEVER (CSF)

Paris, 5 – 7 December 2011

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A meeting of the OIE *ad hoc* Group on Official Disease Status Recognition of Classical Swine Fever (CSF) (hereafter the Group) was held at the OIE Headquarters, Paris, from 5 to 7 December 2011.

1. Opening, adoption of agenda and appointment of a rapporteur

The Group was welcomed by Dr Kate Glynn from the Scientific and Technical Department on behalf of Dr Kazuaki Miyagishima, Head of the Scientific and Technical Department. She provided a brief introduction on the objectives of the meeting and informed the experts of the Group that they would be requested to sign a confidentiality form which had unlimited validity.

Dr Gideon Brückner, President of the Scientific Commission for Animal Diseases (Scientific Commission), provided background on the status on CSF chapter of the Terrestrial Animal Health Code (*Terrestrial Code*). He explained that given the scope of the changes and the schedule of the Scientific Commission meetings, the earliest the CSF chapter could be presented to the World Assembly of Delegates for adoption was in May 2013.

The meeting was chaired by Prof. Trevor Drew and Dr Cristóbal Zepeda was designated as rapporteur. The Group adopted the agenda by adding a sub-item relating to CSF case definition. The adopted agenda and list of participants are attached as Appendices I and II, respectively.

2. Finalisation of the *Terrestrial Code* draft chapter including refinement of the surveillance on CSF taking into consideration the comments of the Scientific Commission.

The Group reviewed and addressed the comments received from Member Countries since the General Session in May 2011 up to August 2011, even though many of these were based on a previous version of the text and had already been considered by the Group in producing the most recent version. In this context, Dr Masatsugu Okita (OIE International Trade Department) joined the meeting briefly to provide clarification on these comments to the Group.

The Group also addressed the comments provided by the Scientific Commission. The rationale of the two-year requirement for the recognition of CSF free countries where vaccination is practiced was discussed. The Group agreed that it was most important to demonstrate the absence of virus circulation. The Group decided to harmonise the time requirement for the date of the last outbreak and the absence of CSF virus circulation to 12 months. The reasoning for the 12 month period was that persistently infected animals usually would die within 3 months but exceptionally might survive for up to 10 months.

The Group noted that the provisions for historical freedom under Article 1.4.6. 1 and 1 a) included compartments and suggested that this should be removed as compartments necessarily require pathogen-specific surveillance.

- **case definition**

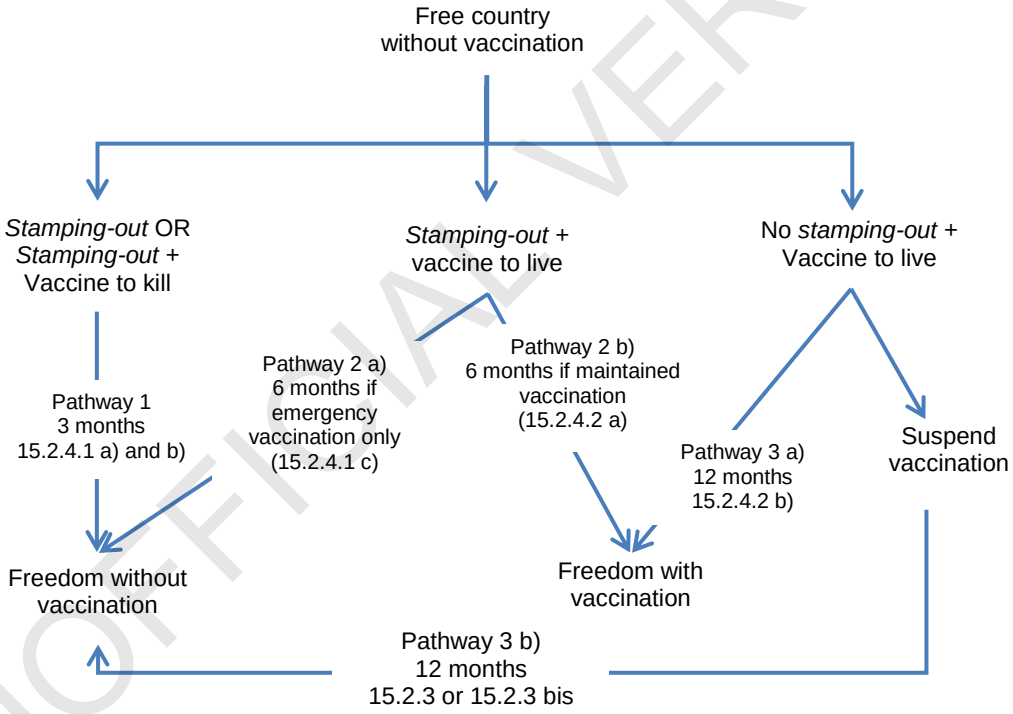
  A revision on CSF case definition was drafted for inclusion in the chapter. In particular, the third alternative to define a case based on serology alone was amended to include an epidemiological link or a suspicion of exposure to CSF virus. This was in line with the equivalent definitions for Foot and Mouth Disease (FMD). There was much discussion on the appropriateness of this definition, but it was considered that the requirement for the antibody to be conclusively shown to be due to CSF along with the link to a confirmed outbreak or a strong suspicion of exposure was sufficient to define a case.

- **management of wildlife vector**

  This point was addressed throughout the Chapter in line with the OIE's policy on the wildlife-domestic animal interface in setting standards, taking also into consideration the new definitions (wild animal, feral animal, captive wild animal and wildlife) adopted in May 2011.

- **vaccination strategy and the related impact in recognising disease status with or without vaccination**

  The Group discussed the different options for recovery of free status. Five pathways were discussed and described in the following chart:



Pathway 1 provided the option of stamping-out, with possible use of emergency vaccination to contain further spread of disease and provided for additional time for a more orderly stamping-out policy. All vaccinated animals, if any, would be killed and destroyed.

Pathway 2 described the options for stamping-out combined with the use of vaccine, but without subsequent killing of vaccinated animals.

- Pathway 2 a) - If vaccination was used for emergency purposes only, reinstatement of freedom without vaccination could be achieved six months after the last case or the last use of vaccine, whichever occurred later, provided that all vaccinated animals were permanently identified and under official animal movement control.
- Pathway 2 b) – If the use of vaccine was continued, the country or zone could recover its status as free with vaccination 6 months after the last outbreak.

Pathway 3 provided the options for vaccination with or without modified stamping-out.

- In pathway 3 a), a country maintaining vaccination could recover its status as free with vaccination 12 months after the last outbreak.
- In pathway 3 b), a country that decided to suspend vaccination could achieve the status of free without vaccination 12 months after the last outbreak and the last vaccination.

The Group suggested that the flowchart should be included in the Chapter for clarity.

A country that was free with vaccination should have vaccinated the entire population, therefore the provisions in Article 15.2.5 bis 3., recommending that animals should not be vaccinated, should be deleted as was suggested by the Scientific Commission.

The Group considered the importation of vaccinated animals from an infected country into a country free with vaccination in Article 15.2.6. but could not identify reliable means of demonstrating that vaccinated animals from an infected country would not pose a risk. The Group also felt that this would be a rare scenario.

The requirement under Article 15.2.9. c) ii referring to vaccination was deleted, as animals should be kept in a compartment and by definition compartments could not be vaccinated.

- **criteria for trade commodities**

The Group considered having different requirements for the export of fresh meat from wild boar. It was felt that the requirement to test the meat should be maintained as there was a possibility of exposure of wild boar populations in free countries to CSF virus infected wild boars in neighbouring countries. Furthermore, surveillance and monitoring in wild boar populations were considered challenging and expensive.

- **developing an Article on the use and interpretation of serological tests**

The Group discussed and drew charts to aid in the interpretation of diagnostic tests, both serological and virological. For many diagnostic tests, interpretation would require additional epidemiological information. In addition, it was noted that some tests required a high level of skills to obtain a valid interpretation and may not be appropriate for all countries. However, it was felt that a wording similar to the text under interpretation of diagnostic tests in the avian influenza chapter should be developed.

The flow charts and the text are in Appendix III and are proposed to be discussed for potential inclusion in the Chapter on CSF of the *Terrestrial Code* as Article 15.2.28 bis. The Group noted that the Scientific Commission would discuss the most appropriate way to address this issue within the OIE standards.

3. Finalisation of the draft questionnaire for Member Countries to support submission of applications for official recognition of CSF free status

The questionnaires for CSF free countries and zones with and without vaccination were reviewed and completed.

4. Adoption of the draft report

The Group reviewed and amended the preliminary outline of the draft report provided by the rapporteur. The Group agreed that the report and revised chapters would be subject to a short period of circulation to the Group for minor comments and final adoption.

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…/Appendices

Appendix I

OIE *AD HOC* GROUP ON OFFICIAL DISEASE STATUS RECOGNITION OF CLASSICAL SWINE FEVER (CSF)

Paris, 5 – 7 December 2011

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Agenda

1. Opening, adoption of agenda and appointment of a rapporteur

2. Finalisation of the *Terrestrial Code* draft chapter including refinement of the surveillance on CSF taking into consideration the comments of the Scientific Commission especially on the following issues:

    - case definition
    - management of wildlife vector
    - vaccination strategy and the related impact in recognising disease status with or without vaccination
    - criteria for trade commodities
    - developing an Article on the use and interpretation of serological tests

3. Finalisation of the draft questionnaire for Member Countries to support submission of applications for official recognition of CSF free status

4. Adoption of the draft report

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Appendix II

OIE *AD HOC* GROUP ON OFFICIAL DISEASE STATUS RECOGNITION

OF CLASSICAL SWINE FEVER (CSF)

Paris, 5 – 7 December 2011

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Appendix III

THE USE AND INTERPRETATION OF SEROLOGICAL TESTS

1. Serological tests

Pigs infected with CSF virus produce antibodies to a number of viral structural and non-structural proteins. Tests for antibodies include indirect, competitive and blocking ELISAs and serum neutralisation (SN) tests. Because CSF virus is non-cytopathic in culture, immunostaining protocols must be employed, either using peroxidise (the neutralising peroxidise-linked assay) or fluorescein (the fluorescent antibody neutralisation test). Because there are some antigenic epitopes that are common to all pestiviruses and ruminant pestiviruses can also infect pigs, a number of CSF and ruminant pestiviruses are used simultaneously within SN tests, in order to differentiate antibody to CSF from that induced by bovine viral diarrhoea or Border disease of sheep. Where the titre to CSF virus is greater than to ruminant pestivirus, it can be concluded that the result is specific to CSF. A range of different strains of pestivirus are employed in these tests, selected for their appropriateness to the local situation. These tests are complex and take up to seven days to perform – they are only performed in specialist laboratories. But it is essential that one of these tests is carried out to determine whether the antibodies are specific to CSF virus.

Indirect and blocking ELISAs are also commonly employed in the detection of CSF antibody. They vary in their ability to detect ruminant pestiviruses, with those employing recombinant proteins and fused viral peptides claiming greater specificity and sensitivity.

Pigs can be vaccinated with a variety of CSF vaccines, being either live attenuated CSF virus vaccines or sub-unit vaccines, comprising recombinant E2 (major envelope) protein. Serological tests cannot differentiate between antibody induced by conventional vaccine and field strains of virus. ELISAs based on detection of antibody to the viral protein Erns can be used to differentiate pigs vaccinated with sub-unit E2 vaccine from those infected with field virus, but antibody to Erns protein can be rather slower to develop than antibody to other viral proteins, so results should only be interpreted on a herd basis.

All herds with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of CSF infection/circulation for each positive herd.

Information should be provided on the performance characteristics and validation of tests used:

i) The follow-up procedure in case of positive test results without vaccination(Figure 1)

Where virus-specific antibody CSF is detected in one or more pigs, an epidemiological investigation should be carried out, to determine whether there are any links to a confirmed or suspect case of CSF, or giving cause for suspicion of previous association or contact with CSF virus, irrespective of whether there are any clinical signs among pigs in the herd consistent with CSF. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. Referral to an OIE Reference Laboratory should also be considered.

ii) The follow-up procedure in case of positive test results if vaccination is used (Figure 2)

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on CSF-vaccinated pigs. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

2. Virological tests

The follow-up procedure in case of positive serological test results indicative of infection for determination of infection due to CSF virus.

The detection of antibodies indicative of a CSF virus infection as indicated in point a)ii) above will result in the initiation of epidemiological and virological investigations to determine if the infection(s) are due to field virus.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of CSF virus, by virus isolation and identification, and/or detection of CSF-specific proteins or nucleic acids (Figure 3). Virus isolation is the gold standard for detecting infection by CSF virus and the method is described in the Terrestrial Manual. It requires specialist facilities and is therefore only usually available in some national laboratories.

The fluorescent antibody test detects the presence of viral antigen directly in the tissues of infected pigs. Whilst it is rapid to perform, it requires great skill to interpret and is highly prone to inconclusive or false positive results. It has generally fallen into disuse, being replaced by nucleic acid detection tests, such as the RT-PCR.

A number of nucleic acid detection tests have been developed and validated; these tests have the same or greater sensitivity as virus isolation, but with the advantage of providing results within a few hours. It can be prone to erroneous results, particularly if used without applying stringent procedures to avoid contamination and confirm that the reaction has been successfully carried out. For this reason, RT-PCR results should be backed up by virus isolation in cases of first confirmation of disease in a previously free country. All CSF virus isolates or nucleic acid should be tested to determine their genotype, since this can provide valuable epidemiological information on possible source and relatedness to other outbreaks which may have occurred in the country or zone.

Antigen ELISAs are generally used with serum or whole blood, though some tests are validated for use with tissues. They are reasonably specific, but not particularly sensitive, but can have value when used to test large numbers of animals, so that herd sensitivity is high. They are generally only used for screening purposes to demonstrate freedom, though they are also used to investigate clinical cases, in countries where other methods of testing are not available. Where cases are detected by antigen ELISA alone, additional confirmatory methods are needed. Positive samples should be submitted for virus isolation or nucleic acid detection.

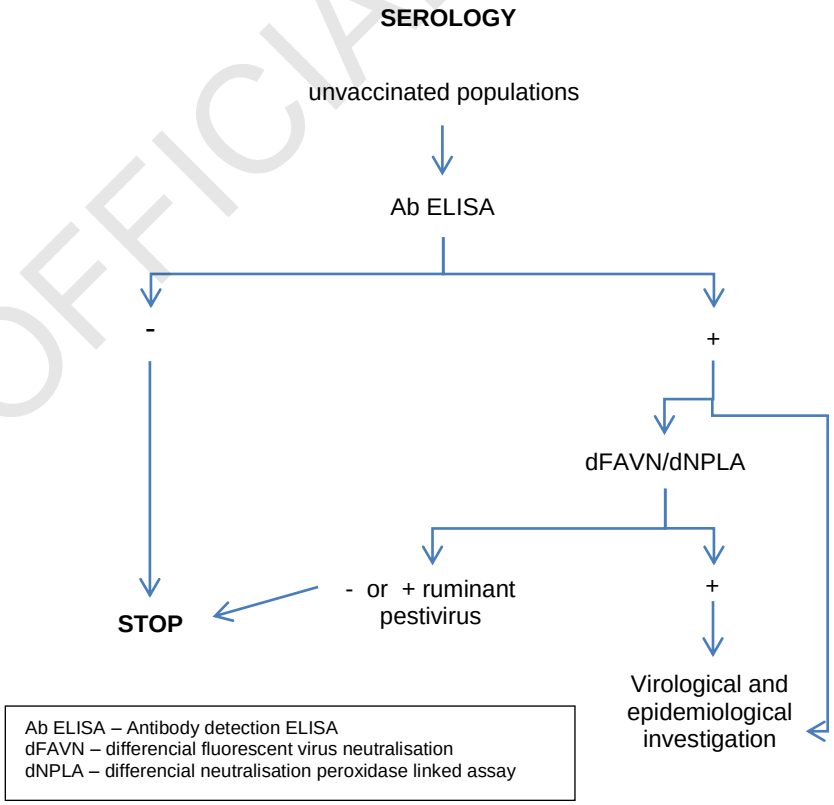

Figure 1. Schematic representation of laboratory tests for determining evidence of CSF infection through or following serological surveys in unvaccinated populations

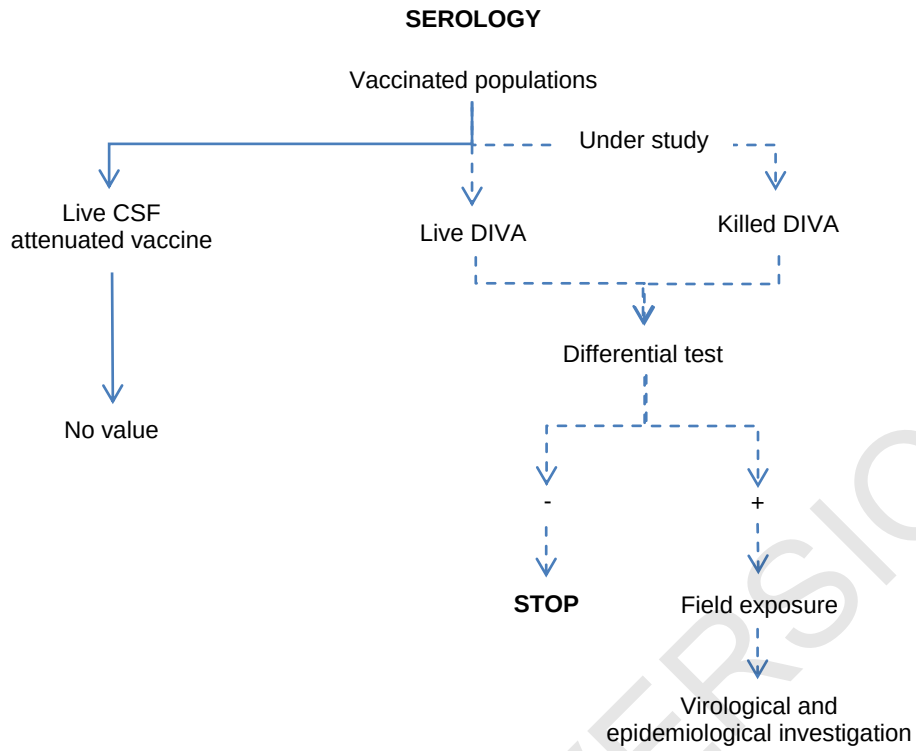

Figure 2. Schematic representation of laboratory tests for determining evidence of CSF infection through or following serological surveys in vaccinated populations

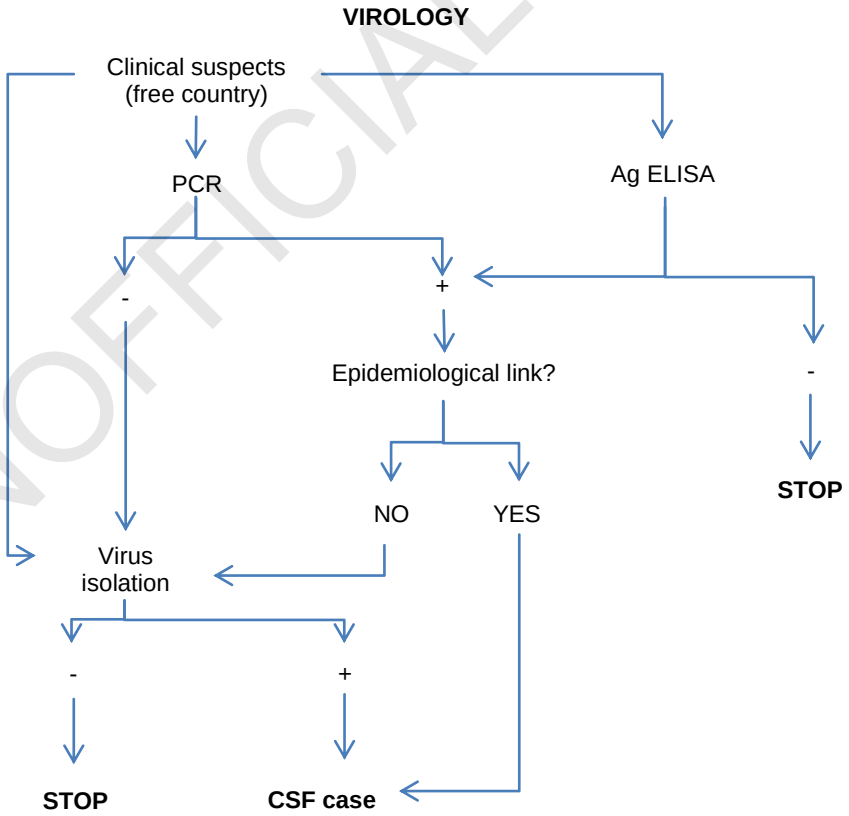

Figure 3. Schematic representation of laboratory tests for virological investigation in all antibody-positive and at risk populations

Appendix VIII

Original: English
November 2011

REPORT OF THE OIE EXPERT MEETING:

Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive

Paris, 30 November – 1 December 2011

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An OIE expert meeting was convened to conduct brainstorming to provide guidance for Member Countries needing to assess the risk of non-native ('alien') animals becoming invasive. The meeting took place on 30 November and 1 December 2011 and was chaired by Dr William Karesh. The list of participants and the Terms of Reference (ToR) are attached as Annexes I and II.

1. Opening

Dr Kazuaki Miyagishima, Deputy Director General of the OIE and Head of the Scientific and Technical Department, opened the meeting and welcomed the participants. He outlined the purpose of the meeting, highlighting the interest of the OIE in providing Member Countries with guidance on assessing the risk of non-native ('alien') animals becoming invasive when introduced into a new country, area of a country or ecosystem.

Dr Junko Shimura, representative of the secretariat of the Convention on Biological Diversity (CBD), expressed her gratitude for the OIE convening this expert meeting, noting that addressing invasive alien species (IAS) is one of the Aichi Biodiversity Targets (Target 9) of the Strategic Plan for Biodiversity 2011-2020 of the CBD.

After short self-introduction by each participant, the agenda of the meeting was adopted (see Annex III).

OIE's activities relevant to the CBD were presented by Dr Masatsugu Okita (see Annex IV).

Subsequently, relevant CBD activities were presented by Dr Shimura (see Annex V).

2. Discussion

2.1. General discussion and scope of the Group's work

In accordance with the ToR, the Group discussed the feasibility of developing guidance for use by OIE Member Countries, including the recommended scope of this work.

The Group discussed the CBD definitions of 'IAS' and 'alien species'. It noted that the CBD definition of IAS would include OIE listed diseases in instances where the diseases are both non-native and harmful to biodiversity. The Group agreed that the focus of its work should be animal species, not diseases, as the latter topic, which is a core part of ongoing OIE activities, is already the subject of standards in the OIE *Terrestrial* and *Aquatic Codes* and introduction risks posed by all diseases may be assessed using standards already adopted by the OIE.

The term 'alien species' is defined by the CBD as 'a species, subspecies or lower taxon, introduced includes any part, gametes, seeds, eggs or propagules of such species that might survive and subsequently reproduce outside its natural past or present distribution'.

The Group agreed that this definition provided an appropriate basis for the drafting of OIE guidelines and that there was no need to develop specific definitions of the terms 'alien species' and 'non-native animal species'. The Group agreed that the purpose of the risk assessment was to determine whether or not a non-native species was likely to be an IAS in a specific context and the non-native species was considered to be a 'hazard' in the risk assessment context.

The Group recognised that the OIE did not (yet) have a formal mandate for setting official standards on assessing the risk of a non-native animal species becoming invasive. However, it noted that there was congruence between this work and the OIE's general mandate to improve animal health, veterinary public health and animal welfare and to contribute to healthy ecosystems. Based on its experience in import risk assessment, the OIE could make a valuable contribution to the management of risks associated with the movement of animals in international trade related to a non-native animal species becoming invasive. The Group encouraged OIE Member Countries to consider animal health in the broadest sense, taking into account that a non-native animal species can threaten terrestrial and aquatic animal health, not only via the entry of OIE listed pathogens (already addressed through the international standards published in the OIE *Codes* and *Manuals*) but also through mechanisms, such as competition for food, destruction of habitat, and predation. The Group noted precedence for this approach in the case of the Small Hive Beetle and Honey Bees.

The Group also highlighted that addressing non-native animal species becoming invasive related to animal health and the relationship with wildlife and human health and biodiversity is in line with the 5th Strategic Plan of the OIE and the recommendations adopted at the OIE Global Conference on Wildlife held in February 2011 in Paris. The topic of IAS related to the concept of the animal-human-ecosystems interface was therefore relevant to the strategy of the OIE in contributing to veterinary services as a global public good and implementing the 'One Health' concept[1].

The Group discussed the potential value for the OIE to define the concept of "animal health". Considering that the OIE's mandate is not limited to disease control but encompassed new challenges, including 'One Health' and climate change, the Group encouraged the OIE to define the factors that should be considered when referring to 'animal health'.

The Group noted that there are several tools available to countries wishing to assess IAS-related risks, including several risk assessment methodologies, information sources, lists of potential IAS and national guidelines on risk assessment for IAS. The Group considered that the development of an additional or new list of IAS would be impractical; whether or not a species is invasive is a context specific issue that is best determined through science-based analysis. However, the Group noted the need for international guidelines as a basis for harmonisation of risk analysis approaches, where warranted.

The Group acknowledged that OIE standards as published in the *Codes* and *Manuals* have a specific status under the World Trade Organization Agreement (WTO) on the application of Sanitary and Phytosanitary measures (the WTO SPS Agreement), which recognises the OIE as the reference standard setting organisation for animal health and zoonoses, alongside the Codex Alimentarius Commission (CAC) for food safety and the International Plant Protection Convention (IPPC) for plant health. While the IPPC standards cover IAS for the plant world, the OIE has not yet addressed IAS in its standards.

The Group noted that the general approach to risk analysis was the same but that details on the factors to be considered within an IAS differed from what one might considered for a disease RA, necessitating additional guidelines.

In discussing the most appropriate means of providing guidance to Member Countries, the Group noted that the OIE *Codes* (both *Terrestrial* and *Aquatic*) contain standards on Import Risk Analysis and discussed the need to avoid possible duplication or confusion.

The Group concluded that complementary approaches should be adopted, i.e. the OIE *Codes* cover OIE listed diseases and provide standards for import risk analysis, which is relevant to both listed and non-listed diseases. The proposed new guidelines would deal with assessing the risk of a non-native animal species becoming invasive.

1 http://www.oie.int/for-the-media/editorials/detail/article/one-world-one-health/

The Group stressed the importance, in the OIE context, of analysing both:

1) the risk of animal invasiveness and

2) the risk of pathogen movement as separate but complementary processes.

Related to the possible formats for guidelines on assessing the risk of non-native (alien) animals becoming invasive, the Group has two options, i.e.:

- draft a chapter for inclusion in the OIE *Terrestrial Animal Health Code* (and possibly the *Aquatic Animal Health Code)*;
- develop guidelines to be published on the OIE website or elsewhere as appropriate.

In the absence of a formal OIE mandate for setting standards with respect to IAS, the Group decided to develop guidelines for consideration by the OIE specialist commissions, which could then recommend either the development of a *Terrestrial Code* chapter or publication on the OIE website.

2.2. Drafting the guidelines

The Group thanked Dr MacDiarmid for developing a draft text on assessing the risk of a non-native animal species becoming invasive and noted that the proposed draft guidelines, which were based closely on Chapter 2.1. of the *Terrestrial Code* (Import risk analysis), were a good starting point.

The Group agreed that the guidelines should deal with the assessment of the probability of non-native animals introduced into a specified area becoming established, spreading and causing harm (consistent with the CBD's concept of "invasive,") or of posing a threat to health of the human, animal or ecosystem.

The definition of 'animal' in the *Terrestrial Code* is 'a mammal, bird or bee'. The Group decided that, to address the broader scope of the draft guidelines, the following definition of 'animal' should be used in the guidelines:

> *Animal means: all species, subspecies or lower taxon of the kingdom Animalia, with the exception of the species that are causative agents of diseases. Note:* the experts did not discuss or conclude if 'species that are causative agents of disease' should or should not be limited to infectious and parasitic diseases.

The Group proposed as title for the document "Guidelines for assessing the risk of non-native ('alien') animals becoming invasive". The choice of the title reflected the scope of the document discussed and agreed by the Group.

The Group agreed that the scope of these guidelines should cover intentional and unintentional introduction of animals. However the unintentional introduction of animals would not be described in detail but rather only mentioned to sensitise the veterinary services of Member Countries that animals can be introduced into a country intentionally or unintentionally and that both could occur through a number of pathways.

The Group noted that OIE standards were normally addressed to the veterinary services but, in the case of invasive animals, other governmental agencies are also involved. There is a need for coordination and collaboration on IAS issues across ministries and sectors.

The Group decided that most of the *Terrestrial Code* definitions that were relevant to IAS needed no modification. However, some terms would need to be clarified for the purpose of the draft Guidelines, e.g. 'hazard' and 'hazard identification'. In addition, the Group recommended the development of a definition of the term 'non-native animal' ('alien animal') used in the guidelines.

The CBD Secretariat proposed to define stakeholder in a broader sense than traditionally identified by the OIE and veterinary services (e.g. including indigenous and local communities).

The Group reviewed and discussed the draft document provided by Dr MacDiarmid in detail, and began the process of modifying it consistent with the views of members. As a general comment, it was noted that the guidelines should provide flexibility to OIE Member Countries, given that invasiveness was context specific to the species and country, area or ecosystem in question.

Owing to time constraints, the Group was not able to finalise the draft document at the meeting and agreed to do this by electronic means by the time of the next meetings of the two Specialist Commissions (February 2012).

The draft guidelines are attached in Annex VI.

2.3. General recommendations

- The Group recognised the importance of formalising a cooperation agreement between the OIE and the CBD.
- The Group highlighted the importance of encouraging research and investigation on the various pathways and processes involved in the entry, establishment and spread of non-native animals.

3. Discussion with the Director General

The Group presented some recommendations arising from the discussion held during the first day, to Dr Bernard Vallat, the Director General of the OIE.

Dr Vallat expressed his gratitude for the contribution of the participants, noting that One Health and associated approaches had been included in the 5th Strategic Plan of the OIE with consensual support of Members. He thanked Dr MacDiarmid for his initiative in providing a draft text. Dr Vallat also noted that the role of the OIE was broader than international trade and animal health; the contribution of environmental health to these was also of critical importance, hence the need for the OIE to be involved in this area.

Dr Vallat noted the importance of the OIE continuing to collaborate with the CBD.

For the purpose of the Group's work, Dr Vallat noted the need to avoid duplication and confusion that could arise from the inclusion of OIE listed pathogens as IAS. Dr Karesh replied that that issue had been discussed and addressed by the Group on the first day of the meeting.

Dr Shimura highlighted the importance of collaboration between the CBD Secretariat and the OIE. Dr Vallat agreed with her and noted that the OIE had proposed a first draft for an official agreement between the two organisations.

4. Next steps

The Group concluded the meeting by proposing the following next steps to the OIE:

- To finalise the revision of the draft guidelines by electronic consultation in time for submission to the Scientific and Terrestrial Animal Health Standards Commissions at their next meetings in February 2012.
- Once the guideline was available as a public document, it could be presented by the OIE to the CBD Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), which would hold its 16th meeting in April/May 2012.
- The guidelines should be reviewed periodically to ensure consistency with other OIE activities and guidelines, and to ensure that they are up to date with current knowledge in the field of IAS.

- If so desired by the specialist Commissions, in the context of Member Countries' responses to the draft guidelines and the present report, to request the Director General to consider convening an *ad hoc* Group on Invasive Alien Species to 1) explore OIE´s further actions in addressing IAS issues, 2) integrate input from an STDF workshop on IAS to be held in July 2012, 3) support OIE's work on IAS under the Liaison Group and through the pending official agreement (termed a Memorandum of Cooperation by CBD) with the CBD.

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…/ Annexes

Annex I

THE OIE EXPERT MEETING: Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive

Paris, 30 November – 1 December 2011

List of participants

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Annex II

THE OIE EXPERT MEETING: Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive

Paris, 30 November – 1 December 2011

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Draft Terms of Reference

Considering:

- that the Conference of the Parties to the Convention on Biological Diversity (CBD), at its sixth meeting (2002), adopted Guiding principles for the prevention, introduction and mitigation of impacts of alien species that threaten ecosystems, habitats or species;

- that the Conference of the Parties to the CBD, at its ninth meeting, requested the Executive Secretary of the CBD to continue to collaborate with the secretariats of the international organisations relevant to invasive alien species (IAS)

- that the OIE actively participated in the interagency liaison group (ILG) on IAS established by the CBD;

- that the objectives set out in the OIE 5th Strategic Plan (2011-2015) include 'developing tools for the analysis of the impact of environmental and climate change, including the problems linked with invasive species, especially in relation to vector-borne diseases and to aquatic animal health':

The expert meeting is asked to conduct a brainstorming and make recommendations on:

- use of risk assessment as a tool to evaluate and manage the risks to ecosystems presented by trade in animals and a proposed definition of 'invasive animals' for the purposes of this work.

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Annex III

THE OIE EXPERT MEETING: Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive
Paris, 30 November – 1 December 2011

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Agenda

Day 1 (Wednesday 30 November)

09:30 / 11:00 – Opening

- Introduction of all participants
- Adoption of the agenda
- Presentation of relevant activities of the OIE
- Presentation of relevant activities of the CBD

11:00 / 13:00 – Brainstorming on guidance for Members to assess the risk of non-native animals becoming invasive

- Definition of Invasive Alien Species (IAS)
- Drafting guidelines for assessing the risk of non-native animals becoming invasive

13:00 / 14:00 – Lunch break

14:00 / 18:00 – Continued discussion

Day 2 (Thursday 1 December) – meeting with the Director General of the OIE

9:00 / 13:00 – Continued discussion

- Discussion with the Director General

13:00 / 14:00 – Lunch break

14:00 / 17:00 – Discussion on the next steps and drafting report

17:00 – End of the meeting

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OIE's activities relevant to the Convention on Biological Diversity

Annex IV (contd)

OIE 5th Strategic Plan (2011-2015)

Cross-Cutting Areas (extract relevant to IAS)

CLIMATE AND ENVIRONMENTAL CHANGES

The OIE will address the role of climate and environmental changes with respect to emerging and re-emerging animal diseases and animal production over the short, medium and long term.
In particular, the OIE, in collaboration with other international organisations, will assist veterinary authorities to develop foresight and other decision-making frameworks that take into account new information about the evolving relationship between ecosystems, invasive species and emerging and re-emerging animal diseases, recognising the need for adaptive policy responses.
Within this overall framework, particular attention will be paid to the effects of climate and environmental changes on aquatic animal health, including problems linked with invasive species.

OIE Activities relevant to IAS

The current mandate addresses diseases eg:

- Transboundary animal diseases (rinderpest, avian influenza)
- Vector-borne diseases: including standards relating to surveillance for disease vectors
- Pests and parasites eg small hive beetle infestation

New challenges

- One Health: animal/human/ecosystem interface
- Role of wildlife as disease reservoirs
- Climate change: vector-borne disease, (re)emerging disease

CBD and OIE relationship

May 2008: CBD Conference of the Parties (COP 9 Decision IX/4)

3. Invites the International Committee of the World Organisation for Animal Health (OIE) to note the lack of international standards covering invasive alien species, in particular animals, that are not pests of plants under the International Plant Protection Convention, and to consider whether and how it could contribute to addressing this gap, including for example by:

a) Expanding the OIE list of pathogens to include a wider range of diseases of animals, including diseases that solely affect wildlife; and

b) Considering whether it may play a role in addressing invasive animals that are not considered as causative agents of diseases under OIE and whether, for this purpose, it would need to broaden its mandate;

CBD and OIE relationship

Since 2010, the OIE has participated in an Inter-Agency Liaison Group (IALG) comprising: CBD, IPPC, OIE, FAO, WTO, ICAO, IMO, CITES, IUCN and GISP

Two meetings have been held to date:
- hosted by the OIE 19-20 April 2010
- hosted by the WTO 14-15 February 2011.

CBD and OIE

November 2011: The CBD Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) 15 (Nov 2011) received advice from the Ad hoc Technical Expert Group recommending that the OIE consider:

- Broadening its mandate by considering the impacts of invasive alien species on ecosystems as falling within the scope of animal health…..;
- Building further on the precedent of listing the amphibian diseases, … in the consideration of additional animal diseases impacting aquatic ecosystems and wild aquatic animals under the OIE Aquatic Code;
- Continuing to develop recommendations on diseases that primarily affect wild rather than domestic animals, including by revision of the OIE Terrestrial Code …; and
- Providing advice and guidance on the assessment of risk of invasive alien species on ecosystems, …;

CBD and OIE

Regarding the advice of the Ad hoc Technical Expert that;
(ii) The OIE could consider:

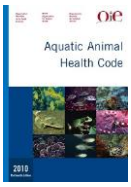
- Broadening its mandate by considering the impacts of invasive alien species on ecosystems as falling within the scope of animal health…..;
- Building on the precedent of listing the amphibian diseases, … in the consideration of additional animal diseases impacting aquatic ecosystems and wild aquatic animals under the OIE Aquatic Code;
- Continuing to develop recommendations on diseases that primarily affect wild rather than domestic animals, including by revision of the OIE Terrestrial Code …; and
- Providing advice and guidance on the assessment of risk of invasive alien species on ecosystems, …;

Annex IV (contd)

OIE Activities relevant to IAS

Aquatic Animal Health Code

Ch 1.2.2. Criteria for listing aquatic animal diseases



Relevant parameters

A. Consequences
   1. … (production loss) or
   2. The disease has been shown to … that it is likely to **negatively affect wild aquatic animal populations** … or
   3. …(Public health concern)

Diseases of amphibians (2008 ~)

Ch 8.1.
Infection with batrachochytrium dendrobatidis
Ch 8.2.
Infection with ranavirus

CBD and OIE

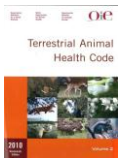
Regarding the advice of the Ad hoc Technical Expert Group that;
(ii) The OIE could consider:

- Broadening its mandate by considering the impacts of invasive alien species on ecosystems as falling within the scope of animal health…..;
- Building on the precedent of listing the amphibian diseases, … in the consideration of additional animal diseases impacting aquatic ecosystems and wild aquatic animals under the OIE Aquatic Code;
- Continuing to develop recommendations on diseases that primarily affect wild rather than domestic animals, including by revision of the OIE Terrestrial Code …; and
- Providing advice and guidance on the assessment of risk of invasive alien species on ecosystems, …;

OIE Activities relevant to IAS

Terrestrial Animal Health Code

Chapter 1.2. Criteria for listing diseases (Proposed text)



Article 1.2.2

The criteria for the inclusion of a *disease* or *infection* in the OIE List are as follows:

1. … (international spread)
2. … (naïve susceptible population)
3. a) … (zoonotic character)

   OR

   b) … (significant impact on domestic animals)

   OR

   c) The *disease* has been shown to… that it would cause significant morbidity or mortality in *wild animal* populations

OIE Activities relevant to IAS

- Terrestrial Animal Health Code
  In future, wildlife will be addressed in all disease chapters, with notification and surveillance standards applied primarily where infection of wildlife is of epidemiological importance
- On-line notification system for diseases in wildlife (WAHIS-wild)

CBD and OIE

Regarding the advice of the Ad hoc Technical Expert Group that;
(ii) The OIE could consider:

- Broadening its mandate by considering the impacts of invasive alien species on ecosystems as falling within the scope of animal health…..;
- Building on the precedent of listing the amphibian diseases, … in the consideration of additional animal diseases impacting aquatic ecosystems and wild aquatic animals under the OIE Aquatic Code;
- Continuing to develop recommendations on diseases that primarily affect wild rather than domestic animals, including by revision of the OIE Terrestrial Code …; and
- Providing advice and guidance on the assessment of risk of invasive alien species on ecosystems, …;

OIE Activities relevant to IAS

December 2011: brainstorming meeting to consider the feasibility of developing guidance on risk assessment in relation to invasive animals

- Definition of "IAS" for the purpose of this work
- Guidance for use by Member countries
- Not intended as a text in the Terrestrial or Aquatic Code
- Guidance to be published on the OIE website

Annex IV (contd)

OIE Activities relevant to IAS

Definition of IAS by CBD (annex to decision VI/23)

- "alien species" refers to a species, subspecies or lower taxon, introduced outside its natural past or present distribution; includes any part, gametes, seeds, eggs, or propagules of such species that might survive and subsequently reproduce;
- "invasive alien species" means an alien species whose introduction and/or spread threaten biological diversity

Future work

The OIE mandate traditionally addresses diseases rather than animals. It is for Members to decide what, if any, new approaches may be appropriate in future.

Any recommendation to broaden the mandate would need to take account of the resources available to the OIE – both at headquarters and in Member countries.

Note: any decision to modify the OIE mandate can only be taken on the basis of adoption of a decision by the World Assembly, meeting at the General Session (May, Paris).

Activities of the Convention on Biological Diversity

Convention on Biological Diversity

United Nations Decade on Biodiversity

Invasive alien species
A cross-cutting issue of the CBD

Junko Shimura

Secretariat of the Convention on Biological Diversity

Convention on Biological Diversity

United Nations Decade on Biodiversity

Convention on Biological Diversity

- The Convention on Biological Diversity was inspired by the world community's growing commitment to sustainable development.
- It represents a dramatic step forward in :
  - the conservation of biological diversity,
  - the sustainable use of its components, and
  - the fair and equitable sharing of benefits arising from the use of genetic resources
- As of 2011 **193** Parties, one of the largest framework conventions under the United Nations

Convention on Biological Diversity

United Nations Decade on Biodiversity

Convention bodies and Parties

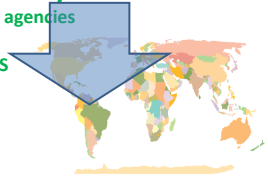
The Convention on Biological Diversity

- Subsidiary Body for Scientific, Technical and Technological Advice
- The Conference of Parties

COP Decisions

- **The Strategic Plan for Biodiversity 2011-2020**

Engagement of implementation agencies
Partners – INTNL ORGs
Inter agency liaison group on IAS



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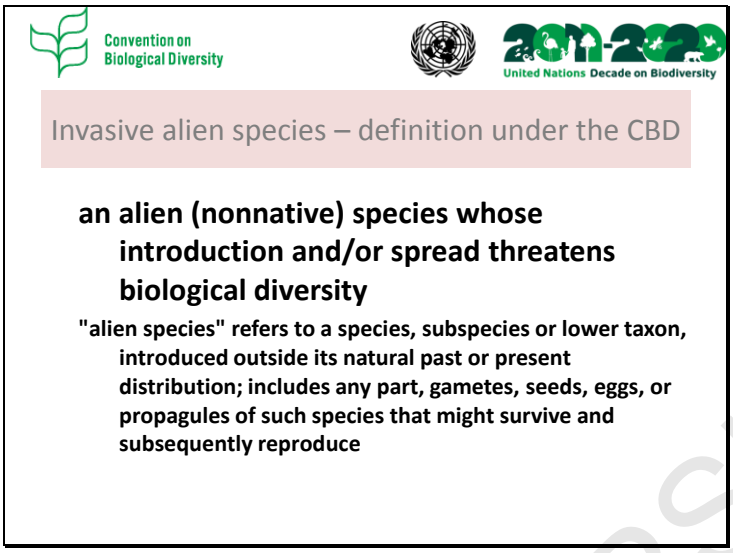

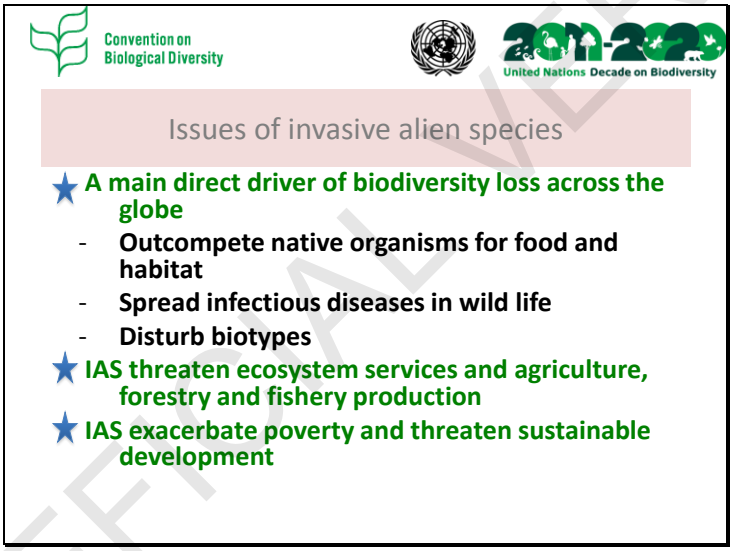

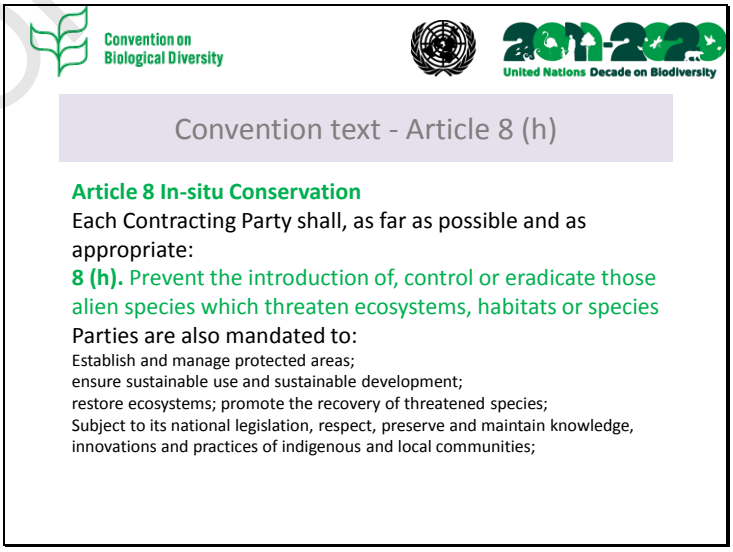

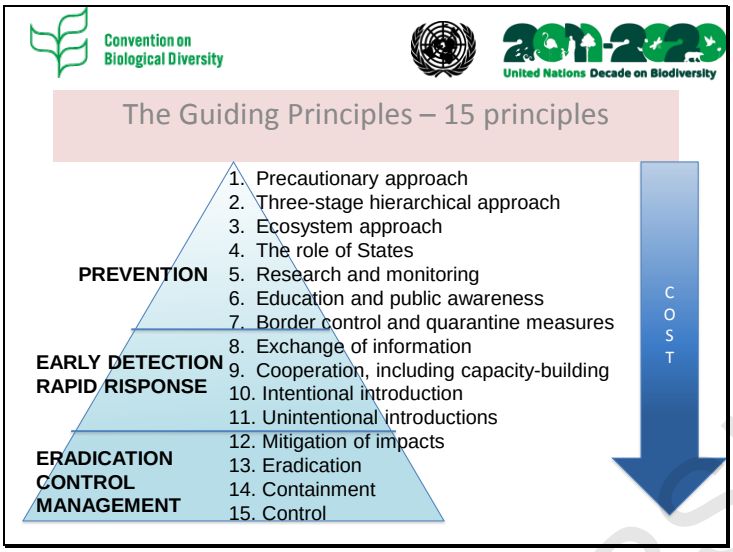

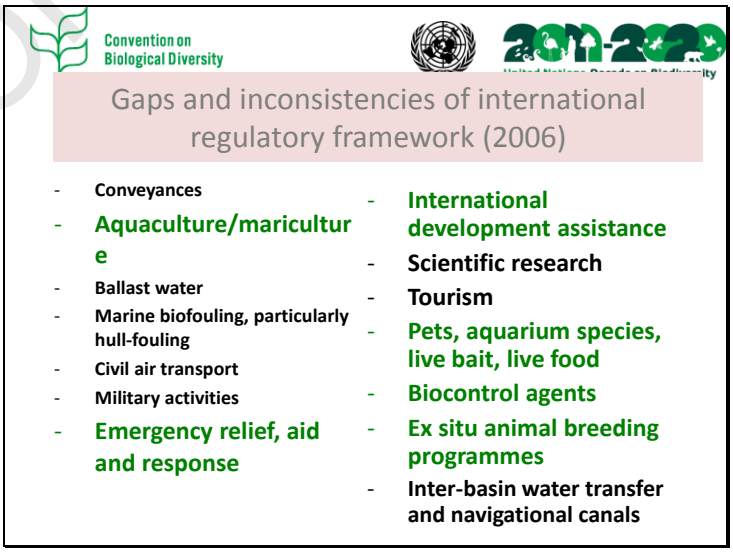

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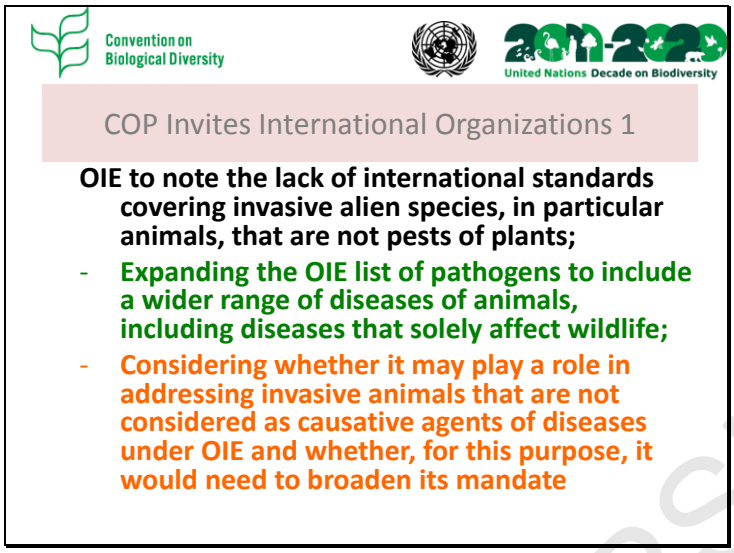
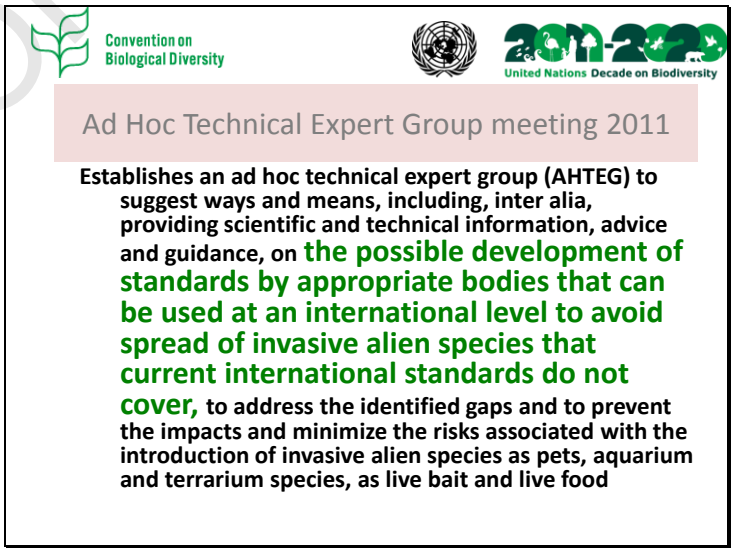
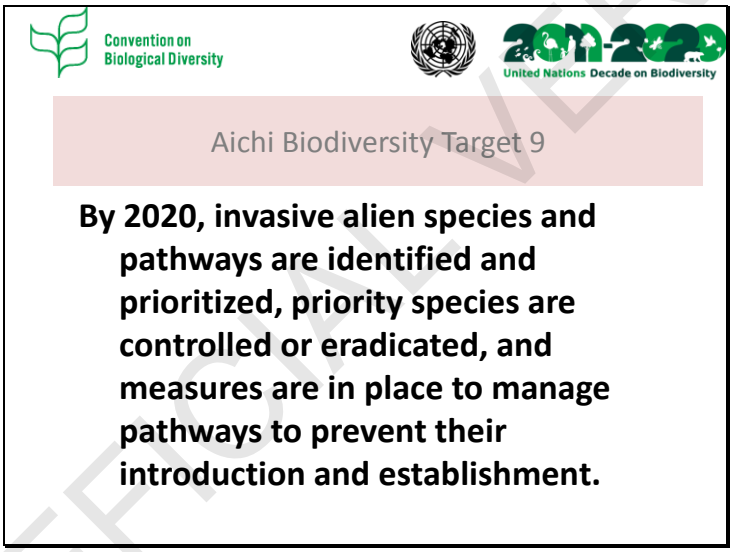
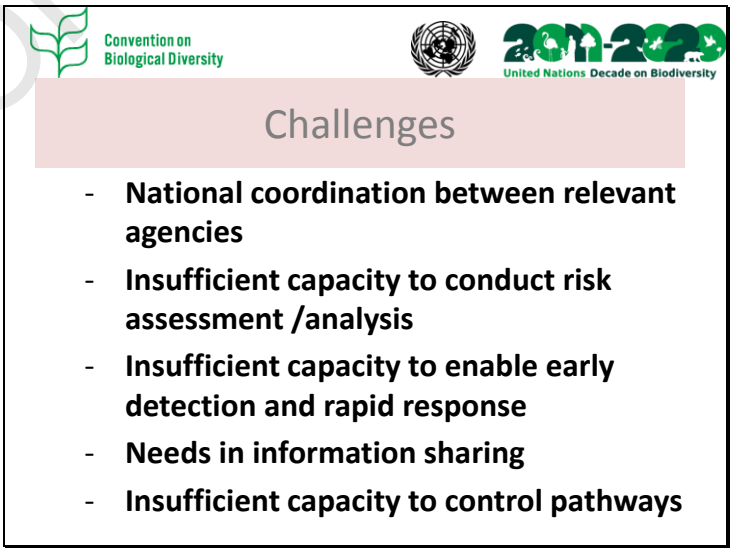








Annex V (contd)

Annex VI

GUIDELINES FOR ASSESSING THE RISK OF NON-NATIVE ANIMALS BECOMING INVASIVE

I. Definitions for the purpose of this document

Animal: means any species, subspecies or lower taxon of the kingdom animalia with the exception of pathogens.

Non-native (or alien) animal: means an animal that is not a native to the country or ecosystem to which it could be intentionally or unintentionally introduced.

Invasive non-native (or invasive alien) animal: means an animal that has been introduced and subsequently become established and spread outside its native distribution area and caused harm to the environment, animal or human health, or the economy.

Hazard: means a non-native animal**.**

Hazard identification: means the process of identifying whether an animal is native or not in the importing country or region.

Hitchhiker organism: means an organism that has an opportunistic association with a commodity or vehicle/vessel or container and which may be transported unintentionally to a new environment.

II. Scope

In the framework of the international movement of animals, it is important to analyse both the risk of a non-native animal becoming invasive and the risk of pathogens being introduced with the animal. These different risks should be assessed as separate, sequential and complementary processes.

The OIE standard for import risk analysis covers the potential movement of pathogens. The guidelines developed in this document are intended to address the complementary process of assessing the risk of non-native animals becoming invasive.

III. Introduction

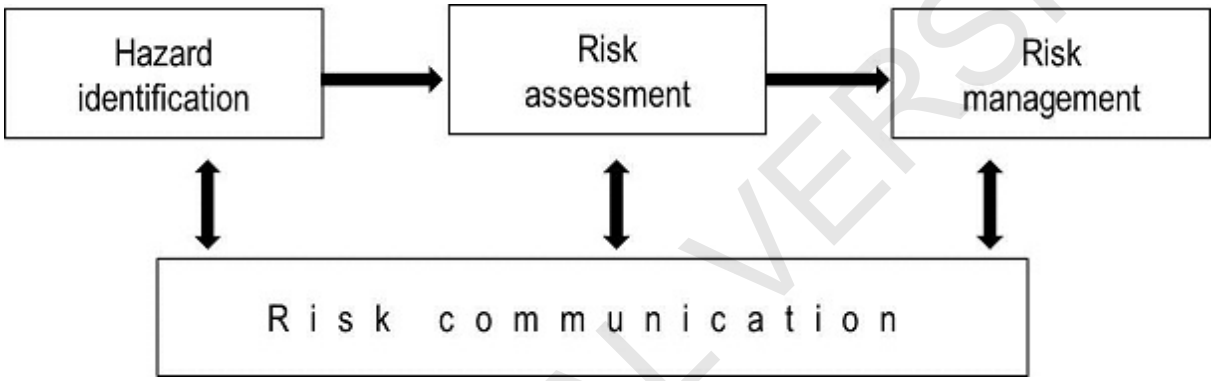
Organisms that have been introduced outside their native distribution and which subsequently become established and harmful to the environment, animal or human health, or the economy are considered "invasive non-native species." Invasive non-native species are one of the major drivers of biodiversity loss world-wide and are particularly a threat to geographically and evolutionarily isolated ecosystems (e.g., islands).

Trade is responsible for the movement of large numbers of live animals, comprising a wide diversity of species, around the world. Although the majority of these animals are not intended for release into the natural environment, some are, and others either escape or are subsequently released when their owners no longer wish to care for them. Trade in live animals thus plays a major role in facilitating invasions by non-native species world-wide. Because of the potential for non-native animals to become invasive, science-based risk analysis should be conducted before decisions are made with respect to the proposed importation of non-native animal species into a country or area. Risk analysis is also an important tool when considering the risks posed by so-called 'hitchhiker' organisms which may be associated with imported commodities or the vehicle/vessel or container in which they are imported.

The principal aim of assessing the risk of non-native animals becoming invasive is to provide importing countries with an objective and defensible method of determining whether such imported animal species are likely to become harmful to the environment, animal or human health, or the economy. The risk analysis should be transparent and participatory, providing stakeholders with the opportunity to contribute to the process and understand the reasons for decisions made. Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

These guidelines provide recommendations and principles for conducting transparent, objective and defensible analyses of the risks posed by the importation of non-native animal species. The guidelines are also useful in assessing the risks posed by hitchhiker organisms. The components of risk analysis described in these guidelines are hazard identification, risk assessment, risk management and risk communication (Figure 1).

Fig. 1. The four components of risk analysis



A risk analysis is initiated either by a request to import a new species or a species for a new purpose. However, even non-native species that are already within a country's borders may be considered for risk analysis, especially if there is a high likelihood of them being introduced, or escaping, into the natural environment. All pathways showing a potential for the introduction of non-native animals should receive some degree of risk assessment, with those pathways that show a high potential for introducing non-native animals being subject to in-depth risk assessment.

IV. Hazard identification

In the case of trade in non-native animals, the animal under consideration is the hazard. This hazard should usually be identified to the level of species although in some instances identification to the level of genus may suffice while in others, identification to the level of breed, subspecies, hybrid or biotype may be required.

In the case of so-called hitchhiker organisms, the hazard identification involves identifying species which could potentially produce adverse consequences if introduced in association with an imported commodity (animals or animal products) or the vehicle/vessel or container in which it is imported.

It is necessary to identify whether each potential hazard is already present in the importing country or area into which the animals are imported. This is not always easy for animals traded widely for a diversity of commercial and private purposes and which may already be present in private collections.

Identifying whether a species is present in a country or region requires historical information on the abundance and distribution of animals and therefore typically requires consultation with a variety of stakeholders. Ecological boundaries, as opposed to political boundaries, should be considered. Consultation and coordination with appropriate authorities in neighbouring countries may help to determine species distribution and abundance. The presence of a particular species in the importing country or area does not necessarily eliminate the need for risk assessment, since the likelihood of non-native animals becoming invasive is also dependent on a number of additional importation factors such as size and frequency of importations, transport methods, intended use, containment etc.

Hazard identification is a categorisation step, identifying animals dichotomously as hazards or not. For the purpose of these guidelines all non-native animals are considered a hazard.

V. Principles of risk assessment

The risk assessment is the component of the risk analysis which estimates the risks associated with a hazard. Risk assessments may be qualitative or quantitative. Qualitative risk assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making.

Risk assessment should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases and different methods may be appropriate in different circumstances. Risk assessment should be able to accommodate the variety of non-native animal species that may be considered for importation, entry and spread scenarios, and types and amounts of data and information.

The aim of a risk assessment is to assist in decision making in the face of uncertainty.

Both qualitative risk assessment and quantitative risk assessment methods are valid.

The risk assessment should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion and that of participating stakeholders.

Consistency in risk assessment methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.

Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.

The risk assessment should be amenable to updating when additional information becomes available.

In addition to the general principles of risk assessment, assessment of the risk of non-native animals becoming invasive needs to consider certain unique aspects such as:

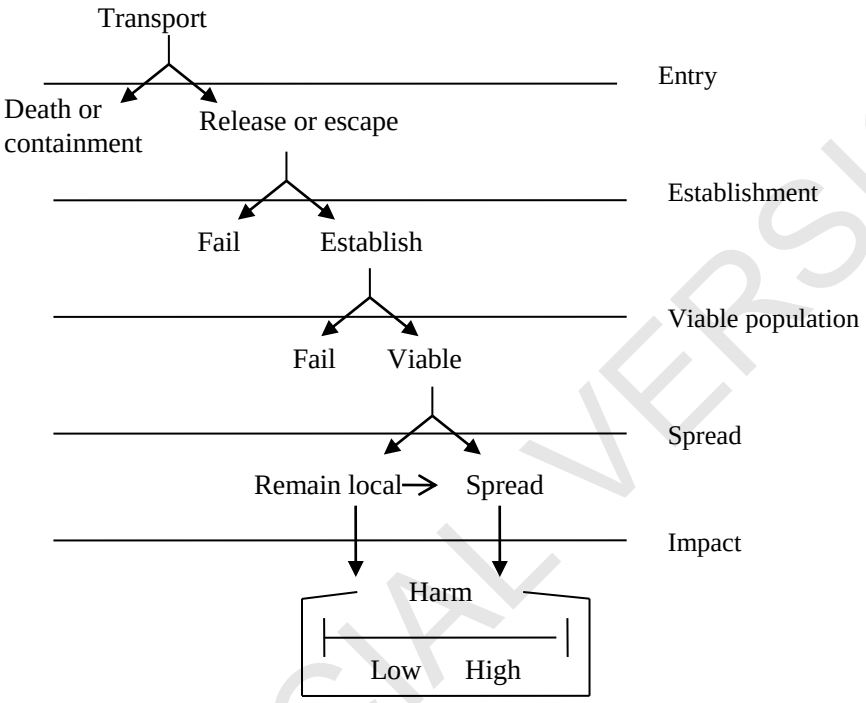
- The risk assessment need not be at a country level, but at an ecosystem level that may be sub-national.
- The risks may be borne by multiple subjects such as people, other animals or landscapes, thus requiring a systems-based approach to risk assessment.
- An invasive animal species may cause harm though a variety of mechanisms, both direct and indirect.
- The effects of an invasive animal species are often dependent on environmental conditions and may thus change over time in response to factors such as climate change.

Annex VI (contd)

VI. Risk assessment steps

The risk assessment examines the entire process by which a non-native animal species could enter a country, be introduced (escape or release) into the environment, become established, spread and cause harm. The steps in this process of invasion are illustrated in Figure 2.

Fig.2. The stages in the process of invasion by non-native animal species



1. Entry assessment

Entry assessment consists of describing the pathway(s), biological or non-biological, necessary for an importation activity to introduce non-native animal species into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The entry assessment describes the probability of the entry of each of the hazards (the non-native animals) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

Circumstances of entry and containment. Do the circumstances of transportation and containment on arrival prevent escape or release? Examples of the kind of inputs that may be required are:

- whether entry is intentional or unintentional;
- whether different commodities, vehicles/vessels or containers are capable of harbouring the animal under consideration;
- security of containment, if any;
- planned movement, use and holding conditions upon and after arrival.

Biological factors. What are the features of the animal that may affect its survival during transport and in its initial holding? Examples of the kind of inputs that may be required are

- species, subspecies or lower taxon, sex, age and breed of animals;
- the ability of the organism to survive the conditions and duration of transport;
- the number of individual animals per importation;
- ease of escape or release from containment;
- ability to survive in the environment of the importing country.

If the entry assessment demonstrates no significant risk, the risk assessment does not need to continue.

2. Establishment and spread assessment

Establishment and spread assessment consists of describing the biological conditions necessary for the hazards (in this case the non-native animals) to survive escape or release and estimating the probability of establishment and spread occurring, either qualitatively or quantitatively.

The probability of establishment and spread of the non-native animals is estimated for the local environment with respect to the number, size, frequency and season of escapes or releases.

a) Biological factors: What are the feature of the animals that may affect the probability of establishment and spread of the animals? Examples of the kind of inputs that may be required are:

- history of invasiveness elsewhere;
- number and size of releases or escapes (propagule pressure);
- reproductive biology and capacity (fecundity, age of sexual maturity, breeding frequency, gestation length, etc.);
- diet;
- whether the animals under consideration are wild or domesticated;
- whether the animals under consideration are generalist or specialised species;
- range of tolerance and adaptability to environment and climate;
- dispersal mode and capacity;
- longevity;
- density dependence.

b) Receiving environment: What are the features of the receiving environment that may affect the probability of establishment and spread of the animals? Examples of the kind of inputs that may be required are:

- climate match with the species native environment;
- presence of suitable food source;
- presence of suitable breeding sites;
- geographical and environmental characteristics;
- presence of predators, competitors, parasites and pathogens.

c) Containment factors: What are the management factors that may affect the probability of establishment and spread? Examples of the kind of inputs that may be required are:

- security capacity for housing, handling and transportation;
- intended use of the imported animals (e.g. pets, zoological collections, live food or bait, research etc.);
- the nature and frequency of human-assisted animal movements;
- live animal disposal practices (euthanasia, release, rehoming, etc.).

If the establishment and spread assessment demonstrates no significant risk, the risk assessment may conclude at this step.

3. Consequence assessment

The consequence assessment describes the potential consequences of a given establishment and spread of the animals and estimates the probability of them occurring. This estimate may be either qualitative or quantitative. The social and biological costs associated with the effects of invasive non-native species are often very difficult to assess and measuring socio-economic impacts of invasive animal species requires data of sufficient magnitude and quality, which are often not available. Examples of consequences include:

a) Direct consequences:

- harm to ecosystems;
- harm to native species;
- economic damage;
- impacts on human health and well-being.

b) Indirect consequences:

- Surveillance, containment, control and eradication costs;
- compensation costs;
- potential trade losses;
- impacts on socio-cultural values.

4. Risk estimation

Risk estimation consists of integrating the results from the entry assessment, establishment and spread assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.

For a qualitative assessment, the final outputs may include:

- estimated costs for surveillance and control in descriptive terms such as ‘high’, ‘medium’ or ‘low’;
- estimated level of impact on animals, ecosystems or habitats, or people in terms such as ‘high’, ‘medium’ or ‘low’;

- lists of potential evidence-based impacts of significance warranting consideration in decision making;
- description of relative risk and range in terms such as 'high to very high' etc.

For a quantitative assessment, the final outputs may include:

- estimated costs for surveillance and control;
- estimated numbers of herds, flocks, animals, ecosystems or habitats, or people likely to experience health impacts of various degrees of severity over time;
- probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;
- portrayal of the variance of all model inputs;
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;
- analysis of the dependence and correlation between model inputs.

VII. Principles of risk management

Risk management is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection in a cost-effective manner, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a Member's desire to minimise the likelihood of incursions of non-native invasive species and their consequences and its desire to import commodities and fulfil its obligations under international trade agreements.

VIII. Risk management components

1. Risk evaluation -the process of comparing the risk estimated in the risk assessment with the Member's appropriate level of protection.

2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation in order to bring it into line with the Member's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse consequences for biodiversity, animal and human health, and the economy. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options but because the assessment of risk from non-native animals must consider socio-cultural aspects, option evaluation must also consider the cultural, ethical and political acceptability of the various risk management options.

3. Implementation - the process of following through with the risk management decision and ensuring that the risk management measures are in place.

4. Monitoring and review - the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.

Annex VI (contd)

IX. Principles of risk communication

1. Risk communication is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a risk analysis, and by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and stakeholders in the importing and exporting countries. It is a multidimensional and iterative process and should ideally begin at the start of the risk analysis process and continue throughout.

2. A risk communication strategy should be put in place at the start of each risk analysis.

3. The communication of the risk should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4. The principal participants in risk communication include the authorities in the exporting country and other stakeholders such as domestic environmental and conservation groups, local communities and indigenous peoples, domestic livestock producers and consumer groups.

5. The assumptions and uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.

6. Peer review is a component of risk communication which is carried out in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

Appendix IX

Original: English
December 2011

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 12–14 December 2011

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1. Opening

The OIE *ad hoc* Group on Antimicrobial Resistance met from 12 to 14 December 2011 at the OIE Headquarters in Paris, France. Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, welcomed the participants on behalf of the Director General of the OIE, Dr Bernard Vallat.

The overall objective of the Group was to revise the relevant OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) chapters relating to the use of antimicrobials and the containment of antimicrobial resistance in veterinary medicine (contained in Section 6 of this *Terrestrial Code*) using, as far as possible, user-friendly text while taking into note of the draft guidelines and the definitions developed by the FAO[1]/WHO[2] Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance.

The specific objective of this third meeting of the Group was to continue with the revision of the *Terrestrial Code* started at the first meeting by addressing Chapter 6.10. Risk assessment for antimicrobial resistance arising from the use of antimicrobials, and considering the comments received from OIE Member Countries on the proposed updated version of Chapter 6.9. of the *Terrestrial Code* drafted at the second meeting of the Group.

A presentation was given by Dr David White from the United States Food and Drug Administration (FDA) comparing and contrasting the antimicrobial resistance risk analysis approaches taken by OIE, Codex and the FDA (see Appendix IV). The OIE risk analysis framework was based on the Covello-Merkhofer model and included four components: hazard identification; risk assessment; risk management; and risk communication, whereas the Codex framework includes three main components: risk assessment; risk management (which includes risk assessment policy), and risk communication. The OIE risk assessment components were release assessment, exposure assessment, consequence assessment, and risk estimate, whereas the Codex risk assessment components were hazard identification, hazard characterisation, exposure assessment, and risk characterisation.

The OIE also circulated to the Group a related paper [Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin; Vose *et al*. (2001). *Rev. sci. tech. Off. Int. Epiz.* **20** (3), 811–827] (see Appendix V). The appendix C of this paper provided comparison between the Codex and the OIE approaches in greater details.

2. Appointment of chairperson and rapporteur

The meeting was chaired by Dr Herbert Schneider and Mr Christopher Teale acted as rapporteur.

3. Adoption of the Agenda

The adopted Agenda, List of Participants, and Terms of Reference are presented in Appendices I, II and III of this report, respectively.

1 FAO: Food and Agriculture Organization of the United Nations
2 WHO: World Health Organization

4. Review and update of Chapter 6.10. Risk assessment for antimicrobial resistance arising from the use of antimicrobials of the *Terrestrial Animal Health Code*

The Group was reminded that Chapter 6.10. of the *Terrestrial Code* had been adopted in 2003. Further revision was deemed necessary to take into account the Codex Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011) developed by the *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance. The chapter was therefore revised with a primary focus on animal health and welfare while taking into account the Codex Guidelines that relate primarily to food.

The Group agreed that further discussion would be useful to clarify the practical application of both sets of guidelines (OIE and Codex), particularly for the overlapping areas of risk analysis process.

The title of the chapter was changed from risk assessment to risk analysis as the Group expanded the sections on risk management and risk communication; Chapter 6.6 would need to accommodate this change.

The Group was of the opinion that a reference in Chapter 6.10. to the article of Vose *et al*. (2001), mentioned above, would be useful to OIE Member Countries. It was also suggested that this article, which was published ten years before being updated.

5. Review of and reply to the technical comments received from OIE Member Countries on the proposed updated version of Chapter 6.9. of the *Terrestrial Animal Health Code*

Comments received from OIE Member Countries were reviewed and taken into consideration in finalising Chapter 6.9. of the *Terrestrial Code*.

6. Finalisation of definitions of the terms identified at the second meeting

Owing to time constraint, the Group was not able to discuss this agenda item.

7. Discussion on the way forward to update the OIE list of antimicrobials of veterinary importance

The Group discussed briefly the OIE list of antimicrobials of veterinary importance and agreed to address fully this matter at its next meeting.

8. Next meeting

Proposed dates of the next meeting: 2–4 July 2012 at the OIE Headquarters, Paris, France.

The main tasks for the next meeting would be:

- to review the OIE list of antimicrobials of veterinary importance and update it, if needed.
- to finalise definitions of the terms identified at the second meeting of the Group and to discuss the need for new definitions to be included in the glossary of the *Terrestrial Code*.
- to address the OIE Member Country comments received on the proposed revisions to Chapter 6.10. drafted at the third meeting.

9. Other matters

The Group noted that a global conference on antimicrobial resistance would be organised by the OIE on 13-15 March 2013, in Paris, France.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 12–14 December 2011

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Agenda

1. Opening
2. Adoption of agenda
3. Appointment of chairperson and rapporteur
4. Review and update of Chapter 6.10.: "Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals" of the *Terrestrial Animal Health Code* taking into account the guidelines for risk analysis of foodborne antimicrobial resistance developed by the ad hoc Intergovernmental Task Force on Antimicrobial Resistance of the Codex Alimentarius
5. Review of and reply to the technical comments received from OIE Member Countries on the proposed updates to Chapter 6.9.: "Responsible and prudent use of antimicrobial agents in veterinary medicine" of the *Terrestrial Animal Health Code* drafted at the last meeting of the *ad hoc* Group
6. Finalisation of definitions of the terms identified at the second meeting (if time allows)
7. Discussion on the way forward to update the OIE list of antimicrobials of veterinary importance (if time allows)
8. Next meeting
9. Other matters
10. Adoption of report

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 12–14 December 2011

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List of Participants

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Appendix III

MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 12–14 December 2011

Terms of Reference

Review and update the chapters of the *Terrestrial Animal Health Code* related to antimicrobials and antimicrobial resistance in the following order:

- Chapter 6.8.: Monitoring of the quantities of antimicrobials used in animal husbandry;
- Chapter 6.7.: Harmonisation of national antimicrobial resistance surveillance and monitoring programmes;
- Chapter 6.9.: Responsible and prudent use of antimicrobial agents in veterinary medicine;
- Chapter 6.10.: Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals

Appendix IV

OIE, CODEX and FDA Risk Analysis Strategies

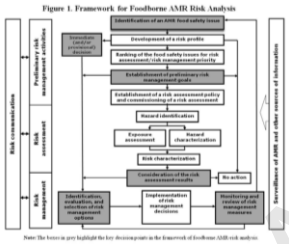
Codex Alimentarius

- An international inter-governmental body that develops food standards and guidelines to promote consumer protection and facilitate world trade
- CAC created the *Ad-Hoc* Intergovernmental Task Force on Antimicrobial Resistance at its 29th (2006) session
  - Hosted by Republic of Korea
  - Limited existence – 4 meetings (2007-2010)
  - CTFAMR

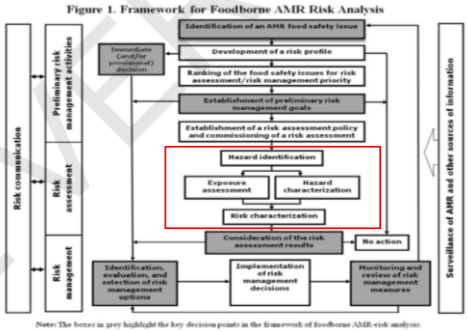
- Assess the risks to human health associated with the presence in food and feed including aquaculture and the transmission through feed and food of AMR microbes and resistance genes and to develop appropriate risk management strategies

CTFAMR

Goal was to develop a Codex AMR risk analysis approach that allows countries or regions to implement actions based upon identified and prioritized needs and available resources



CTFAMR



OIE Terrestrial Animal Health Code 20th Edition, 2011

- Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programs
- Chapter 6.8 Monitoring of the quantities of antimicrobials used in animal husbandry
- Chapter 6.9 Responsible and prudent use of antimicrobial agents in veterinary medicine
  (also – 2011 Aquatic Animal Health Code)
- Chapter 6.10 Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals

  - Provide a transparent, objective and scientifically defensible method of assessing and managing the human and animal health risks associated with the development of resistance arising from the use of antimicrobials in animals

http://www.oie.int/eng/normes/mcode/en_sommaire.htm

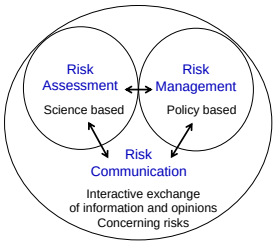
OIE Risk Analysis Methodology

Rev. sci. tech. Off. Int. Epiz., 2001, 20(3), 811-827

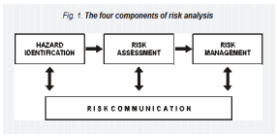
- The Ad hoc Group of experts on antimicrobial resistance, appointed by OIE, has developed an objective, transparent and defensible risk analysis process, providing a valid *basis for risk management decisions* in respect to antimicrobial resistance. The components of risk analysis and of different possible approaches in risk assessment (*qualitative, semi-quantitative, and quantitative*) are defined. The Ad hoc Group recommended the following: an *independent* risk assessment based on *scientific data*; an *iterative* risk analysis process; a qualitative risk assessment systematically undertaken *before* considering a quantitative approach; the *establishment of a risk assessment policy*; and the availability of technical assistance for developing countries.

Contrast Components of Food and Animal RA Models

Codex Risk Analysis Framework



OIE Risk Analysis Framework



Definition of the Risk

- The infection of humans with microorganisms that have acquired resistance to a specific antimicrobial used in animals, and resulting in loss of benefit of antimicrobial therapy used to manage the human infection

The Components of Risk Analysis: a comparison of the systems used by the Codex Alimentarius and the Office International des Epizooties (OIE)

Codex Alimentarius
- Risk Assessment
  - Hazard Identification
  - Hazard Characterization
  - Exposure Assessment
  - Risk Characterization
- Risk Management
- Risk Communication

OIE
- Hazard Identification
- Risk Assessment
  - Risk Release Assessment
  - Exposure Assessment
  - Consequence Assessment
  - Risk Estimate
- Risk Management
- Risk Communication

Vose et al. Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin *Rev. sci. tech. Off. int. Epiz.*, 2001, 20 (3), 811-827

Difference between OIE and Codex

- Place of hazard identification in the models
  - OIE – Identification of "risk agents" (hazards) and the conditions under which they might potentially produce adverse consequences
  - 2 types of hazards exist
    - Bacteria that have acquired resistance due to the use of a particular antimicrobial in animals
    - Resistance determinants selected as a result of the use of a particular antimicrobial in animals

Release Assessment

- Describes the biological pathways necessary for the use of a specific antimicrobial in animals to lead to the release of resistant microorganisms or resistance determinants into a particular environment
  - Estimates either qualitatively or quantitatively the probability of that complete process happening

Exposure Assessment

- Describes the biological pathways necessary for exposure of humans to the resistant microorganisms or resistance determinants released from a given antimicrobial use in animals
  - Estimates the probability of the exposures occurring

Consequence Assessment

- Describes the relationship between specified exposures to resistant microorganisms or resistant determinants and the consequences of those exposures
  - Describes the potential consequences of a given exposure and estimates the probability of them occurring

Risk Estimation

- Integrates the results from the risk assessment, exposure assessment and consequence assessment to produce overall estimates of risks associated with hazards
  - Takes into account the whole risk pathway from hazard identification to unwanted consequences

Risk Management and Communication

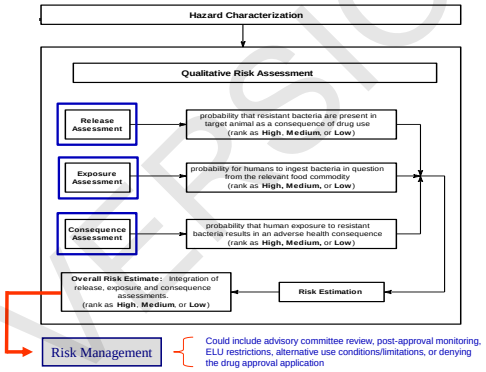
- Have to be continuously monitored and reviewed in order to ensure that objectives are being achieved
  - OIE Terrestrial Code Articles
    - 2.1.5 Principles of Risk Management
    - 2.1.6 Risk Management Components
    - 2.1.7 Principles of Risk Communication

FDA/CVM Regulatory Approach
Microbial Food Safety Risk Assessment

- Part of the human food safety evaluation that looks at the impact of the use an antimicrobial drug has on the development of resistance among pathogenic zoonotic bacteria of human health concern
  - October 23, 2003
- Approach applies to antimicrobial drugs intended for food-producing animals
  - Human exposure through ingestion of animal-derived food
- Qualitative risk assessment approach
  - Based on the process described by the OIE *Ad Hoc* Group on Antimicrobial Resistance
  - GFI152 - Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern

Qualitative Risk Assessment

- Release assessment
  - Describes factors related to antimicrobial drug and its use in animals that contribute to the emergence of resistant bacteria or resistant determinants in the animal
- Exposure assessment
  - Describes likelihood of human exposure to resistant bacteria or resistance determinants through animal-derived food
  - Evaluation based on relative consumption and contamination of those commodities
- Consequence assessment
  - Describes human health consequence of exposure to resistant bacteria (or determinants) based on importance of drug (or related drugs) to humans
  - Ranking of antimicrobial drugs
    - CDER
    - Critically important, Highly important, Important



Hazard Identification

The **hazard** has been defined as human illness, (that is):

- caused by an antimicrobial-resistant bacterium;
- attributable to an animal-derived food commodity, and;
- treated with a human antimicrobial drug of concern.

Qualitative Risk Assessment

Step 1: Release Assessment

Describes factors related to an antimicrobial drug and its use in animals that contribute to the emergence of resistant bacteria or resistant determinants in the animal

Release Assessment

Probability that resistant bacteria will emerge in the target animals

Relevant parameters	Extent to which relevant factors favor emergence of resistance	Release H, M, or L
	Comments/conclusions regarding factors	
Mechanism of action		
Spectrum of activity		
Pharmacokinetics		
Pharmacodynamics		
Resistance mechanisms		
Resistance transfer		
OTHER		

Qualitative Risk Assessment

Step 2. Exposure Assessment

Describes likelihood of human exposure to food-borne bacteria of human health concern through animal-derived food products

Exposure Assessment

- Probability that humans consuming animal derived foods will be exposed to resistant bacteria of public health concern
- Evaluation based on relative consumption and contamination of those commodities
- Variety of data sources – all welcome to better address the concern
  - NARMS, CIPARS, DANMAP, etc

Exposure Assessment

	Per capita consumption of the food commodity		
Probability of food commodity contamination	High	Medium	Low
High	↓		
Medium	↓		
Low →	Medium		

Exposure Assessment

Probability that humans consuming animal derived foods will be exposed to resistant bacteria of public health concern

Evaluation based on relative consumption of commodities and relative contamination of those commodities

EXAMPLE *per capital* consumption data for the year 2005

Commodity	Consumption (pounds per capita per year)	Qualitative Ranking H, M, or L
Beef	62.4	HIGH
Chicken	60.4	HIGH
Pork	46.5	HIGH
Fish and shellfish	16.1	MEDIUM
Turkey	13.1	MEDIUM
Lamb and mutton	0.8	LOW
Veal	0.4	LOW
Total meat	199.7	

Source: USDA Economic research Service, boneless trimmed equivalent

Qualitative Risk Assessment

Consequence Assessment

Describes human health consequence of exposure to resistant bacteria based on importance of drug (or related drugs) to humans (ranking of antimicrobials)

Consequence Assessment

Probability that human exposure to resistant bacteria results in an adverse health consequence

Evaluation based in part on importance of the antimicrobial to human health

Critically Important

3rd generation cephalosporins, macrolides, fluoroquinolones

Highly Important

4th generation cephalosporins, aminoglycosides, clindamycin

Important

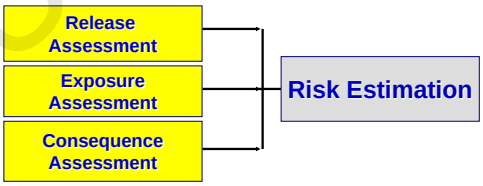
1st & 2nd generation cephalosporins, monobactams, quinolones

Criteria for Ranking

1. Antimicrobial drugs used to treat enteric pathogens that cause food-borne disease
2. Sole therapy or one of few alternatives to treat serious disease or drug is essential component among many antimicrobials in the treatment of human disease
3. Antimicrobials used to treat enteric pathogens in non-food-borne disease
4. No cross-resistance within drug class and absence of linked resistance with other drug classes
5. Difficulty in transmitting resistance elements within or across genera and species of organisms

Critically important: Meet **BOTH** criteria 1 and 2
Highly important: Meet either 1 or 2
Important: Meet either criteria 3, 4, or 5

Qualitative Risk Integration

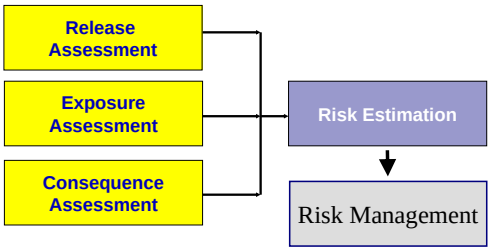


Risk estimation integrates results from release, exposure and consequence assessments to produce overall measure of risk associated with hazards.

Risk Estimation

Release	Exposure	Consequence	Risk Estimation
Low Medium High	Low Medium High	Important Highly Important Critically Important	Low Medium High

Qualitative Risk Assessment



Possible risk management steps range from denying the drug approval application to approving the application under various use conditions that assure the safe use of the product

Extent-of-use limitations

Possible process for ranking (High, Medium, Low) of extent of antimicrobial drug use in animals based on duration and method of administration (GFI#152, Table 7, Page 23)

Duration of use	Intended administration to:		
	Individual animals	Select groups or pens of animals	Flocks or herds of animals
Short (<6 days)	L[1]	M[2]	H[3]
Medium (6-21 days)	L	M	H
Long (>21 days)	M	H	H

Examples of Possible Risk Management Strategies Based on the Level of Risk (H, M, or L)

Approval conditions	Risk Category		
	Category 1 (H)	Category 2 (M)	Category 3 (L)
Marketing status	Rx	Rx/VFD	Rx/VFD/OTC
Extra-label use	ELU restriction	Restricted in some cases	ELU permitted
Extent of use	Low	Low, medium	Low, medium, high
Post-approval monitoring	NARMS	NARMS	NARMS
Advisory committee review	YES	In certain cases	NO

GFI #152, Table 8, pp. 25

Appendix V

Rev. sci. tech. Off. int. Epiz., 2001, 20 (3), 811-827

Antimicrobial resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin

D. Vose [1], J. Acar [2], F. Anthony [3], A. Franklin [4], R. Gupta [5], †T. Nicholls [6], Y. Tamura [7], S. Thompson [8], E.J. Threlfall [9], M. van Vuuren [10], D.G. White [11], H.C. Wegener [12] & M.L. Costarrica [13]

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This report, prepared by the OIE Ad hoc Group of experts on antimicrobial resistance, has not yet received the approval of the International Committee of the OIE

Summary

The Ad hoc Group of experts on antimicrobial resistance, appointed by the Office International des Epizooties, has developed an objective, transparent and defensible risk analysis process, providing a valid basis for risk management decisions in respect to antimicrobial resistance. The components of risk analysis and of different possible approaches in risk assessment (qualitative, semi-quantitative and quantitative) are defined. The Ad hoc Group recommended the following: an independent risk assessment based on scientific data; an iterative risk analysis process; a qualitative risk assessment systematically undertaken before considering a quantitative approach; the establishment of a risk assessment policy; and the availability of technical assistance for developing countries.

Keywords

Antimicrobial resistance – Containment of resistance – Food – Human medicine – International standards – Public health – Risk analysis – Risk assessment – Risk management – Veterinary medicine.

Introduction

This document presents the concept of risk analysis, comprising the components of hazard identification, risk assessment, risk management and risk communication, as applicable to antimicrobial resistance. The inter-relationship of these components is described and the respective distinct responsibilities of risk assessors and risk managers are identified. An example of a risk analysis methodology is given both in relation to animal health and to human health.

Background

Use of antimicrobials in animals for therapeutic, preventative and growth promotion purposes can reduce the therapeutic value of antimicrobials used in animal and human medicine because of losses in susceptibility of pathogenic bacteria. This risk may be represented by the loss of therapeutic value of one or several antimicrobial drugs and includes the emergence of multi-resistant bacteria.

The principal aim of risk analysis of antimicrobial resistance in bacteria from animals is to provide Member Countries of the Office International des Epizooties (OIE) with an objective and defensible method of assessing and managing the human and animal health risks associated with the development of resistance due to the use of antimicrobial drugs in animals, including appropriate communication measures. The procedure should be transparent and clearly separate responsibilities in risk assessment and risk management. Risk assessment should be based on the available scientific data. Transparency is essential because data are often uncertain or incomplete, and without full documentation, the distinction between facts and value judgements may not be clear. Risk management should also be a structured approach so that all stakeholders (for example, agricultural and pharmaceutical industries, healthcare providers and consumer groups) are provided with clear reasons for the imposition of risk management controls (for example, on the animal use of the antimicrobial in question, more stringent slaughtering or processing requirements, or import restrictions on products from animals that have been treated with antimicrobials).

A policy framework for the authority regulating antimicrobials should be established to provide risk managers and risk assessors with a consistent set of legal, regulatory and political rules within which risk analyses must be conducted.

This Guideline explains the recommendations of the OIE Ad hoc Group on antimicrobial resistance for guidelines and principles for conducting transparent, objective and defensible risk analyses to control the impact of using antimicrobials in animals, and provides recommended definitions of terms used in risk analysis.

Two principal sets of terminology are currently in use in risk analysis relating to this topic, namely: the United States (US) National Academy of Science (NAS) system on which the Codex Alimentarius Commission (Codex) approach is based, developed for food safety issues, and the Covello-Merkhofer system on which the OIE *International Animal Health Code* risk analysis is based. Beyond their apparent differences, both systems are very similar and largely contain the same components. The way these components are ordered in each of these two systems has evolved because of the type of risks that are being addressed. The terminology presented in this document follows the Covello-Merkhofer system. Comparison between the two systems and definitions of terms are given in Appendix C.

The risk analysis process

Risk analysis is defined in the OIE *Code* as 'The process composed of hazard identification, risk assessment, risk management and risk communication'. It is a term frequently used to describe the complete process of properly addressing a risk issue. It encompasses assessing and managing the risk together with all the appropriate communication between risk assessors, stakeholders and risk managers. A typical risk analysis proceeds as detailed below.

a) A policy framework will previously have been established by risk managers that describes the types of risk that need to be addressed, implying, among other things, the ranking of these risks among the other risk issues. In consultation with technical experts and risk assessors, a strategy for the assessment of the risk is then formulated. The policy framework also provides an explanation of the type of risk management options that can be considered under the legislative and regulatory framework of the country. Finally, the policy framework should explain the risk decision-making process, including methods of evaluating and quantifying risks and the level of risk deemed to be acceptable.

b) A risk issue and plausible risk management actions that could be taken to reduce or eliminate the risk are identified by management.

c) In consultation with technical experts, risk assessors and other stakeholders, a strategy for a preliminary assessment of the risk is formulated, including precisely how the risk is to be evaluated.

d) Risk assessors execute a preliminary qualitative assessment (scoping study) and advise management on the feasibility of assessing quantitatively the risk and on the identified risk management strategies. This report is made public.

e) Managers will determine from this scoping study whether the risk is sufficiently severe to warrant further action, including whether resources (which could be very limited) can be dedicated to the issue. If the risk is considered sufficiently important, and if feasible, risk managers may then instruct risk

assessors to fully assess the risk (qualitatively, and/or quantitatively) and the reduced level of risk that would exist after each identified risk reduction option. Refining of the risk reduction options and risk assessment may go through several iterations.

f) The risk assessment may be presented for review at various stages until the final risk assessment report has been produced, which is then made public. This aspect of risk communication is particularly helpful in ensuring transparency of the risk analysis as a whole and the efficient collection of data.

g) Risk managers use the results of the risk assessment in order to determine, in line with previously defined policy, the appropriate actions to take in order to manage the risk in question in the most efficient manner.

h) The risk management decision by a regulatory authority is made public with the greatest possible clarity.

i) The risk managers have to implement their decision and to organise the follow-up of these regulatory and other measures in order to evaluate the impact of these decisions with regard to the expected results.

j) The data acquired by the follow-up must be assessed in order to allow a possible amendment of the risk analysis policy, of the assessment strategy, of the outcome of the scientific assessment, and of the regulatory and other actions that have been taken.

The following sections elaborate on these stages, categorised into four parts according to the Covello-Merkhofer system. References refer to where in the above bullet points each stage appears:

– hazard identification (*b*)

– risk assessment (*c, d, e, f*)

– risk management (*b, g, i, j*)

– risk communication (*c, d, f, h*).

Hazard identification

Hazard identification is defined under the OIE system as 'The process of identifying the pathogenic agents that could potentially be introduced in the Commodity considered for importation'. It is the identification of 'risk agents' (hazards) and the conditions under which they might potentially produce adverse consequences. In terms of risk issues related to antimicrobial-resistant bacteria, the risk agent is most generally represented by the resistance determinant that emerges as a result of the use of a specific antimicrobial in animals. This definition then reflects the development of resistance in a species of bacterium that is pathogenic, as well as the development of a resistance determinant that may be passed to other bacteria that are pathogenic. The conditions under which the risk agent might potentially produce adverse consequences include any feasible scenarios via which humans or animals become exposed to pathogens which contain that resistance determinant, fall ill and where the human or animal would be treated with an antimicrobial that is no longer effective because of the resistance.

Risk management

Risk management policy

Risk management policy is a new term defined as 'The regulatory policy framework for monitoring, measuring, assessing and managing risks involved in the use of antimicrobials in food producing animals'. A critical precursor to the risk analysis process is the development and public explanation of such a policy framework. This framework, aimed at providing the guidelines for conducting an appropriate risk assessment, has to be developed by the risk managers with the technical support of the scientific experts in charge of the risk assessment.

The policy framework explains the philosophy behind monitoring and controlling risks involved in the use of antimicrobials in food producing animals. It must explain methods for involving risk assessment in the approval of new drug use, the various restrictions of use that might be applied to control and reduce any adverse impact and the procedure for retracting approval of use of the drug. It must also explain how the human or animal impact due to resistance will be measured, what level of impact will be considered unacceptable and how this information is used in the registration of new drugs.

The policy framework may also address the additional importance of certain antimicrobial drugs needed to treat infectious diseases in human medicine for which there are no effective alternative therapies. Furthermore, it should explain the range of risk reduction actions that management can select within legislative and regulatory restrictions.

The framework should explain the impact of uncertainty on the risk management decision. It should also address what actions will be taken in the event of identifying an unquantifiable risk due to antimicrobial use.

The establishment of a population of resistant bacteria as a result of the use of an antimicrobial in animals means that the human or animal health impact may continue long after the animal use of an antimicrobial has ceased. The policy framework should therefore address how to measure a long-term impact, and may include some cut-off period or discount factor that recognises the reduced value of a therapeutic drug as new drugs become available.

However, the policy framework should not necessarily restrict risk management from considering potential risk management options that may be outside the current domain of the

regulatory authority. Clear explanation of these conditions allows the pharmaceutical and agricultural industries and the veterinary and healthcare professional bodies to plan and test current and future antimicrobial products in a predictable environment and modify their use to achieve clear objectives.

Clearly stating the policy framework ensures transparency during the risk management phase of a risk analysis. People react to risk in very different and often emotional ways: a clear policy on how to measure risk and what is deemed acceptable implicitly recognises that a zero risk policy is unachievable and greatly reduces any suspicion of false argument.

Risk management components

Risk management is conducted by risk managers who have a comprehensive understanding of policy, and an appropriate level of technical background to communicate effectively with the risk assessors. The OIE defines risk management as consisting of the steps described below.

Risk evaluation

The process of comparing the risk estimated in the risk assessment with the appropriate level of protection of the Member Country.

Option evaluation

The process of identifying, evaluating the efficiency and feasibility of, and selecting measures in order to reduce the risk associated with an importation in line with the appropriate level of protection of the Member Country. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse biological and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment followed by comparison of the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.

Implementation

The process of following through with the risk management decision and ensuring that the risk management measures are in place.

Monitoring and review

The ongoing process by which the risk management measures are continually audited to ensure that they are achieving the results intended.

Risk decision when data are insufficient or inadequate

In the event that insufficient or inadequate data are available to reasonably assess the importance of a potential risk issue, and it is considered that the risk is potentially of such severity that one cannot wait for sufficient data before taking action, it is reasonable for the risk managers to take a temporary risk avoidance action that minimises any exposure to the risk. There are five extremely important considerations when faced with this situation, as follows:

a) a risk assessment must first be attempted, and all reasonable efforts made to acquire the necessary data, within the allowable timeframe, before taking the temporary risk avoidance action

b) the risk avoidance action must be chosen to provide the required level of protection in the manner least restrictive to trade

c) the risk avoidance action should be commensurate with the potential severity of the risk

d) in all cases, particularly in international trade, the risk avoidance action should be taken in conjunction with a commitment to acquire the necessary data, within a reasonably short and defined time, to help assess the severity of the risk and the most appropriate risk reduction strategy

e) the process must remain transparent.

Risk assessment

Risk assessment is defined in the OIE *Code* as 'The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an importing country'. There are a number of approaches to assessing the magnitude of a risk and the value of potential risk reduction options. These can be broadly categorised into three types: qualitative, semi-quantitative and quantitative risk assessments. Whichever approach is taken, the risk assessment must be designed to address the specific question posed by the risk managers.

The risk assessment process is usually sub-divided into four components: risk release assessment; exposure assessment; consequence assessment; and risk estimation. Their meanings are described below and examples of factors that may be considered in each component are listed in Appendices A and B.

Release assessment

Defined in the OIE *Code* as 'Description of the biological pathways necessary for the use of an antimicrobial in animals to release resistant bacteria or resistance determinants into a particular environment, and estimating the probability of that complete process occurring either qualitatively or quantitatively'.

Exposure assessment

Defined in the OIE *Code* as 'Describing the biological pathways necessary for exposure of animals and humans to the hazards released from a given source, and estimating the probability of the exposure occurring, either qualitatively or quantitatively'.

Consequence assessment

Defined in the OIE *Code* as 'Description of the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative or quantitative'.

Risk estimation

Defined in the OIE *Code* as 'Integration of the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome'.

The policy framework will provide guidelines to the risk assessors on how to assess the complete impact of any risk issue and risk reduction strategies. For example, removing an antimicrobial from veterinary use may mean that another antimicrobial is used in its place with potentially worse consequences. Unless these secondary impacts, whether positive or negative, are addressed, the risk management strategy may be sub-optimal.

The initial planning stages of a risk assessment can be performed as described below.

a) The risk issue in question is formally expressed to ensure that all participants agree on the problem to be addressed. The potential mechanisms and pathways via which the hazard can result in an adverse effect are also described. This system, as understood by the risk assessment team, can be explained using one or more flow diagrams. At this point, the diagram is purely conceptual and there is therefore no need for data. The purpose of such diagrams is to focus thought on what data would be useful, what possible risk management options exist, and to integrate and review the level of knowledge about the system in general. It is advisable to involve a broad participation in the exercise and to circulate widely to stakeholders and relevant experts.

b) A preliminary data search is conducted to assess what components of the system might be adequately quantified. Components might include, for example: the prevalence of resistant bacteria in faeces, water or carcasses; the distribution by animal species, season and geographical region of use of an antimicrobial; the frequency of the use of the antimicrobial in human medicine and the health status of those receiving the antimicrobial. At this stage, it is sufficient to know of the availability of data. Requests for data that might help quantify the components of the system can also be made to stakeholders and relevant experts. Strong consideration should also be given to useful data that may not be immediately available, but that could become available within a reasonable period, perhaps with some research effort. The interpretation of what constitutes a reasonable period will reflect the imminence and severity of the risk issue in question. It may be appropriate to consider completing a risk assessment rapidly to help decision makers identify the immediate actions to be taken, recognising that a re-evaluation of the risk issue when more data become available may lead the decision makers to alter the preliminary actions that were taken.

c) A review of the system, as perceived by the risk assessment team, together with the data available to quantify the components of that system can provide important guidance. It can illustrate which risk management options can be properly assessed for their effectiveness. It can also guide the risk assessor regarding the production of a quantitative risk assessment, if required, that would be based on data as well as supplying guidance as to whether such a model could be validated in some way. It is the combination of feasible risk management options, together with the data that could be available to assess those options, that should direct the risk assessment team towards the form of their assessment. If the system is not sufficiently well understood, or insufficient data are available to meaningfully quantify the model, it may only be possible to produce a qualitative risk analysis. However, quantification of certain aspects of the system may also be possible, which could enable the evaluation of a restricted number of risk management options. The risk assessment model can be kept as simple as possible to support the range of risk management decisions being considered. The model structure may not include a complete pathway analysis of the risk scenario if there are limited risk reduction strategies the benefits of which can be addressed in a far simpler model. Flexibility in the approach to modelling will reduce the effort required to produce the assessment and limit the number and type of assumptions that may have to be made in the model. However, the model may not then be useful in addressing other questions that arise over the same risk issue and may not help other stakeholders contribute to efficiently managing the risk. It may also be difficult to demonstrate consistency between models where different model structures have been used together with quite different assumptions.

A full assessment of the risk to human and animal health from antimicrobial-resistant bacteria resulting from use of antimicrobials in food-producing animals can be divided into three parts, as follows:

a) production of the resistant bacteria of interest as a result of antimicrobial use, or more particularly, production of the resistant determinants if transmission is possible between bacteria. (If it is the use of the antimicrobial in animals that is being considered as the hazard, there may be several different species of bacteria to consider.)

b) consideration of the realistic pathways via which humans can become exposed to these resistant bacteria or resistance determinants, together with the possible range of bacterial load ingested at the moment of exposure

c) consideration of the response of the person to the exposure.

Risk assessment of antimicrobial issues can be technically difficult, and it is essential that the assessment is the work of a team of professionals with broad expertise in risk analysis modelling, microbiology, veterinary medicine and animal husbandry, human healthcare and medicine, chemistry and any other relevant disciplines. Published chemical, microbial and genetic risk assessments can provide useful generic illustrations for modelling components of the risk assessment.

Qualitative risk assessment

Qualitative risk assessment is defined in the OIE *Code* as 'An assessment where the outputs on the likelihood of the outcome or the magnitude of the consequence are expressed in qualitative terms such as high, medium, low or negligible'. A qualitative risk assessment is always completed first as part of a preliminary evaluation (scoping study), whether or not one progresses to a semi-quantitative or fully quantitative assessment. It is the collation of all available information that will enable the determination of the probability and impact of the risk in question. A qualitative risk assessment discusses the steps necessary for the risk to occur, which pathways are feasible and which can be logically discounted. In a risk assessment of a human health impact due to use of a specific antimicrobial in food producing animals, for example, factors would include patterns of use of the antimicrobial, rates of resistance acquisition in exposed bacteria, the ecology of these resistant bacteria, pathways via which these bacteria may directly or indirectly transfer resistance to pathogens that infect humans, and the rates at which antimicrobials analogue to the animal antimicrobial are prescribed for the infected humans.

A qualitative risk assessment would also need to discuss the level of loss of benefit of the human medicine antimicrobial. All of these factors constitute a risk scenario on which one can overlay possible risk reduction strategies and discuss the benefits they might provide. Appendices A and B list factors that may be useful in an assessment. At this stage, a risk may be determined to be logically insignificant because, for example, the biological pathway is not possible or the risk is logically less severe than another for which a full analysis has been completed and determined to be acceptably small. As more risk assessments are conducted on antimicrobial issues, there may be broad agreement concerning the likely risks associated with particular hazards. In such cases, a qualitative assessment may frequently be the sole requirement. Qualitative assessment does not require mathematical modelling skills and so will often be the type of assessment used for routine decision-making.

When all easily-obtainable information has been collected, a preliminary report to the risk managers is necessary to advise of any further information that will be needed to complete the picture, or perhaps any additional information that will be necessary to complete a more quantitative analysis. It should also be apparent at this stage whether data are or can be made available to assess each risk reduction strategy and communicating this to the risk managers enables them to assess which risk reduction strategies are worth pursuing in greater depth.

Quantitative risk assessment

Quantitative risk assessment is defined in the OIE *Code* as 'An assessment where the outputs of the risk assessment are expressed numerically'. The purpose of quantitative risk assessment is to numerically evaluate the probability and impact(s) associated with a risk issue. Two principal mathematical approaches are feasible: the most common is to use a Monte Carlo simulation model to describe the risk event (the development of the hazard into an actual impact), together with its uncertainty (lack of knowledge) and variability (inherent randomness); the second method is to use the algebra of probability theory to produce a formulaic model of the risk event. Monte Carlo simulation is almost always preferred over algebraic methods because it is far simpler to execute, particularly with modern software. It offers greater modelling flexibility, is easy to understand, check and explain, and less prone to human error in model development. However, Monte Carlo simulation of rare events can become onerous, in which case a combination of calculating some simpler parts of a risk scenario and simulating the remainder may sometimes prove more efficient.

A quantitative risk assessment produces a mathematical model that estimates the effect of possible risk management actions. It may be desired that any possible action between and including production of the food animal and the final human health effect be evaluated quantitatively. If so, the quantitative risk assessment model must simulate all important microbial pathways between the farm and the exposed human or animal in sufficient detail to evaluate possible changes in the system as a result of a risk management action. For risk management purposes, it may only be necessary to evaluate changes in the human or animal health impact as a result of a risk management action, not the underlying base health risk, although it may be informative to be able to estimate the base health risk for other purposes.

Thus, a full risk assessment model may need to consider a wide range of pathways. For example, *Enterococcus faecium* is a hardy organism that can survive for long periods outside its original host. Feasible pathways may include, for example, runoff from manure lagoons or fields sprayed with manure entering waterways used by swimmers, or the consumption of vegetables that have been grown in fields sprayed with manure. By contrast, these pathways would not be important for *Campylobacter* which succumb rapidly to changes in their environment. Failure to appreciate the range of pathways

could lead to a misevaluation of the effect of some risk management action. For example, irradiation of poultry carcasses may be effective against *Campylobacter* if consumption of meat were to be considered the primary exposure pathway. However, irradiation might prove ineffective for *E. faecium* if the primary exposure pathway was from consumption of raw vegetables.

Microbial food safety risk assessments have for some time attempted to model very similar risk issues to those posed by antimicrobial resistance. A variety of modelling techniques exists for microbial risk assessments, based around the principles of stochastic simulation of risk scenarios (14, 18, 19, 22). Spreadsheet models are generally used together with Monte Carlo simulation add-ins to create simulations of the entire 'farm-to-fork' continuum, finishing with the way in which the consumer is affected by consumption of the bacteria. Other commercially available dynamic simulation applications can achieve much the same effect. There are a variety of formula-based models available from the field of predictive microbiology to estimate the growth and attenuation of various bacteria when exposed for different amounts of time to different environments, particularly level of moisture, temperature and pH. Thus, a quantitative risk assessment combines probability mathematics (11, 17), usually from the binomial and Poisson processes, with empirical curve-fitting equations and sometimes theoretically based formulae from predictive microbiology, to attempt to characterise the exposure events. Microbial food safety models consider the redistribution, growth and attenuation of bacteria during the various actions in slaughtering, processing, food handling and cooking. For example, the microbial load on contaminated carcasses will be reduced drastically through correct handling, removal of the most contaminated parts of the carcass, scalding and washing. In contrast, cross-contamination between carcasses through aerosols, splashing, workers, etc., may mean that the proportion of contaminated carcasses leaving the slaughter plant is greater than the proportion of contaminated animals entering the plant. Much of the modelling principles necessary in antimicrobial resistance risk assessment parallel those used in microbial food safety risk assessment. At the time of writing (November 2000), very few antimicrobial resistance risk assessments have been published (http://www.fda.gov/cvm/fda/mappgs/antitoc.html; 23) but a significant number of microbial food safety risk assessments have been completed which provide practical illustrations of the techniques employed (2, 8; http://www.fsis.usda.gov/ophs/risk/index.htm; http://www.foodriskclearinghouse.umd.edu/risk_assessments.htm; http://www.fsis.usda.gov/OPHS/ecolrisk/home.htm; http://www.nal.usda.gov/fnic/foodborne/risk.htm).

Microbial risk assessments typically use logarithmic scales in estimating the microbial load because of the range of numbers that can be involved and the multiplying nature of bacterial growth and attenuation. Subsequent estimations of the probability of infection, illness or perhaps death from specific exposures are made through dose-response equations to produce a final estimate of the total human health impact. Risk assessments that model the complete microbial pathway from the farm to final ingestion are sometimes called 'farm-to-fork' or 'farm-to-table' risk assessments, though these are potentially misleading terms in cases where significant exposure pathways are associated with ingestion via other means (e.g. consumption of vegetables, ingestion through soil or water, and human-to-human or animal-to-human transmission). A full 'farm-to-fork' model invariably contains a host of potentially contestable assumptions because of the inherent complexity of the system being modelled and the gaps in knowledge of that system. It also relies a great deal on the validity of a dose-response model, the weaknesses of which are well known (21).

In general, a risk assessment model should only be as complex as necessary to evaluate the risk management options available to the regulatory authority, therefore a full 'farm-to-fork' model may not be necessary. For example, the risk assessment completed by the United States Food and Drug Administration Center for Veterinary Medicine (USFDA-CVM) on the human health effect of fluoroquinolone-resistant *Campylobacter* (http://www.fda.gov/cvm/fda/mappgs/antitoc.html) considered only the effect of removal of fluoroquinolone use in poultry. This assessment avoided any modelling of the 'farm-to-fork' pathways. It estimated the number of human cases of campylobacteriosis that would have been affected by the fluoroquinolone-resistance from poultry, to provide an estimate of the current risk. The argument was that removing fluoroquinolone from poultry would have the effect of reducing the human impact by this amount, which was supported by the low survivability of *Campylobacter* outside its host, so resistance would rapidly disappear. The assessment then related this risk to the level of prevalence of fluoroquinolone-resistant *Campylobacter* contaminated broiler carcasses at the end of the slaughter plant. The argument then presented was that changes in that prevalence and/or the load on the contaminated carcasses can be mapped to a corresponding change in the human health impact. The structure of models like this can be used very effectively in other countries, using data appropriate to that country, where similar assumptions would apply.

All parameters in a quantitative risk assessment model must be quantified. The most transparent approach, least likely to attract criticism, is to use published data from peer-reviewed papers. However, such data will frequently not be available and reasonable surrogates may be used in their place, together with supporting arguments for the surrogacy. Expert opinion may also be used, but it is more transparent if any data from which the expert has based his or her opinion can be used in its place (12). Unpublished data from reliable sources may also be used. Regardless of the source, all data used in the risk assessment must be critically reviewed.

A quantitative risk assessment must explicitly model the uncertainty associated with the model parameters using techniques like the bootstrap (5, 6), Bayesian inference (9, 20) and classical statistics (1, 10, 13). Bayesian inference is particularly useful at explicitly stating the contribution arising from observations, interpretation of those observations and any subjective estimation. Bayesian inference also allows the analyst to combine information from different sources, such as two different random surveys of a population for contamination with different test sensitivities and specificities.

The results of the risk assessment are presented as a report to the risk managers, explaining the methods used, characterising the risk in appropriate terms according to policy, together with the benefits of any risk reduction strategies that could be assessed. All quantified terms should be reported with their uncertainties in an easily understandable form. The relative frequency distribution provides an excellent visual representation of the level of uncertainty, whilst cumulative distribution plots allow the risk manager to evaluate the risk at any desired level of confidence. Sensitivity analyses should be performed to determine the key uncertainty parameters of the model and illustrated using techniques such as spider plots and tornado charts. Key assumptions must also be explicitly described, together with a balanced argument of the reasoning for the assumptions and a discussion of the inaccuracy of the predictions of the model should those assumptions be false. This model uncertainty must be keenly analysed, and possible methods of validating assumptions must be considered, perhaps through scientific experiments or comparison with the experience of other nations. Inclusion and discussion of all types of uncertainty in the risk assessment report allow the risk managers to apply the appropriate level of conservatism in valuing the risk and any risk reduction options. It should be emphasised that failure to properly address uncertainty in the risk assessment report equates to an implicit value judgement of the risk that is not the remit of the risk assessor.

Semi-quantitative risk assessment

Semi-quantitative risk assessment is a new term defined as 'An assessment where estimates of the likelihood of the outcome and the magnitude of the consequences are expressed in semi-quantitative terms via some scoring mechanism'. It will frequently not be possible to perform a complete quantitative risk assessment on each item in a portfolio of risk issues facing risk managers because of lack of appropriate data. In such circumstances, it would nonetheless be useful to have a method for comparing the magnitude of risks and the benefits of risk reduction strategies for those risks. Semi-quantitative risk assessment, when properly executed, is a transparent approach that supports the efficient management of a portfolio of risk issues without requiring complete quantification of the risks or excessive risk avoidance. Semi-quantitative risk assessment techniques are commonly used for risk analysis in commercial projects, but are currently not widely accepted in international risk issues because of the difficulty in retaining transparency and because the process is open to abuse without proper guidelines.

The principle of semi-quantitative risk assessment (22) is initially to estimate the probability and size of the potential consequences into broad, but well-defined categories, then convert these estimates using a scoring system to produce a severity score for the risk. Various risk management options can be evaluated according to the degree to which they would reduce the severity score of the risk. The technique has a number of advantages, as follows:

– the risks can be compared in a systematic fashion

– a severity threshold can be set for unacceptable risk

– an efficient and consistent policy framework can be developed which minimises the total severity scores for all risks given the resources available.

Risk communication

As defined in the OIE *Code*, 'Risk communication is the interactive exchange of information on risk among risk assessors, risk managers and other interested parties'. There are many aspects to risk communication. Failure to pay proper attention to risk communication may easily result in failure of the risk analysis process. Both risk managers and risk assessors should be well versed in the concepts of risk analysis. The risk assessors should have a clear understanding of policy. Similarly, the risk managers should be fully conversant with the taxonomy and terminology of risk assessment and appreciate the level of effort and variety of disciplines involved in producing a reliable risk assessment. The goals of risk communication are the following:

– to promote awareness and understanding of the specific issues under consideration during the risk analysis process, by all participants

– to promote consistency and transparency in arriving at and implementing risk management decisions

– to provide a sound basis for understanding the risk management decisions proposed or implemented

– to improve the overall effectiveness and efficiency of the risk analysis process

– to strengthen working relationships and mutual respect among all participants

– to promote the appropriate involvement of all stakeholders in the risk communication process

– to exchange information on the knowledge, attitudes, values, practices and perceptions of stakeholders concerning the risks in question.

Rev. sci. tech. Off. int. Epiz., 20 (3)

The joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Consultation on the application of risk communication to food standards and safety measures, held in 1998 in Rome, provides an in-depth discussion on the subject (7).

Communication between assessors and managers

Management must provide clear instructions for the risk issue that is to be analysed, together with the preferred method(s) of characterisation (e.g. person days of illness per year). Assessors must ensure that the managers have reasonable expectations of the assessment and may also advise of other potential information the assessment may provide that would help the management with their decision-making. There should be communication between the risk assessors and risk managers throughout the assessment process to ensure that the assessment is completed in a timely fashion and that the required resources are made available.

Communication between assessors and stakeholders

It is extremely helpful to widely publicise the intended method of assessment, including model structure and assumptions at the earliest possible opportunity, together with an expression of flexibility in the eventuality of any new information or ideas. This allows stakeholders to provide input, improves transparency of the process and improves support for the assessment and any resultant risk management decision.

Communication between managers and stakeholders

Risk managers will usually need to advise stakeholders of the intention to perform a risk analysis at the beginning of the project. At this stage, communication with stakeholders is an important opportunity to gather political and scientific support for the risk assessment, as well as a data gathering exercise. When the risk assessment has been completed, it is advisable to make the report publicly available with a reasonable comment period to ensure that there are no large errors in the assessment or additional data available. The World Wide Web is an excellent means for maximising the availability of the assessment and may include downloadable, self-contained versions of the risk assessment. Publishing comments received, together with any responses from the risk assessment and risk management teams, underlines the transparency of the process. These can be included in the final risk analysis document that explains the results of the risk assessment together with the risk management decision that has been made.

Recommendations

To effectively manage antimicrobial resistance risk issues, the OIE Ad hoc Group recommends that:

– risk analysis should be conducted in an objective and defensible manner

– the risk analysis process should be transparent and consistent

– risk analysis should be conducted as an iterative and continuous process

– risk management and risk assessment functions should be kept separate to ensure the independence of decision-making and evaluation of the risk

– risk management should be conducted in reference to a policy framework setting out the domain of the regulator and the range of risk reduction actions that may be considered

– the risk assessment should be based on sound science and conducted according to a strategy established by the risk managers in co-operation with the risk assessors

– risk assessment requires a multidisciplinary team and should be conducted in broad consultation with available scientific expertise

– qualitative risk assessment should always be undertaken, and provides information on whether progression to full quantitative risk assessment is feasible and/or necessary

– risk assessment of antimicrobial resistance issues requires very specific, technical skills that may not be available to developing countries. The OIE and its Member Countries should work towards helping these countries to develop or access these skills, to ensure that risk assessment itself does not become a barrier to trade

– communication between managers, assessors and stakeholders is essential. Effort should be made to establish such communication early in the process, to allow opportunity for responses, and should be continued throughout the risk analysis process.

Antibiorésistance : méthodologie d'analyse du risque appliquée à l'impact potentiel sur la santé publique des bactéries d'origine animale résistantes aux antibiotiques

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Résumé

Le Groupe ad hoc d'experts sur l'antibiorésistance créé par l'Office international des épizooties a élaboré une procédure d'analyse du risque à la fois objective, transparente et justifiée, offrant une base valable pour les décisions de gestion du risque relatives à l'antibiorésistance. Les auteurs définissent les éléments constitutifs de l'analyse du risque et les différentes approches possibles de l'évaluation du risque (qualitative, semi-quantitative et quantitative). Les recommandations du Groupe ad hoc portent sur les points suivants : évaluation du risque indépendante basée sur des données scientifiques ; processus itératif d'analyse du risque ; réalisation systématique d'une évaluation qualitative du risque avant toute approche quantitative ; élaboration d'une politique d'évaluation du risque ; enfin, prestation d'une assistance technique pour les pays en développement.

Mots-clés

Analyse du risque – Antibiorésistance – Denrées alimentaires – Évaluation du risque – Gestion du risque – Maîtrise de la résistance – Médecine humaine – Médecine vétérinaire – Normes internationales – Santé publique.

■

Resistencia a los antimicrobianos: metodología de análisis de riesgos para determinar la eventual incidencia en la salud pública de bacterias de origen animal resistentes a los antimicrobianos

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Resumen

El Grupo Ad hoc de expertos sobre la resistencia de las bacterias a los productos antimicrobianos, creado por la Oficina Internacional de Epizootias, ha elaborado un proceso de análisis de riesgos objetivo, transparente y defendible, brindando con ello una sólida base para tomar decisiones de gestión de riesgos ligados a la

Rev. sci. tech. Off. int. Epiz., 20 (3)

resistencia a los antimicrobianos. Los autores exponen los elementos que configuran el análisis de riesgos y los distintos planteamientos que se pueden aplicar (cualitativo, semicuantitativo y cuantitativo). El Grupo Ad hoc recomendó los siguientes procedimientos: una evaluación de riesgos independiente y basada en datos científicos; un proceso iterativo de análisis de riesgos; una evaluación cualitativa sistemática previa a la eventual aplicación de un método cuantitativo; la definición de una política de evaluación de riesgos; y la prestación de asistencia técnica a los países en desarrollo.

Palabras clave
Alimentos – Análisis de riesgos – Contención de las resistencias – Evaluación de riesgos – Gestión de riesgos – Medicina humana – Medicina veterinaria – Normas internacionales – Resistencia a los productos antimicrobianos – Salud pública.

Appendix A

Risk assessment of human health impact due to the use of antimicrobials in animals

The following lists, although not exhaustive, describe factors that may need consideration in a risk assessment of human health impact.

Definition of the risk

The infection of humans with bacteria that have acquired resistance to the use of a specific antimicrobial in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.

Hazard identification

Two types of hazard exist, as follows:

– bacteria that have acquired resistance due to the use of a particular antimicrobial in animals

– resistance determinants selected as a result of the use of a particular antimicrobial in animals.

The identification of the hazard must include considerations on the class or subclass of antimicrobial.

Release assessment

Release assessment consists of describing the biological pathways necessary for the use of a specific antimicrobial in animals to lead to the release of resistant bacteria or resistant determinants into a particular environment, and estimating the probability of that complete process occurring either qualitatively or quantitatively. The release assessment describes the probability of the release of each of the potential hazards under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the release assessment are as follows:

– species of animal treated with the antimicrobial in question

– number of animals treated, geographical distribution of those animals

– variation in methods of administration of the antimicrobial

– bacteria developing resistance as a result of the antimicrobial use

– mechanism of direct or indirect transfer of resistance

– capacity of resistance transfer (chromosomes, plasmids)

– cross-resistance and/or co-resistance with other antimicrobials

– surveillance of animals, animal products and waste products for the existence of resistant bacteria.

Exposure assessment

Exposure assessment consists of describing the biological pathways necessary for exposure of humans to the resistant bacteria or resistance determinants released from a given antimicrobial use in animals, and estimating the probability of the exposures occurring, either qualitatively or quantitatively. The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and the number, species and other characteristics of the human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are as follows:

– human demographics and consumption patterns, including traditions and cultural practices

– prevalence of food and/or the animal environment contaminated with resistant bacteria

– prevalence of animal feed contaminated with resistant bacteria

– microbial load in contaminated food at the point of consumption

– survival capacity and redistribution of resistant bacteria during the agrofood process (including slaughtering, processing, storage, transportation and retailing)

– disposal practices for waste products and the opportunity for human exposure to resistant bacteria or resistance determinants in those waste products

– point of consumption of food derived from the food-producing animal (professional catering, home cooking)

– variation in consumption and food-handling methods of sub-populations

– capacity of resistant bacteria to settle in human intestinal flora

– human-to-human transmission of the bacteria under consideration

– capacity of resistant bacteria to transfer resistance to human commensals

– exposure to resistance determinants from other sources

– amount of antimicrobials used in response to human illness

– dose, route of administration (oral, injection) and duration of human treatment

– pharmacokinetics (metabolism, bioavailability, access to intestinal flora).

Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to resistant bacteria or resistance determinants and the consequences of those exposures. A causal process must be believed to exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative or quantitative. Examples of consequences include the following:

– dose-response relationships

– variation in susceptibility of sub-populations

– variation and frequency of human health effects resulting from loss of efficacy of antimicrobials

– changes in human medicine practices resulting from reduced confidence in antimicrobials

– changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary risks

– associated costs

– interference with a classical first line antibiotherapy in humans

– perceived future of the drug (time reference).

Risk estimation

Risk estimation consists of integrating the results from the release assessment, exposure assessment and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus, risk estimation takes into account the whole of the risk pathway from the hazard identified to the unwanted outcome. For a quantitative assessment, the final outputs may include the following:

– number of people falling ill

– increased severity or duration of disease

– number of person/days of illness per year

– deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population)

– importance of the pathology caused by the bacteria

– absence of alternate antibiotherapy

– level of resistance observed in humans

– some arbitrary scale of impact to allow weighted summation of different risk impacts (e.g. illness and hospitalisation).

Risk management options to evaluate

The following risk management measures could be implemented:

– decision not to grant a licence for use of a new antimicrobial

– review of licence authorisation and label indications

– revoking of licence

– restrict use of antimicrobial (e.g. in particular industries, therapeutic only)

– review of prudent use guidelines

– establish monitoring of veterinary use of antimicrobials

– revision of treatment guidelines.

Appendix B

Risk assessment of impact on animal health due to the use of antimicrobials in animals

The following lists, though not exhaustive, describe factors that may need consideration in a risk assessment of animal health impact.

Definition of the risk

The infection of animals with bacteria that have gained resistance from the use of a specific antimicrobial in animals, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal infection.

Rev. sci. tech. Off. int. Epiz., 20 (3)

Hazard identification

Possible hazards are as follows:

– bacteria that have acquired resistance due to the use of a particular antimicrobial in animals

– resistance determinants selected as a result of the use of a particular antimicrobial in animals.

The identification of the hazard must include consideration of the class or subclass of antimicrobial.

Release assessment

Examples of the type of inputs that may be required in the release assessment are as follows:

– species of animal treated with the antimicrobial in question

– number of animals treated, geographical distribution of those animals

– variation in methods of administration of the antimicrobial

– bacteria developing resistance as a result of the antimicrobial use

– mechanism of direct or indirect transfer of resistance

– capacity of resistance transfer (chromosomes, plasmids)

– cross-resistance and/or co-resistance with other antimicrobials

– surveillance of animals, animal products and waste products for the existence of resistant bacteria.

Exposure assessment

The following are examples of the type of inputs that may be required in the exposure assessment:

– prevalence of resistant bacteria in ill animals

– prevalence of food and/or the animal environment contaminated with resistant bacteria

– animal-to-animal transmission of the bacteria under consideration

– number/percentage of animals treated with the particular antimicrobial

– dissemination of resistant bacteria from animals (animal husbandry method, movement of animals)

– prevalence of animal feed contaminated with resistant bacteria

– amount of antimicrobial used in animals

– treatment (dose, route of administration, duration)

– microbial load in contaminated food at point of consumption

– survival capacity of resistant bacteria (competition of mixed populations, survival in the environment, contamination cycles including potentially the following elements: animals, humans, animal feed, environment, food, non-food producing animals, wildlife)

– dissemination of resistant bacteria and resistance determinants

– disposal practices for waste products and the opportunity for human exposure to resistant bacteria or resistance determinants in those waste products

– capacity of resistant bacteria to become established in animal intestinal flora

– exposure to resistance determinants from other sources

– dose, route of administration (oral, injection) and duration of human treatment

– pharmacokinetics (metabolism, bioavailability, access to intestinal flora).

Consequence assessment

Examples of consequences include the following:

– dose-response relationships

– variation in susceptibility of sub-populations

– variation and frequency of animal health effects resulting from loss of efficacy of antimicrobials

– changes in veterinary medicine practices resulting from reduced confidence in antimicrobials

– associated costs

– perceived future of the drug (time reference).

Risk estimation

For a quantitative assessment, the final outputs may include the following:

– number of therapeutic failures due to resistant bacteria

– animal suffering (level and increase)

– economic cost (treatment with antibiotics, veterinary services, husbandry, reduced income, loss of market)

– deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population)

– level of resistance observed in animals.

Risk management options to evaluate

The following risk management measures could be implemented:

– decision not to grant a licence for use of a new antimicrobial

– review of licence authorisation and label indications

– revoking of licence for antimicrobials already used

– restrict use of antimicrobial (e.g. in particular industries, therapeutic only)

– review of prudent use guidelines

– establish monitoring of veterinary use of antimicrobials

– revision of treatment guidelines.

Appendix C

Comparison of systems and terms used by the Codex Alimentarius and the Office International des Epizooties

The terms used in this document comply with the OIE terminology, as defined in Section 1.4. of the *Code* (16) based on the Covello-Merkhofer system (4). The Codex Alimentarius (3) uses a different, but equally valid system, designed by the US NAS (15). The issue of antimicrobial resistance arising from the use of antimicrobials in food-producing animals bridges the domain of OIE for animal husbandry and that of the FAO for food safety. It is therefore useful to compare these two systems and define terms used in this paper, to help integrate the two approaches.

Two risk analysis terminology systems: description

Table I summarises the components of risk analysis in the OIE and Codex models.

Table I
The components of risk analysis: a comparison of the systems used by the Codex Alimentarius and the Office International des Epizooties (OIE)

Components of risk analysis system	
Codex Alimentarius	**OIE**
Risk assessment	Hazard identification
Risk management	Risk assessment
Risk communication	Risk management
	Risk communication

Table II summarises the components of risk assessment in the OIE and Codex models.

Table II
The components of risk assessment: a comparison of the United States National Academy of Science model (used by the Codex Alimentarius) and the Covello-Merkhofer model (used by the Office International des Epizooties [OIE])

Components of risk assessment model	
Codex Alimentarius	**OIE**
Hazard identification	Risk release assessment
Hazard characterisation	Exposure assessment
Exposure assessment	Consequence assessment
Risk characterisation	Risk estimate

In a system based on the NAS model (called the 'Codex system' here), there are only three components of risk analysis, whereas in the system based on the Covello-Merkhofer model (called the 'OIE system' here), four components are present. Both systems include risk assessment, risk management and risk communication as components of risk analysis. However, the OIE system also includes hazard identification as a component of risk analysis, whereas the Codex system includes hazard identification as a sub-component of risk assessment. The terms risk management and risk communication are equivalent under both systems.

The NAS system was initially developed to assess the risks to health from exposure to chemicals. Codex has adapted this system for food safety purposes. The Covello-Merkhofer system was initially developed to assess a wide range of risks from any potential hazard. The specific wording of the explanations in Table III reflects those differences.

The first difference centres around the place of hazard identification in the models. The initial report of the NAS model (15), describes hazard identification as a major undertaking. The definition relates specifically to chemicals, and even in this case, NAS indicates that it includes weighing the available evidence relevant to cause and effect, as well as evidence relating to the magnitude of effect for the specified chemical. It is essentially a qualitative process of considerable magnitude. Given the number of potential pathogen hazards present in animals and animal products, the OIE risk analysis system, with a separate hazard identification step, is more adapted to pathogenic risk management.

The second difference is the presence in the OIE system of a step called release assessment, absent in the Codex system. Covello and Merkhofer argue that this is necessary for describing the probability of a given system (e.g. an industrial complex, a meat processing plant or another risk source) to release risk agents into the environment of interest. They believe this to be an essential step in obtaining an accurate understanding of risk. From a practical standpoint, this is an essential explicit step either to assess the risks due to a particular hazard from a specific source or process, or to undertake a cost-benefit analysis of putting in place release reduction safeguards for that source or process.

'Release' comes before the possibility of exposure in actual exposure events. Thus, the Covello-Merkofer system follows release assessment by assessing the probability of exposure for each potential exposure route of interest. The third difference between the models is that the NAS system places exposure assessment after the dose response (hazard characterisation) step. The precise definitions are also slightly different.

The fourth difference is in the place and meaning of consequences in the two models. Exposure can then lead to consequences – unwanted consequences when considering a hazard. Thus, the Covello-Merkhofer system places consequence assessment after exposure assessment, and defines it broadly (any consequences that can occur can be considered, and their probability assessed). However, the NAS system looks only at the consequences of variation in dose of the chemical being considered (i.e. a dose-response assessment, also called hazard characterisation).

Table III
Definition of risk analysis terms: a comparison of the systems used by the Codex Alimentarius and the Office International des Epizooties

Term	Office International des Epizooties definition or equivalent	Codex Alimentarius definition or equivalent
Acceptable risk	Risk level judged by Member Countries to be compatible with the protection of animal and public health within their country	No equivalent defined
Consequence assessment	Description of the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of these consequences occurring. This estimate may be either qualitative or quantitative	Codex equivalent: dose-response assessment
Dose-response assessment	OIE equivalent: consequence assessment	The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response) — see 'hazard characterisation'
Exposure assessment	Describing the biological pathways necessary for exposure of animals and humans to the hazards released from a given source, and estimating the probability of the exposure occurring, either qualitatively or quantitatively	The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant
Hazard	In the context of the *Code*, any pathogenic agent that could produce adverse consequences on the importation of a commodity	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect
Hazard characterisation	Embodied in the 'consequence assessment' in the OIE system	The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable
Hazard identification	The process of identifying the pathogenic agents which could potentially be introduced to the commodity considered for importation	The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods
Implementation	The process of following through with the risk management decision and ensuring that the risk management measures are in place	No equivalent defined
Monitoring and review	The ongoing process by which the risk management measures are continually audited to ensure that they are achieving the results intended	No equivalent defined
Option evaluation	The process of identifying, evaluating the efficiency and feasibility of, and selecting measures in order to reduce the risk associated with an importation in line with the appropriate level of protection of the Member Country. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse biological and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options	No equivalent defined
Qualitative risk assessment	An assessment in which the outputs on the likelihood of the outcome or the magnitude of the consequence are expressed in qualitative terms such as high, medium, low or negligible	No equivalent defined
Quantitative risk assessment	An assessment in which the outputs of the risk assessment are expressed numerically	No equivalent defined
Release assessment	Description of the biological pathways necessary for the use of an antimicrobial in animals to release resistant bacteria or resistance determinants into a particular environment, and estimation of the probability of that complete process occurring, either qualitatively or quantitatively.	No equivalent defined
Risk	The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time period	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food

Table III (contd)

Term	Office International des Epizooties definition or equivalent	Codex Alimentarius definition or equivalent
Risk analysis	The process composed of hazard identification, risk assessment, risk management and risk communication	A process consisting of three components: risk assessment, risk management and risk communication
Risk assessment	The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an importing country	A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment and (iv) risk characterisation
Risk characterisation	OIE equivalent: risk estimation	The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment
Risk communication	Risk communication is the interactive exchange of information on risk among risk assessors, risk managers and other interested parties	The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions
Risk estimation	Integration of the results from the release assessment, exposure assessment and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus, risk estimation takes into account the entire risk pathway from the hazard identified to the unwanted outcome	Codex equivalent: risk characterisation
Risk evaluation	The process of comparing the risk estimate in the risk assessment with the appropriate level of protection of the Member Country	Embodied in 'risk management' in the Codex system
Risk management	The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk	The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed, selecting appropriate prevention and control options
Sensitivity analysis	The process of examining the impact of the variation in individual model inputs on the model outputs in a quantitative risk assessment	No equivalent defined
Transparency	Comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced	No equivalent defined
Uncertainty	The lack of precise knowledge of the input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the scenario being assessed	No equivalent defined
Variability	A real-world complexity in which the value of an input is not the same for each case due to natural diversity in a given population	No equivalent defined

Table IV
Definition of new terms introduced in this document

Term	Definition
Risk management policy	The regulatory policy framework for the monitoring, measuring, assessing and managing of risks involved in the use of antimicrobials in food-producing animals
Semi-quantitative risk assessment	An assessment where estimates of the likelihood of the outcome and the magnitude of the consequences are expressed in semi-quantitative terms via a scoring mechanism

References

1. Casella G. & Berger R.L. (1990). – Statistical inference. Brooks/Cole Publishing Company, Pacific Grove, California, 650 pp.
2. Cassin M.H., Lammerding A.M., Todd E.C.D., Ross W. & McColl R.S. (1998). – Quantitative risk assessment for *Escherichia coli* O157:H7 in ground beef hamburgers. *Int. J. Food Microbiol.*, **41** (1), 21-41.
3. Codex Alimentarius Commission (Codex) (1999). – Principles and guidelines for the conduct of microbiological risk assessment, CAC/GL-30. Food and Agriculture Organization, Rome, 6 pp. Website: ftp://ftp.fao.org/codex/standard/volume1b/en/GL_030e.pdf (document accessed on 13 September 2001).
4. Covello V.T. & Merkhofer M.W. (1993). – Risk assessment methods: approaches for assessing health and environmental risks. Plenum Press, New York and London, 334 pp.
5. Davison A.C. & Hinkley D.V. (1997). – Bootstrap methods and their applications. Cambridge University Press, Cambridge, 582 pp.
6. Efron B. & Tibshirani R.J. (1993). – An introduction to the bootstrap. Chapman & Hall, New York, 436 pp.
7. Food and Agriculture Organization (FAO) (1998). – The application of risk communication to food standards and safety matters. Food and Nutrition Paper No. 70. Report of a Joint FAO/World Health Organization Expert Consultation. FAO, Rome, 46 pp.
8. Food and Agriculture Organization (FAO) (2000). – Joint FAO/WHO Expert Consultation on risk assessment of microbiological hazards in foods. Food and Nutrition Paper No. 71. FAO, Rome, 54 pp.
9. Gelman A., Carlin J.B., Stern H.S. & Rubin D.B. (1995). – Bayesian data analysis. Chapman & Hall, London, 526 pp.
10. Groebner D.E. & Shannon P.F. (1993). – Business statistics: a decision-making approach. Macmillan, New York, 1,119 pp.
11. Jeffreys H. (1961). – Theory of probability, 3rd Ed. Oxford University Press, Oxford, 470 pp.
12. Kaplan S. (1999). – Beyond the domain of direct observation: how to specify a probability distribution that represents the state of knowledge about uncertain inputs. *Risk Analysis*, **19**, 131-134.
13. Levin R.I. & Rubin D.S. (1994). – Statistics for management. Prentice Hall, New Jersey, 1,024 pp.
14. Morgan M.G. & Henrion M. (1990). – Uncertainty: a guide to dealing with uncertainty in quantitative risk and policy analysis. Cambridge University Press, New York, 332 pp.
15. National Academy of Sciences National Research Council (NAS-NRC) (1983). – Risk assessment in the Federal Government: managing the process. NAS-NRC Committee on the Institutional Means for the Assessment of Risks to Public Health. National Academy Press, Washington, DC, 191 pp.
16. Office International des Epizooties (OIE) (1999). – International animal health code: mammals, birds and bees, 8th Ed. OIE, Paris, 468 pp.
17. Olkin I., Glaser L.J. & Derman C. (1980). – Probability models and applications. Macmillan, New York.
18. Ripley B.D. (1987). – Stochastic simulation. Wiley, New York, 252 pp.
19. Rubinstein R. (1981). – Simulation and Monte Carlo methods. Wiley, New York, 278 pp.
20. Sivia D.S. (1996). – Data analysis: a Bayesian tutorial. Oxford University Press, Oxford, 189 pp.
21. Teunis P.S.N. & Havelaar A.H. (2000). – The beta Poisson dose-response model is not a single-hit model. *Risk Analysis*, **2** (4), 513-520.
22. Vose D. (2000). – Risk analysis: a quantitative guide. Wiley, Chichester, 418 pp.
23. Wooldridge M. (1999). – Risk assessment report: qualitative risk assessment for antibiotic resistance. Case study: *Salmonella* Typhimurium and quinolone/fluoroquinolone class of antimicrobials. Annex IV. *In* Antibiotic resistance in the European Union associated with the therapeutic use of veterinary medicines: report and qualitative risk assessment by the Committee for Veterinary Medicinal Products, 14 July 1999. European Agency for the Evaluation of Medicinal Products, London, 41 pp.

Appendix X

Original: English
February 2012

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF HONEY BEES

Paris, 31 January – 2 February 2012

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1. Opening and purpose of the meeting

The OIE *ad hoc* Group on Diseases of Honey Bees met from 31 January to 2 February 2012 at the OIE Headquarters in Paris, France. The participants were welcomed by Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department, on behalf of Dr Bernard Vallat, Director General of the OIE. Dr Miyagishima introduced to the Group the new requirements under the Basic Texts of the OIE concerning the obligation for experts participating in *ad hoc* Group meetings to fill in and sign an undertaking of confidentiality and a declaration of interest.

2. Designation of chairperson and rapporteur

The meeting was chaired by Dr Wolfgang Ritter and Dr Howard Pharo acted as rapporteur.

3. Adoption of the Agenda and Terms of Reference

The adopted Agenda and Terms of Reference, and the List of Participants, are presented in Appendices I, II and III of this report, respectively.

4. Review of and reply to the technical comments received from OIE Member Countries on the proposed updated versions of the honey bee disease chapters for the *Terrestrial Code*

Chapter 4.14. on Official Health Control of Bee Diseases

The comments received from OIE Member Countries by the OIE Headquarters in January 2012 were reviewed and taken into consideration in the proposed updated version of Chapter 4.14.

With regards to the article 4.14.3. *Official registration of the apiaries by the Veterinary Authority in the whole country*, the Group proposed, based on the comments received from some Member Countries, a text less detailed and therefore more flexible for its application.

With regards to the article 4.14.4., *Organisation for permanent official sanitary surveillance of apiaries*, the Group made changes, based on the comments received from some Member Countries, to clarify the text. However the Group agreed to maintain the three bullet points as they described what should be the general responsibilities of official surveillance service.

General Comments on the disease-specific chapters

The Group reviewed all the comments received from Member Countries on the disease-specific chapters of the *Terrestrial Code* related to bees. Changes were proposed taking into account these comments and with the aim of maintaining consistency among the different chapters.

Regarding point 2 (free status as a result of an eradication programme) of the generic article 9.X.4. on country or zone free from a pest in each of the disease-specific chapters, the Group was conscious that for most of the bee diseases (in particular small hive beetle infestation, *Tropilaelaps* infestation and varroosis), it would be practically impossible for Member Countries to achieve free status owing to the fact that these diseases were

almost impossible to eradicate once established in a country (see also the report of the meeting of the Group in July 2011). However, because eradication might be possible in certain zones (islands, oases or in northern countries outside the natural range of bees), the Group agreed to keep this article even if the recovery from an incursion/outbreak would be very difficult in most cases. Regarding the requirement in point 2, that there is no wild or self-sustaining feral population of bees of the genus *Apis*, the Group recognised that it was impossible to apply this requirement in certain countries. However, with wild or feral populations, a country could not be considered as free because it was impossible to control the contact between domesticated and wild/feral bees. Therefore the Group proposed an alternative: the ongoing surveillance in wild and feral populations of species of bees of the genus *Apis*.

In the proposed procedures for the treatment of some commodities, the Group decided, based on a comment, to harmonise in all the chapters the treatment by freezing and proposed that freezing be at –12°C for 24 hours. The Group was able to find on Internet a number of documents where –12°C was mentioned as the standard, but no primary reference could be found specifying that –12°C was necessary (rather than –4°C or –15°C for example). However, the Group noted that –12°C was one of several industrial standards for freezing.

In reply to a comment requesting the reason for the different levels of irradiation treatment in Chapters 9.4. to 9.6., the Group indicated that these treatments were based on recommendations developed by the International Plant Protection Convention (IPPC): IPPC (2003) Guidelines for the use of irradiation as a phytosanitary measure, FAO, Rome, Publication No. 18. April 2003.

New procedures were proposed by Member Countries in addition to or in replacement of some already mentioned treatments. However these new proposals were not supported by validation or peer-rewieved publications, and thus the Group found it difficult to accept such proposals. Following intensive discussion on the best approach to allowing for new procedures to be used or included in these disease-specific chapters, the Group proposed to keep the examples already mentioned and to add, as an alternative, the possibility to use a procedure that has been accepted both by Veterinary Authorities of the importing and exporting countries.

Chapter 9.1. on Infestation of honey bees with *Acarapis woodi*

The comments received from OIE Member Countries by the OIE Headquarters in January 2012 were reviewed and taken into consideration in the proposed updated version of Chapter 9.1.

Chapter 9.2. on American foulbrood (AFB) of honey bees

The comments received from OIE Member Countries by the OIE Headquarters in June 2011 were reviewed and taken into consideration in the proposed updated version of Chapter 9.2.

The Group discussed the important distinction between infection and disease, and noted that infection with *P. larvae* at low levels was more or less ubiquitous, whereas AFB was a clinical syndrome that was seen only when the organism reached a certain level of spores in colonies.

With regards to the safe commodities, the Group agreed with the comments requesting to include eggs in the safe commodities and amended the articles 9.2.2. and 9.2.6. accordingly.

With regards to Article 9.2.5. *Recommendations for the importation of live queen , worker and drones honey bees with or without associated brood combs*, the recommendations proposed were based on the fact that the export process ensured that the level of spores in the bees' guts was negligible by the time of export – even if bees were shook swarm from a hive with a high level of AFB, the majority of spores would be in the bees' crop, and after a few days in quarantine their crop contents would have been used up as they would be fed with a clean food source; the number of spores on the exterior surface of the bees was relatively low, which was why they pose a negligible risk.

In follow-up to the second meeting and for consistency between the different disease specific chapters, the Group proposed procedures for the part of the chapter referring to "procedures recommended by the OIE" (under study).

With regards to Article 9.2.8. *Recommendation for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for use in apiculture*, as direct feeding of imported honey to bees will result in outbreaks of clinical AFB, the Group considered that measures applied to honey imported for use in apiculture were justified, even in countries that were not free, but where there was an official control

programme. The Group agreed that these commodities posed a negligible risk when they were for human consumption. However, for a free country this risk might be unacceptable. The Group therefore developed Article 9.2.9. *Recommendation for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly for human consumption*, to be applied only by the importing countries free from AFB.

Chapter 9.3. on European foulbrood (EFB) of honey bees

The comments received from OIE Member Countries by the OIE Headquarters in June 2011 were reviewed and taken into consideration in the proposed updated version of Chapter 9.3.

The approach was the same as for AFB. The only difference was in Articles 3 and 4 of each chapter. For EFB, the Group noted a need to have field and laboratory investigations in case of any clinical cases suggestive of the disease because clinical signs are not pathognomonic.

Chapter 9.4. on Infestation with *Aethina tumida*

The comments received from OIE Member Countries by OIE Headquarters in January 2012 were reviewed and taken into consideration in the proposed updated version of Chapter 9.4.

As safe commodities, the Group included extracted and filtered honey (at a level allowing the prevention of larvae, but not to the removal of pollen). However the Group did not refer to a minimum filter size suitable for SHB larvae as there was no standard on this.

In a reply to a comment mentioning that adult SHB can be introduced via imports of refined or rendered beeswax, the Group was of opinion that this commodity was safe as such. However the Group pointed out that reinfestation of or hitchhiking through commodities by SHB was possible with many different commodities including beeswax.

For Article 9.4.4., the Group decided not to include the sub-item on the wild and feral populations of bees as this was not necessary for the SHB chapter given that the sensitivity of surveillance of managed honey bees for a period of 5 years was adequate (the first host of SHB being honey bees) and the added value of surveillance of wild/feral honey bees or other bees, such as stingless bees, would be minimal.

For the same article and in a reply to a comment pointing out the difficulty of establishing SHB infestation at low infestation levels, the Group agreed that the clinical signs might be very difficult to detect at low infestation levels, but that a recent article had proved that it was possible (Schaefer, M., Pettis, J.S., Ritter, W., Neumann, P. 2008. A scientific note on quantitative diagnosis of small hive beetles, *Aethina tumida*, in the field. Apidologie. 39:564-565)

Regarding the recommendations for importation, comments from a Member Country suggested that some proposed requirements would not prevent the introduction of SHB in a free country. The Group pointed out that the requirements should not be seen as stand-alone requirement and that, when all the stated requirements were applied by the Veterinary Authority of the exporting country, this would ensure a high level of confidence.

Chapter 9.5. on Infestation of honey bees with *Tropilaelaps* spp.

The comments received from OIE Member Countries by OIE Headquarters in January 2012 were reviewed and taken into consideration in the proposed updated version of Chapter 9.5.

With regards to Article 9.5.5., a comment had been received on the difficulty to keep honey bees isolated for 21 days. The Group was of opinion that even if it was challenging, it was technically feasible and therefore agreed to keep an isolation period of 21 days which was providing a safety margin.

Chapter 9.6. on Infestation of honey bees with *Varroa* spp.

The comments received from OIE Member Countries by OIE Headquarters in January 2012 were reviewed and taken into consideration in the proposed updated version of Chapter 9.6.

The Group highlighted that, even if *varroa destructor* had almost a global distribution, certain locations such as remote islands, oases or countries located in the far north beyond the natural zone for honey bees could be free of *varroa destructor*. Therefore requirements related to this disease for the importation of honey bees or

bee products were still useful. In reply to a comment indicating the need to consider in the chapter other species of the genus *Varroa* that could become significant in the future, the Group expressed the view that this was already recognised in the title of the chapter and in the general provision where a reference was made to *Varroa* spp. and not only to *Varroa destructor*.

In reply to a comment asking for the reason why there were differences in the requirements between the chapter on *Tropilaelaps* spp. and the chapter on *Varroa* spp. knowing that both mites had the same transmission routes, the Group considered that these differences were justified as in fact there were important differences between the two mites and their routes of transmission. Infestation with *Tropilaelaps* could easily be managed by an isolation period of 21 days because even under the most favorable conditions the parasite would not survive longer than 21 days without brood while *varroa* parasite could survive a longer period.

5. Revision of the relevant parts of Chapter 5.10. Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

The Group reviewed Chapter 5.10. and in particular Article 5.10.4. and 5.10.5., which were relevant for bees. The Group considered that there was no need for revision of the certificates. Though it was noted that there was no model certificate for the equipment used in apiculture, the Group was of the opinion that for this commodity the model described in Article 5.10.4. "Model of veterinary certificate for international trade in products of animal origin" might be used.

6. Preparation of a general introductory text, to be considered by the Code Commission, to precede the disease-specific chapters of the *Terrestrial Code*

The Group developed a draft document but owing to time constraints, it did not have time to finalise it. The Group proposed to further develop it by correspondence with a view to finalising it at a future meeting.

7. Other matter

The Group proposed a further meeting in 2012 to finalise the draft general introductory paper, to review the OIE listed diseases of bees based on the new criteria (if adopted at the next General Session) and to reply, if needed, to any comments on the proposed revised version of the disease-specific chapters of the *Terrestrial Code* related to bees.

…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF HONEY BEES

Paris, 31 January – 2 February 2012

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Agenda

1. Opening
2. Designation of chairperson and rapporteur
3. Adoption of the agenda
4. Review of and reply to the technical comments received from OIE Member Countries on the proposed updated versions of the honey bee disease chapters for the *Terrestrial Code;*
5. Revision of the relevant parts of Chapter 5.10. Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin;
6. Preparation of a general introductory text, to be considered by the Code Commission, to precede the disease-specific chapters of the *Terrestrial Code*.
7. Other matters
8. Adoption of the report

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF HONEY BEES

Paris, 31 January–2 February 2012

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Terms of Reference

- Review and address OIE Members' comments received following the updates of the chapters of the *Terrestrial Code* related to honey bees:

    i. Chapter 4.14. Hygiene and disease security procedures in apiaries,

    ii. Chapter 9.1. Acarapisosis of honey bees,

    iii. Chapter 9.6. Varroosis of Honey bees,

    iv. Chapter 9.5. *Tropilaelaps* infestation of honey bees,

    v. Chapter 9.4. Small hive beetle infestation (*Aethina tumida*),

    vi. Chapter 9.2. American foulbrood of honey bees,

    vii. Chapter 9.3. European foulbrood of honey bees.

- Review and update if necessary the relevant part of Chapter 5.10. Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin

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Appendix III

MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF HONEY BEES

Paris, 31 January–2 February 2012

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List of Participants

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Appendix XI

Original: English
February 2012

MEETING OF THE OIE *AD HOC* GROUP ON THE EMERGENCE OF A NEW ORTHOBUNYAVIRUS IN EUROPE (PROVISIONALLY NAMED 'SCHMALLENBERG VIRUS')

Paris, 9 February 2012

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1. Opening

A meeting of the OIE *ad hoc* Group on the emergence of a new Orthobunyavirus in Europe (provisionally named 'Schmallenberg virus') (hereafter the Group) was held at the OIE Headquarters, Paris, on 9 February 2012. Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department, welcomed the Group on behalf of Dr Bernard Vallat, Director General of the OIE and thanked the experts to have accepted to join the meeting in so short a notice. The experts and observers had been chosen from the countries that had experience in recent disease outbreaks.

Dr Miyagishima reminded the component of the OIE mandate to promote safe trade in live animals and animal products and thus to provide science-based recommendations to its Member Countries. The recommendations from the OIE were globally well respected and constituted international points of reference. Following the emergence of Schmallenberg virus in Europe, some Member Countries had already taken provisional trade-restrictive measures. In this context, the OIE decided to convene this meeting to review the current knowledge while being aware that the available information was yet limited and more evidence would become available in coming months.

Dr Miyagishima informed the participants that the report of the Group would be presented to the Scientific Commission for Animal Diseases (the Scientific Commission) for endorsement and emphasized the importance of the work of the Group as the basis of the future OIE recommendations. The Group was requested to document the reasons for recommendations and associate them with degree of uncertainty in order to facilitate the Member Countries understanding and interpretation.

Dr Miyagishima reminded the Group that if more scientific information became available and the need review recommendations arose, the OIE would be willing to consider convening additional meeting of the Group in the future.

2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group was chaired by Dr Martin Beer and Ir Brigitte Cay acted as rapporteur. The Group endorsed the proposed agenda.

The Agenda and list of participants are presented as Appendices I and II of this report, respectively.

3. OIE Factsheet on Schmallenberg virus

On the basis of a draft document prepared by the secretariat, the Group produced an OIE Factsheet according to the most update knowledge on Schmallenberg virus and similar viruses. In its work, the Group took into account the most relevant published and unpublished information that was available to the meeting. The resulting document is presented as Appendix III.

4. Recent findings regarding Schmallenberg virus (clinical signs, virology, epidemiology, diagnostic tools, vectors…)

The Group was satisfied that the current knowledge was reflected in the updated OIE Factsheet the Group produced. Nevertheless the following areas of priority were identified for further research and data collection:

- Virology:
  - Further classification of the virus in comparison with other Simbu sero-group viruses.
  - Better understanding of the mechanism of virulence - pathogenesis.
  - Virus cycle in hosts and vectors
  - Determination of infectious materials for virus transmission (including milk, embryo, semen)
- Immunology:
  - protection of naturally infected animals
  - innate immunity/acquired immunity
- Diagnostic:
  - ELISA for mass screening
  - Selection of the most suitable diagnostic material
- Epidemiology:
  - identification of relevant vectors,
  - role of vectors and transmission routes,
  - role of semen and embryos in transmission
  - role of viraemic newborns,
  - sero-prevalence studies and incubation period
  - intervention and control strategies
- Pathogenesis:
  - infection experiments with pregnant cows, sheep and goats,
  - acute infection in small ruminants
- Vaccine development
- Risk assessment for zoonotic transmission

5. Risk assessment and possible guidance on the potential spread of the disease through trade of live animals, semen, embryos, meat and milk

The Group considered that the risk for human health was negligible according to the current knowledge.

Regarding the risk of transmission to animals, and from the current knowledge, the Group came to the following conclusions relying on validated and suitable assays for serology and on the nature of the acquired immunity of previously infected animals:

Meat:

Relevant knowledge: Only clinically healthy animals are slaughtered. The viraemic period is very short. Transmission of the virus is most likely by vectors.

Risk of transmission to humans and animals: negligible

Milk:

Relevant knowledge: Milk is only collected from clinically healthy animals. The viraemic period is very short. Transmission of the virus is most likely by vectors.

Risk of transmission to humans and animals: negligible

Semen:

Relevant knowledge: The viraemic period is very short. Semen is collected from clinically healthy animals. From 8 bulls experimentally infected with Akabane virus, virus was not found in semen even during the viraemic period (*Experimental infection of bulls with Akabane virus*, Parsonson IM, Della-Porta AJ, Snowdon WA, O'Halloran ML, Res Vet Sci. 1981 Sep;31(2):157-60.). From other vector-borne diseases like bluetongue, it is known that transmission through semen, collected from viraemic animals, is possible.

Risk of transmission to animals: Negligible for sero-negative bulls. Further experiments are needed.

Recommendation: according to the current knowledge, the risk is probably lower than the risk for bluetongue and the recommendation similar to the one for bluetongue should therefore provide sufficient assurance of safety for semen, taking into consideration a much shorter infective period of Schmallenberg virus.

Embryos:

Relevant knowledge: The viraemic period is very short. Embryos are collected from clinically healthy animals. Akabane virus is classified under the category 4 (diseases or pathogenic agents for which studies have been done or are in progress that indicate that either no conclusions are yet possible with regard to the level of transmission risk; or the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled between collection and transfer). Schmallenberg virus is known to have a tropism for embryos and foetuses.

Recommendation: According to its virology, safety measures applicable to Akabane virus should be followed. With further research, the measures should be reviewed and specified.

Risk of transmission: according to the current knowledge, the risk from sero-negative donor animals is negligible. These animals should stay sero-negative 21 days after the collection.
Sero-positive and PCR-negative donor animals at the day of insemination should be also considered with negligible risk.

Live adult non-pregnant animals:

Relevant knowledge: The viraemic period is very short. Mild clinical signs might occur. Transmission is most likely by vectors.

Recommendation: the measures taken should be similar to those for bluetongue, taking into consideration a much shorter infective period.

Risk of transmission: negligible for the following animals according to the current knowledge related to the limited data available. All measures are aimed to allow a reasonable but high safety margin. All measures have to be carefully reviewed when more data will be available.

- Sero-negative twice in quarantine (within 28 days) or,
- Sero-positive twice with an interval of 14 days or,
- PCR-negative after 7 days in a vector-free environment or,
- Sero-positive and PCR-negative.

Live pregnant animals:

Relevant knowledge: The virus can persist in the foetus; this can result in the birth of virus positive calves, lambs and kids. Some pre-colostral calves are sero-positive. The vectors are unknown yet and the relevant pregnancy time to induce viraemic newborns is not exactly known.

Risk of transmission:

- Negligible for the offspring of sero-negative animals tested twice in quarantine (within 28 days),
- Negligible for the offspring of animals sero-positive before insemination,
- Undetermined for the offspring of all animals not covered by the previous bullets.

Recommendation: It is urgently needed to collect more data about the relevant infection periods inducing viraemic newborn.

Live newborns:

Relevant knowledge: to the available knowledge, no viraemic healthy newborn was reported, all viraemic live newborns were malformed or had health problems.

Risk of transmission: to the available knowledge, the risk of transmission from healthy newborns is hypothetic.

Recommendation: A study to evaluate the potential existence of viraemic healthy newborn is needed.

6. Adoption of report

The Group reviewed and amended the preliminary draft report provided by the rapporteur.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP
ON THE EMERGENCE OF A NEW ORTHOBUNYAVIRUS IN EUROPE
(PROVISIONALLY NAMED 'SCHMALLENBERG VIRUS')

Paris, 9 February 2012

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Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. OIE factsheet on Schmallenberg virus
4. Recent findings regarding Schmallenberg virus (clinical signs, virology, epidemiology, diagnostic tools, vectors…)
5. Risk assessment and possible guidance on the potential spread of the disease through trade of live animals, semen, embryos, meat and milk
6. Adoption of report

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP
ON THE EMERGENCE OF A NEW ORTHOBUNYAVIRUS IN EUROPE
(PROVISIONNALLY NAMED 'SCHMALLENBERG VIRUS')
Paris, 9 February 2012

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Appendix III

SCHMALLENBERG VIRUS

Aetiology | Epidemiology | Diagnosis | Prevention and Control | References

Schmallenberg virus was discovered recently (November 2011) and epidemiological, immunological and microbiological investigations are still on-going in several European countries. The information presented in this technical disease card describes the epidemiological observations and research done during the first months following its discovery, and data extrapolated from genetically similar viruses of the same genus and serogroup.

AETIOLOGY

Classification of the causative agent

The provisionally named "Schmallenberg virus" is an enveloped, negative-sense, segmented, single-stranded RNA virus. It belongs to the *Bunyaviridae* family, within the *Orthobunyavirus* genus. The Schmallenberg virus is related to the Simbu serogroup viruses, in particular Shamonda, Akabane, and Aino virus. So far, sequence data suggests the closest relationship to Shamonda virus. This classification has to be confirmed with further sequence data and investigations e.g. about the serological relationship to other Simbu sero-group viruses.

Even though the exact role of Schmallenberg virus needs to be further investigated, first inoculation experiments as well as the diagnostic data from malformed lambs and calves strongly suggest a causal relationship between the presence of the virus and the reported clinical signs.

Resistance to physical and chemical action

From extrapolation from the California serogroup of Orthobunyaviruses:

Temperature: Infectivity lost (or significantly reduced) at 50–60°C for at least 30 minutes.

Chemicals/Disinfectants: Susceptible to common disinfectants (1 % sodium hypochlorite, 2% glutaraldehyde, 70 % ethanol, formaldehyde)

Survival: Does not survive outside the host or vector for long periods

EPIDEMIOLOGY

According to the epidemiological investigations, reinforced by what is already known about the genetically related Simbu serogroup viruses, Schmallenberg virus affects domestic ruminants. It is unlikely to be zoonotic. The spatial and temporal distribution suggests that the disease is first transmitted by insect vectors and then vertically *in utero*.

Hosts

- Cattle, sheep, goats
- Bison
- No information on the susceptibly of exotic ruminants (camelids, llamas, etc.), or other wild ruminants, or on other species. It is worth noting that other viruses of the Simbu serogroup affect wild ruminants and that antibodies to Akabane virus have been found in horses, donkeys, buffalo, deer, camels and even in pigs. Some viruses of the Simbu serogroup (Mermet, Peaton and Oropouche viruses) have also been detected in birds. Mice and hamsters can be infected experimentally.
- *Humans:* No human disease related to Schmallenberg virus have been reported in the affected zone so far, and the genetically most related Orthobunyaviruses do not cause disease in humans. Thus current risk assessments conclude that the virus is unlikely to cause disease in humans even if it cannot be fully excluded at this stage. Nevertheless, close collaboration between public health and animal health services is recommended for the early detection of potential human cases, particularly in farmers and veterinarians in close contact with potentially infected animals, and especially during interventions for dystocia.

Transmission

The transmission of Schmallenberg virus needs to be confirmed but hypotheses have been developed through recent epidemiological investigations and comparison with other Orthobunyaviruses:

- It is likely to be transmitted via insects vectors (biting midges and/or mosquitoes)
- Vertical transmission across placenta is proven
- Direct contamination from animal to animal or animal to human is very unlikely but needs further investigation (first experiments have been started)

Further research is still needed to confirm these transmission routes and to determine the competent insect species.

Viraemia and incubation period

Experimental infection in 3 calves showed mild clinical signs of acute infection at 3 to 5 days post-inoculation and viraemia at 2 to 5 days post-inoculation. No data are available for sheep and goats up to February 2012.

Sources of virus

Source of transmission:

- Likely to be infected insect vectors.

Material found to be positive in virus isolation (up to February 2012):

- Virus has been isolated from blood from affected adults and infected foetus and brain from infected foetus.

Material found PCR positive (up to February 2012):

- Organs and blood of infected foetuses, placenta, amniotic fluid, meconium.

All these findings have to be further investigated for their role in transmission.

Occurrence

Only some Orthobunyaviruses had been reported in Europe: e.g. Tahyna virus from the California serogroup, but viruses from the Simbu serogroup had never been isolated in Europe before.

First phase: Schmallenberg virus was first detected in November 2011 in Germany from samples collected in summer/autumn 2011 from diseased (fever, reduced milk yield) dairy cattle. Similar clinical signs (including diarrhoea) were detected in dairy cows in the Netherlands where the presence of Schmallenberg virus was also confirmed in December 2011.

Second phase: In early December 2011, congenital malformations were reported in newborn lambs in the Netherlands, and Schmallenberg virus was detected in and isolated from the brain tissue. Up to February 2012, Belgium, Germany, United Kingdom, France, Luxembourg and Italy have reported stillbirth and congenital malformations with PCR positive results.

For more recent, detailed information on the occurrence of this disease worldwide, see the *OIE World Animal Health Information Database* (WAHID) interface [http://www.oie.int/wahis/public.php?page=home].

DIAGNOSIS

Clinical diagnosis

Manifestation of clinical signs varies by species: bovine adults have shown a mild form of acute disease during the vector season, congenital malformations have affected more species of ruminants (to date: cattle, sheep, goat and bison). Some dairy sheep and cow farms have also reported diarrhoea.

- Adults (cattle)
  - Probably often inapparent, but some acute disease during the vector-active season
  - Fever (>40°C)
  - Impaired general condition
  - Anorexia
  - Reduced milk yield (by up to 50%)

  - Diarrhoea
  - Recovery within a few days for the individuals, 2–3 weeks at the herd scale

- Malformed animals and stillbirths (calves, lambs, kids)
  - Arthrogryposis
  - Hydrocephaly
  - Brachygnathia inferior
  - Ankylosis
  - Torticollis
  - Scoliosis

The exact rate of malformation is not known up to February 2012. Some sheep farms have reported in a period related to acute infection in Summer and Autumn 2011 more than 25% malformed lambs.

Lesions

In malformed newborn

- Hydranencephaly
- Hypoplasia of the central nervous system
- Porencephaly
- Subcutaneous oedema (calves)

The symptoms can be summarised as arthrogryposis and hydranencephaly syndrome (AHS)

Differential diagnosis

For the acute infection of the adults:

- Bluetongue virus
- Epizootic haemorrhagic disease (EHD) virus
- Foot and mouth disease (FMD) virus
- Bovine viral diarrhoea (BVD) virus, border disease and other pestiviruses
- Bovine herpesvirus 1 and other herpesviruses
- Rift Valley fever virus
- Bovine ephemeral fever virus
- Toxic substances

The symptoms are not specific. Other sources of diarrhoea and milk reduction could be taken into account.

For the malformation of calves, lambs and kids:

- Toxic substances
- Genetic factors
- Bluetongue virus
- Pestiviruses
- Other viruses of the Simbu serogroup (Akabane)

Laboratory diagnosis

Samples

From live animals for the detection of acute infection:

- EDTA blood
- Serum
  - At least 2 ml, transported cooled

From stillborns and malformed calves, lambs and kids:

- From necropsy: Tissue samples of brain (cerebrum and cerebellum), additional samples: central nervous system, spleen and blood
- From live newborn: blood, (preferably pre-colostral) serum and meconium
  - Samples should be transported cooled or frozen
- Placenta and amniotic fluids

Procedures

Identification of the agent

- Real-time RT-PCR
- Cell culture isolation of the virus

Serological tests on serum samples

- Indirect Immunofluorescence
- Neutralization test
- ELISA to be developed

PREVENTION AND CONTROL

- There is currently no specific treatment or vaccine for Schmallenberg virus

Sanitary prophylaxis

Control of potential vectors during the vector-active season may decrease the transmission.

Delay of breeding may decrease the number of foetal malformations.

REFERENCES AND OTHER INFORMATION

- Friedrich-Loeffler-Institut – Update of Information on 'Schmallenberg virus': http://www.fli.bund.de/de/startseite/aktuelles/tierseuchengeschehen/schmallenberg-virus.html
- Friedrich-Loeffler-Institut – New Orthobunyavirus detected in cattle in Germany: http://www.fli.bund.de/fileadmin/dam_uploads/press/Schmallenberg-Virus_20111129-en.pdf
- Friedrich-Loeffler-Institut – Schmallenberg virus factsheet: http://www.fli.bund.de/fileadmin/dam_uploads/tierseuchen/Schmallenberg_Virus/Schmallenberg-Virus-Factsheet-20120119-en.pdf
- National institute of public health and the environment – Risk Profile Humaan Schmallenbergvirus: http://www.rivm.nl/dsresource?objectid=rivmp:60483&type=org&disposition=inline
- European Centre for Disease Prevention and Control, Risk assessment: New Orthobunyavirus isolated from infected cattle and small livestock – potential implications for human health: http://ecdc.europa.eu/en/publications/Publications/Forms/ECDC_DispForm.aspx?ID=795
- The Center for Food Security and Public Health, Iowa State University - Akabane Disease. September 2009 – Akabane disease card. Available at: http://www.cfsph.iastate.edu/Factsheets/pdfs/akabane.pdf
- Public Health Agency of Canada - California serogroup - Material Safety Data Sheets http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/msds27e-eng.php
- Direction générale de l'alimentation - Note de Service du 4 janvier 2012 : Emergence orthobunyaviridé (Schmallenberg virus) – surveillance du territoire pendant l'hiver 2011/2012 : http://agriculture.gouv.fr/IMG/pdf/DGALN20128007Z.pdf
- Mosquito-borne viruses in Europe, Zdenek Hubálek, in Vector-Borne Diseases: Impact of Climate Change on Vectors and Rodent Reservoirs, Berlin, 27 & 28 September 2007: http://www.umweltbundesamt.de/gesundheit-e/veranstaltungen/vector-borne-diseases/06_%20Hubalek.pdf
- Peaton virus: a new Simbu group arbovirus isolated from cattle and *Culicoides brevitarsis* in Australia - St George T.D., Standfast H.A., Cybinski D.H., Filippich C., Carley J.G., *Aust. J. Biol. Sci.,* 1980, **33** (2), 235–43. http://www.publish.csiro.au/?act=view_file&file_id=BI9800235.pdf
- Distribution and prevalence of Mermet virus infections in the central United States. Calisher C.H., Ahmann S.J., Grimstad P.R., Hamm J.G., Parsons M.A. *Am. J. Trop. Med. Hyg*., 1981, **30** (2), 473–6.
- An outbreak of Oropouche virus diease in the vicinity of santarem, para, barzil. Pinheiro F.P., Travassos da Rosa A.P., Travassos da Rosa J.F., Bensabath G. *Tropenmed. Parasitol*., 1976, **27** (2), 213–23.
- ProMED-Mail from Published Date: 2011–11-19 Subject: PRO/AH/EDR> Undiagnosed illness, bovine - Germany, Netherlands (02): new virus susp. Archive number: 20111119.3404: http://www.promedmail.org/direct.php?id=20111119.3404
- Hoffmann B, Scheuch M, Höper D, Jungblut R, Holsteg M, Schirrmeier H, et al. Novel orthobunyavirus in cattle, Europe, 2011. Emerg Infect Dis 2012 Mar [08/02/2012]. http://dx.doi.org/10.3201/eid1803.111905

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The OIE will update this Technical Factsheet when relevant