



**WORLD ORGANISATION FOR ANIMAL HEALTH**  
*Protecting animals, preserving our future*

*Original: English*  
September 2015

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

**Paris, 7–11 September 2015**

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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 7 to 11 September 2015.

Dr Bernard Vallat, Director General of the OIE, welcomed the Commission and congratulated its members for their election and re-election wishing them a successful mandate.

Dr Vallat acknowledged the crucial role of the Commission in the preparation of the OIE standards adopted every year, and reiterated the importance of coordination with the Terrestrial Animal Health Standard Commission (Code Commission) to ensure scientific excellence of the standards. He reminded the Commission of the 2 year-cycle procedure target for the adoption of new standards and using the one-year cycle only in very specific circumstances such as new emerging disease or new scientist evidences with impact in disease control. The Director General confirmed again that the Commission had the responsibility of contributing to the scientific integrity of the *Terrestrial Animal Health Code (Terrestrial Code)*.

Dr Vallat insisted on the independence of the Commission and confirmed the OIE responsibility in facilitating its work which included providing scientific support to the Commission by convening expert *ad hoc* Groups when requested. He reminded that it is the Director General's mandate to select the appropriate experts based on their scientific excellence, being often experts from the OIE Reference Centres using proposals from Specialist Commissions and Working Group, and ensuring geographical balance. Members of the Specialist Commissions were usually invited to the *ad hoc* Group meetings as observers to support the Group in addressing the issues raised by the Specialist Commissions and included in their terms of reference. All the convened *ad hoc* Groups and Working Groups must report back to the responsible Specialist Commission for endorsement of the relative reports and for considering recommendations formulated by the *ad hoc* Groups and Working Groups. The Specialist Commissions would decide when *ad hoc* Group reports would be annexed to their Commission reports.

It was reiterated that the evaluation of Member Country applications for official disease status recognition with the support of dedicated *ad hoc* Groups was part of the Commission's mandate. Dr Vallat drew attention to the fact that the OIE staff remained available to provide technical support to those Member Countries in the process of preparing the dossiers to be submitted for evaluation.

Dr Vallat mentioned that some of the topics included in the Commission's agenda or in the agenda of the joint meeting between the two Commissions were urgently awaited by Member Countries, such as: the revision or finalisation of some *Terrestrial Code* chapters (ASF, glanders, and PRRS) and also the health certificate for High Health Performance horses.

Dr Brückner, President of the Commission welcomed the members of the Commission and reminded them that they were accountable to the World Assembly of Delegates and therefore not representing their individual Member Countries. He highlighted that all members of the Commission signed a declaration of interest and also a confidentiality undertaking form to warrant independence and transparency of their decisions.

The President emphasised the importance of country missions, mostly related to official disease status recognition, to reinforce the Commissions' decisions reflecting the transparency and consistency of the process.

Dr Brückner summarised the most critical aspects in the proposed agenda and outlined to the Commission the priority issues and the work plan for the week.

## **1. Adoption of the agenda and appointment of rapporteur**

The draft agenda was adopted by the Commission with minor changes. The meeting was chaired by Dr Gideon Brückner and the OIE secretariat acted as rapporteur. The agenda and list of participants are attached as Annexes 1 and 2 respectively.

## **2. Feedback from the 83rd General Session**

The President briefly outlined the most important outcomes emanating from the 83rd General Session related to the work of the Commission. He highlighted the adoption of the revised chapter on FMD and the decision of not considering atypical BSE for the purpose of the official disease status recognition. He acknowledged with appreciation the support received from Member Countries for the work of the Scientific Commission.

## **3. Issues from the last meeting of the Scientific Commission**

### **3.1. Member Country comments received for SCAD consideration**

#### **a) Glossary – proposal from the Code Commission**

The Commission considered and amended the definitions drafted by the Code Commission and reviewed by the Biological Standard Commission on vaccination, vaccination programme, emergency vaccination, routine vaccination, OIE standards and OIE guidelines.

The Commission recommended to the Code Commission that the definitions related to vaccination should preferably first be considered by the planned *ad hoc* Group on vaccination, before circulation to Member Countries for comments.

With regards to the proposed definition of an OIE standard, the Commission observed that currently not all the standards are included in the *Terrestrial Code* or *Manual*. For instance, some Resolutions (e.g. list of countries officially recognised as having a disease free status) were also adopted by the OIE World Assembly of Delegates and should be considered in the definition.

The Commission agreed with the definition proposed for an OIE Guideline and indicated that OIE guidelines were not always necessarily endorsed by a Specialist Commission but were sometimes developed on an *ad hoc* basis with the main purpose of providing information to Member Countries on relevant issues.

The proposed amendments to the definitions were forwarded to the Code Commission for consideration.

#### **b) Chapter 4.16 High health status horse subpopulation**

The Commission acknowledged that Member Countries reviewed the chapter before the handbook for the management of high health, high performance (HHP) horses (hereafter handbook) became available. The Commission strongly recommended that Member Countries should consult this document for further clarification. This document will be made available on the OIE website.

The Commission clarified that the organisation of events under the HHP concept would require a biosecure management system ensuring a functional separation between HHP horses and those not qualified as HHP horses. The Commission also referred to the handbook for the provisions on the maintenance of the HHP status of the compartment.

The Commission made specific remarks to indicate that in countries not officially free from AHS, it would not be possible to maintain a compartment indefinitely. In those countries, the compartments would be managed with a “single-use” strategy as described in the handbook.

The revised Chapter addressing the Member Countries Comments was forwarded to the Code Commission for further consideration.

**c) Model veterinary certificate for the international movement not exceeding 90 days of high health-high performance horse for competition or race**

The Commission considered the health specification and purpose of the draft Model Certificate in the context of HHP concept which differed from the model passport for international movement of competition horses in Chapter 5.12 of the *Terrestrial Code*.

After a thorough review of all the Member Countries’ comments, the Scientific Commission, in agreement with Code Commission, decided ~~to~~ not to consider inclusion of the HHP certificate in the *Terrestrial Code* but to rather include it in the section related to certification in the handbook since at this stage, although the concept as such is complete, the certificate is not yet ready to be proposed for adoption as a *Terrestrial Code* Chapter. Further work such as alignment with existing *Code* Chapters and testing of the concept in the field is required before a proposal for adoption as a *Code* Chapter can be reconsidered. Both Specialist Commissions agreed that the Model HHP Certificate would be considered an integral part of the concept and should be implemented by those Member Countries wishing to apply the concept. The implementation of the model certificate for HHP horses would thus first be on a trial basis and once it has proven to be fully meeting the intended needs, it could be considered for inclusion in the OIE *Terrestrial Code* as a model health certificate should the member countries request. The Commissions decided that the amended model certificate would be included in the handbook as part of the guidelines and the justification for the amendments provided by the Scientific Commission and Code Commission would be annexed to the report of the Scientific Commission. The endorsed handbook including the certificate would be published by the OIE as guidelines to support Member Countries in implementation of the HHP concept. Please refer to point 4.1.e. of this report for further information on the handbook.

The Commission considered Member Countries’ comments received on the Model Certificate for international movement of HHP that was circulated for comments in 2015. The Commission acknowledged that many of the comments requesting clarification were addressed by the information now included in the handbook and encouraged Member Countries to refer to this document and also to the document already published on risk mitigation strategies and establishment of specific health requirements for HHP horses<sup>1</sup>.

The detailed rationale for both Commissions’ proposed amendments is attached as Annex 3

#### **4. Ad hoc and Working Groups**

##### **4.1. Meeting reports for endorsement**

###### **a) Ad hoc Group on international horse movement for equestrian sport. 3–5 March 2015**

The Commission considered the report of the *ad hoc* Group that was convened for the fifth time to discuss the outcomes and implications of Member Countries’ comments on the previous report and to further discuss and elaborate key documents including the HHP health certificate,

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<sup>1</sup> [http://www.oie.int/fileadmin/Home/eng/Our\\_scientific\\_expertise/docs/pdf/Chevaux/HHPRiskMitigation.pdf](http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Chevaux/HHPRiskMitigation.pdf)

operationalisation proposals, biosecurity guidelines and the equine diseases free zone (EDFZ) concept.

The Commission took note of the request for updating the *Terrestrial Code* and *Terrestrial Manual* and concluded that the priorities would be established in coordination with the other Specialist Commissions.

The Commission reminded that the self-declaration of freedom from African horse sickness was not recognised by the OIE, thus, to create an EDFZ which includes freedom from AHS, the country or zone should be officially recognised by the OIE as having an AHS free status.

The Commission was updated on the progress made by countries envisaging applying for an EDFZ and on the research priorities relevant to the HHP concept that were proposed by the expert Group.

The Commission was informed that no further meetings of this *ad hoc* Group were planned and the majority of the tasks included in its terms of references were completed.

The endorsed report of the *ad hoc* Group is attached as [Annex 4](#).

**b) *Ad hoc* Group on prioritisation of disease for which vaccines could reduce antimicrobial use in animals. 21–23 April 2015**

The Commission considered the report of the *ad hoc* Group that was convened to explore and provide directions to policy makers on how to improve the utilisation of vaccines already available and to invest in research to develop new vaccines with the overall objective of reducing the need for antimicrobial use in animals.

The Commission commended the *ad hoc* Group on the scientific quality of the report and strongly recommend that the OIE disseminate the results of the discussion by the *ad hoc* Group among Member Countries, industry and other stakeholders. It was also recommended that the conclusions of the *ad hoc* Group should be considered with the recommendations of the conference organised by the OIE in Buenos Aires in 2004 on the control of infectious diseases by vaccination.

The Commission not only highlighted the importance of developing new vaccines but also how to improve the accessibility and use of existing vaccines to reduce the use of antimicrobials in animals.

The Commission encouraged the OIE to consider inviting a publication on this topic for the OIE *Scientific Review* and to publish an article summarising the recommendations of the *ad hoc* Group, in the OIE *Bulletin*.

The endorsed report of the *ad hoc* Group is attached as [Annex 5](#).

**c) *Ad hoc* Group on porcine reproductive and respiratory syndrome. 23–25 June 2015**

The Commission reviewed the report of the *ad hoc* Group that was tasked to consider Member Countries' comments on the draft Chapter on porcine reproductive and respiratory syndrome that was first circulated among Member Countries for comments in 2014.

The Commission evaluated the modifications proposed by the *ad hoc* Group on the draft chapter. The Commission extensively discussed the proposed testing protocol to detect early infection with PRRSV in semen and considered the peer-review article suggested by a Member Country. The Commission concurred with the *ad hoc* Group and concluded that testing donor serum with PCR would have higher sensitivity in detecting PRRSV during the early infection than testing a sample of the semen to detect virus nucleic acid.

The Commission suggested to the Code Commission to consider making explicit provisions in Chapter 4.5. of the *Terrestrial Code* for early detection systems for all relevant animal diseases, including PRRS.

The endorsed report of the *ad hoc* Group is attached as Annex 6.

The revised draft chapter and the endorsed *ad hoc* Group report were forwarded to the Code Commission for further consideration.

**d) *Ad hoc* Group on equine trypanosomosis including Surra to draft a *Terrestrial Code* chapter. 21-23 July**

The Commission considered the report of the *ad hoc* Group that was convened to assess the progress made on the development of differential diagnosis for Surra and Dourine and treatment options for Dourine. The *ad hoc* Group was also requested to provide an expert opinion on the need to have a specific *Terrestrial Code* Chapter on Surra and to update the existing Chapter on Dourine.

The Commission extensively discussed the report and the unfinished draft chapters. Based on the information provided, the Commission decided not to endorse the report and to request the Director General to convene a new *ad hoc* Group to finalise the task. The Commission agreed to also propose experts to the Director General not only with technical knowledge on the two diseases but also with experience in drafting OIE *Terrestrial Code* Chapters. The Commission also suggested that a Commission member should attend the meeting to guide the experts on their terms of reference.

**e) *Ad hoc* Group on biosecurity for the HHP concept. 28–29 July 2015**

The Commission considered the report of the *ad hoc* Group that was convened to finalise the handbook for the management of high health, high performance horses. This document is intended to provide guidance to the *Veterinary Services* and OIE Delegates on the implementation of the HHP concept. The handbook would serve as a reference for the horse industry to develop its own operational manuals. The handbook would also include the model health certificate to be used by Member Countries when implementing the HHP concept.

The Commission discussed the obligations to comply with the provisions described in the handbook, for Member Countries wanting to adopt the HHP concept, and emphasised that biosecurity measures described in the handbook including the model health certificate were to be considered important pre-requisites to be considered for the successful implementation. The Commission supported the use of the word “should” within the document rather than “must” as is the practice in the *Terrestrial Code*.

The Commission reviewed in detail the handbook and acknowledged with thanks the clarity and high technical quality of the document.

The Commission in its review of the text aimed at ensuring consistency throughout the document with the *Terrestrial Code* chapters, in particular with Chapter 4.3. and Chapter 4.4. on principles of compartmentalisation and relevant specific disease *Terrestrial Code* chapters. It was also recommended to use italics when terminology was referring to definitions already included in the *Terrestrial Code* Glossary.

The Commission discussed at length the introduction of new horses into a compartment during the qualification period and confirmed the importance to take into consideration that new horses should not be introduced in the compartment during the last two weeks of the qualification period. The new entrants should initially be isolated within the compartment from the other horses for at least two weeks (14 days). The Commission also clarified that the new entrants should then be maintained within the compartment for further 76 days (to complete the full qualification period) before being qualified as HHP horses. The Commission stressed that in countries not officially free from AHS, new entrants would not be permitted in the compartment. In those countries, the compartment should be managed as an “all-in, all out” system following the “single use strategy”. The Commission agreed that similar provisions would apply for the introduction of new horses in an already approved compartment.

The Commission insisted on the importance that new horses imported from another country in a compartment during the qualification period, should be imported in accordance with the requirements of the *Terrestrial Code*.

For the maintenance of the HHP status and regardless the travelling schedule of the HHP horses, it would require a minimum of annual testing, regular vaccination and annual auditing on biosecurity management by the *Veterinary Authority*. With regard to the HHP priority diseases, it would also require compliance with the specific testing and vaccination provisions included in the model health certificate before a HHP horse was qualified for traveling.

The consequences of a disease incident during the compartment qualification period were extensively discussed. The epidemiological investigation should clearly demonstrate that the disease incidence was not as a consequence of a breach in the biosecurity of the stable to be qualified otherwise the qualification period should start from the beginning.

The possibility for horses in the compartment qualification period to attend “approved competitions” at national level was also considered. The Commission indicated that such competitions should be managed under the HHP biosecurity conditions ensuring a functional separation between HHP horses and those of different health status.

The Commissions provisionally endorsed the handbook pending the inclusion of the modifications requested during the meeting. It was agreed to electronically revise the draft version of the handbook before final endorsement and publication on the OIE website<sup>2</sup> as guidelines. The endorsed handbook would replace the explanatory document to the Model HHP Certificate. The draft handbook with the Commission’s comments was forwarded to Code Commission for consideration.

The endorsed report of the *ad hoc* Group is attached as Annex 7.

#### **f) *Ad hoc* Group on antimicrobial resistance 25–27 August 2015**

The Commission was updated on the work done by the OIE and upcoming activities on antimicrobial resistance in the framework of the Tripartite (FAO, OIE and WHO) Agreement.

The Commission considered with appreciation the *ad hoc* Group report that was tasked with the finalisation of the template and instructions for OIE Member Countries to report on the use of antimicrobial agents in animals. The Group also addressed Member Countries’ comments made on Chapter 6.7.

The Commission took note and agreed with the proposal to review Chapter 6.7. of the *Terrestrial Code* and Chapter 6.4. of the *Aquatic Code* to include additional criteria for the selection of animal pathogens for antimicrobial resistance surveillance.

The Commission considered and provisionally endorsed the proposed definition for ‘therapeutic use’ and ‘non-therapeutic use’ of antimicrobials for further consideration by the Code Commission.

The endorsed report was forwarded to the Code Commission for information with specific consideration to point 6 and 7 which were relevant for the modification of Chapter 6.7.

The endorsed *ad hoc* report is attached as Annex 8.

#### **4.2. Planned *ad hoc* Groups and confirmation of proposed agendas**

The Commission reviewed the draft agendas of the following *ad hoc* Groups scheduled until the next Commission meeting in February 2016 and endorsed them with minor modifications.

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<sup>2</sup> [http://www.oie.int/fileadmin/Home/eng/Our\\_scientific\\_expertise/docs/pdf/Chevaux/HHP\\_Handbook.pdf](http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Chevaux/HHP_Handbook.pdf)

**a) *Ad hoc* Group on FMD. 6–8 October and 1–3 December 2015**

The Commission concluded that in addition to assessing Member Country applications for official disease status recognition, the *ad hoc* Group should revise the questionnaires for the application dossiers (Articles 1.6.6. and 1.6.11. of the *Terrestrial Code*).

Acknowledging the number of applications received by the OIE, the Commission agreed that one meeting would be sufficient to consider the applications. However, the Commission requested to convene another meeting of the *ad hoc* Group to consider other pending topics raised by Member Countries on the application of the amended Chapter.

**b) *Ad hoc* Group on CBPP. 27–29 October 2015**

The Commission concluded that in addition to assessing Member Country applications for official disease status recognition the *ad hoc* Group should revise the questionnaires for the application dossiers (Articles 1.6.7. and 1.6.13. of the *Terrestrial Code*) and also consider amendments to the CBPP Chapter (Article 1.6.7. of the *Terrestrial Code*).

**c) *Ad hoc* Group on CSF. 3–5 November 2015**

The Commission concluded that in addition to assessing Member Country applications for official disease status recognition, the *ad hoc* Group should revise the questionnaire for the application dossiers (Article 1.6.10. of the *Terrestrial Code*)

The Commission also requested the *ad hoc* Group to consider the request of a Member Country with regards to recommendation for importation of pigs for immediate slaughter from an infected zone to a CSF-free zone. The *ad hoc* Group should also consider and identify the needs for future revision of the *Terrestrial Code* Chapter on CSF (See point 10.1)

**d) Wildlife Working Group. 29 September – 2 October 2015**

The Commission endorsed the proposed draft agenda for the Working Group for the upcoming meeting and acknowledged the impact of the work done by the Working Group and the valuable information reported by Member Countries through WAHIS wild. It was recommended to the OIE to consider including information on WAHIS wild in the WAHIS report to World General Assembly of Delegates.

**e) *Ad hoc* Group on BSE. 24–26 November 2015**

The Commission concluded that in addition to assessing Member Country applications for official disease status recognition, the *ad hoc* Group should revise the questionnaire for the application dossiers (Article 1.6.5. of the *Terrestrial Code*).

The Commission also requested the Director General to convene an *ad hoc* Group dedicated to the revision of the *Terrestrial Code* Chapter on BSE.

As mentioned in item 7.3.b), the Commission requested the *ad hoc* Group to pre-assess the annual reconfirmations of risk status received from targeted Member Countries.

**f) *Ad hoc* Group on PPR. 15–17 December 2015**

The Commission concluded that in addition to assessing Member Country applications for official disease status recognition, the *ad hoc* Group should revise the questionnaires for the application dossiers (Articles 1.6.9. and 1.6.12. of the *Terrestrial Code*).

As mentioned in item 7.3.b), the Commission requested to the *ad hoc* Group to pre-assess the selected annual reconfirmations of disease status received from targeted Member Countries.

**g) *Ad hoc* Group to update Chapter 11.12 on Theileriosis: 23–25 February 2016 (tentative)**

The OIE Headquarter will draft the agenda with the support of the Commission.

**h) *Ad hoc* Group on AHS. 19–21 January 2016**

The Commission concluded that in addition to assessing Member Country applications for official disease status recognition the *ad hoc* Group should revise the questionnaire for the application dossiers (Article 1.6.8. of the *Terrestrial Code*).

As mentioned in item 7.3.b), the Commission requested the *ad hoc* Group to pre-assess the selected annual reconfirmations of disease status received from targeted Member Countries.

**i) *Ad hoc* Group on AMR: 19–22 January 2016**

The working plan of the *ad hoc* Group was endorsed by the Commission.

**j) *Ad hoc* Group on Lumpy skin disease (caused by group III virus, type Neethling) to update Chapter 11.11 of the *Terrestrial Code*: 12–14 January 2016**

Following Member Countries' request, the Commission acknowledged the importance of amending the current chapter incorporating specific articles on surveillance to support affected Member Countries. The terms of reference of the *ad hoc* Group will include a consideration of the findings of the numerous ongoing research projects on lumpy skin disease. The Commission would propose a list of experts to be considered by the Director General when convening the *ad hoc* Group.

**k) *Ad hoc* Group on trypanosomosis transmitted by tsetse flies and by other vectors**

Date to be decided.

**l) *Ad hoc* Group on equine trypanosomosis (Surra, Dourine)**

See point 6.1.d.

**m) *Ad hoc* Group on vaccination: 17–19 November 2015**

The Commission reviewed and endorsed with modifications the terms of reference for the *ad hoc* Group on vaccination drafted by the Scientific and Technical Department. The Commission recommended that this new chapter should become a horizontal chapter of the *Terrestrial Code*. The importance of including clear definitions of common terminology used when describing vaccination strategies was acknowledged.

The Commission noted that numerous *Terrestrial Manual* chapters on vaccines were under revision, being an opportunity to ensure cross-references between the *Terrestrial Code* and *Manual* in all issues referring to vaccine and vaccination. The Commission fully supported the participation of a representative of the Biological Standard Commission and the Code Commission in the forthcoming *ad hoc* Group meeting.

## **5. Official disease status**

### **5.1. Expert missions**

**a) FMD Namibia: 13–17 July 2015**

The Commission was updated on the outcome of the mission to Namibia in which the OIE participated to provide support to Namibia in its progression towards the application of its endorsed official control programme despite the recent FMD incursion in the Northern Communal Areas.

**b) FMD Zimbabwe: planned 21–24 September 2015**

The Commission was updated on the preparation of an upcoming mission to Zimbabwe.



**c) Feedback from the OIE mission to Colombia–Venezuela’s high surveillance zones**

The Commission was updated on the outcome of an OIE mission by the OIE Regional Representative for the Americas and a consultant that took place at the border of Colombia and Venezuela, in the high surveillance zones.

**d) Bolivia and Paraguay (tentatively January 2016)**

As agreed after their last mission in Bolivia, the Commission reiterated the need to carry out a follow-up mission to this country to assess the maintenance of the official disease status. It was suggested to also include Paraguay in the mission for similar purposes.

**5.2. Update on official disease status**

**a) BSE**

- Ireland

The Commission acknowledged with appreciation the very detailed and high quality information provided by Ireland and reaffirmed the decision taken electronically in June 2015 by the Commission to re-instate the BSE controlled risk status of Ireland

**b) FMD**

- Algeria

Further to the re-occurrence of FMD in Algeria in 2015, the Commission had requested Algeria to provide information on its FMD situation in relation to the implementation of its endorsed official control programme, based on the consideration that a country having an endorsed official control programme for FMD should be able to provide information related to disease control in a timely manner.

The Commission concluded that the information provided by Algeria was not sufficient to conclude whether the official control programme was still compliant with the requirements of the *Terrestrial Code* (Article 8.8.39, in particular), and if Algeria had implemented the adjustments recommended by the Commission at its February 2015 meeting.

The Commission therefore suggested that further information be provided for consideration by the *ad hoc* Group on FMD at its forthcoming meeting. The conclusion reached by the *ad hoc* Group on the information provided by Algeria will then be forwarded to the Commission for consideration.

- South Africa: The Commission acknowledged with appreciation the information provided by South Africa in response to the request of the Commission during its February meeting to substantiate the Member Country’s capability to maintain their official disease status recognition.
- China: The Commission acknowledged with appreciation the information provided by China to substantiate its capability to evaluate the progress made with the implementation of its endorsed official control programme.

**c) Method for revision of disease status questionnaire**

- As discussed during its February 2015 meeting, the Commission requested that each *ad hoc* Group revise the questionnaire(s) related for the relevant disease during the period October–February 2015. The Scientific and Technical Department would then collate the proposed changes and identify where harmonisation between the questionnaires would be feasible. The Commission would finalise the revision at its February 2016 meeting.

**5.3. Update on situation of countries/zone with suspended disease status**

The commission was informed on the state of play of the countries with suspended official disease status.

#### **5.4. Annual reconfirmations of official status**

##### **a) Web-based tool**

The Commission noted with appreciation the progress made with the development of a new on-line system for annual reconfirmation of officially recognised status and endorsed control programmes, which will be fully operational and on-line by November 2015.

For BSE annual reconfirmation, the Scientific and Technical Department had processed the surveillance data collected for the six previous years in the on-line system to help countries to ensure that they are compliant with the requirements of the *Terrestrial Code* for which surveillance had to be conducted during seven consecutive years. However, due to the heterogeneity of some of the historical surveillance data, Member Countries would be requested to kindly check and validate the historical data processed in the on-line system when completing the annual reconfirmation for 2015.

##### **b) Selection of countries for comprehensive evaluation of annual reconfirmation when the countries having a recognised status or endorsed programme are requested to reconfirm their situation.**

The Commission confirmed its commitment made during the February 2015 meeting, to make a comprehensive evaluation of the annual reconfirmations of all countries having an endorsed official control programme and of a selection of countries having an official disease or risk status. The Commission identified a number of countries to be evaluated.

The Commission proposed to request those *ad hoc* Groups on the evaluation of disease status of Member Countries that would meet between the end of November and the February 2016 meeting of the Commission, to pre-assess the annual reconfirmations, if that fits in with their agendas.

The Commission would assess the reconfirmations at its February 2016 meeting.

##### **c) Validation of the annual reconfirmation form for FMD freedom**

The Commission endorsed the revised annual reconfirmation form for maintenance of FMD free status and maintenance of the endorsement of official control programme, following the adoption of the revised FMD *Terrestrial Code* Chapter at the 83rd General Session in May 2015.

#### **5.5. Revision of the Standard Operation Procedures for official disease status recognition**

##### **a) Proposal from Member Countries**

The Commission considered a proposal received from Member Countries regarding the improvements of the Standard Operation Procedures for official disease status recognition (SOPs) and the answer already provided by the OIE.

The Commission supported the OIE position that the dossiers provided by Member Countries applying for official status recognition should remain confidential, and that they could only be shared via bilateral agreement between countries. However, the Commission endorsed the change in the SOPs encouraging applicant Member Countries to commit themselves and provide, within a maximum of 10 days, the whole or part of their dossier to another Member Country, should it be requested during the 60 day comment period prior to the General Session.

##### **b) Impact of an outbreak in a non-contiguous territory on official status**

The Commission discussed the situation of Member Countries that had included non-contiguous territories in their national applications for disease free status and the impact that an outbreak in a non-contiguous territory would have on the disease status of the entire national territory. The Commission concluded that according to the current legal framework, the preferred way to proceed would be to establish a containment zone in the infected non-contiguous territory. However, the

procedure imposes that the status of the whole country remains suspended until the formal establishment of the containment zone that can only occur after the completion of two incubation periods after the last outbreak.

The Commission concluded that, in those circumstances, the final decision would be taken on a case by case basis considering that the epidemiological circumstances and legal framework of the territories may greatly differ.

#### **5.6. The impact on disease status of the use of emergency vaccination in response to risk of incursion**

The Commission acknowledged that the current FMD chapter did not consider the possible need for FMD free countries or zones without vaccination to conduct vaccination in response to an increased risk of FMDV introduction without losing their official disease status. It was decided to refer this issue to an *ad hoc* Group for further consideration of its impact and to advise the Commission accordingly.

### **6. FMD and PPR control strategies**

#### **6.1. Peste de Petits Ruminants - Global Eradication Strategy**

The Commission was updated on the state of play of the PPR Global control and eradication strategy with the focus primarily on 70 endemic countries. The next step in the process would be to formally establish the Secretariat and working group. The Commission was informed that the mechanism for a vaccine bank for West Africa was functional and countries could make use of it when necessary. However, it would need further financial support to ensure maintenance of operability.

#### **6.2. Foot and Mouth Disease Global Control Strategy**

The Commission was updated on the evolution on the implementation of the Global Control Strategy for FMD. The Commission took note that the GF-TADs FMD working group planned to review the Progressive Control Pathway Guide and other supportive documents of the Global Strategy to better integrate the importance of strengthening the Veterinary Services. The Commission also took note that socio economic guidelines to be labelled under GF-TADs was under development to support the Global Strategy.

The Commission reiterated its decisions of previous meetings and urged the OIE and the FAO to publish the finalised post vaccination monitoring guide.

### **7. OIE Collaborating Centres**

#### **7.1. Follow up of the proposal for an OIE Collaborating Centre for Training Veterinary Officials, Diagnosing infectious Animal Diseases and Zoonoses, and for the Control of Veterinary Chemicals in Sub-Saharan Africa**

The Commission took note of the response sent by a candidate Collaborating Centre applicant to the Director General proposing a modification of the title to: OIE Collaborating Centre for Training Veterinary Officials, Diagnosing infectious Animal Diseases and Zoonoses, and for the Control of Veterinary Chemicals in Sub-Saharan Africa”.

The Commission discussed the terms “veterinary chemicals” proposed by the applicant, which excludes vaccines but includes acaricides and other drugs used in veterinary medicine. It also reiterated that providing training to Member Countries was inherent to the general terms of reference of all OIE Collaborating Centres and therefore, the application should clearly describe the specification of the training to be provided. The Commission proposed the use of the term “veterinary drugs” in the title of the Collaborating Centre rather than “veterinary chemicals” to bring it in alignment with the denomination of other already approved Collaborating Centres.

Considering the Member Countries that the candidate Collaborating Centre would focus on, the Commission proposed that the candidate Collaborating Centre rather refer to West and Central Africa instead of all countries in Sub-Saharan Africa.

A letter reflecting the discussions and recommendations of the Commission will be sent to the applicant Collaborating Centre.

## **8. Liaison with other Commissions**

### **8.1. Terrestrial Animal Health Standard Commission**

Please refer to the joint meeting between the two Commissions attached as [Annex 9](#).

### **8.2. Biological Standards Commission**

The Commission was informed that the newly elected Biological Standard Commission had identified its priorities, which included a thorough revision of *Terrestrial Manual* chapters related to vaccination. The Commission requested the collaboration and support of the Biological Standard Commission in the upcoming *ad hoc* Group on Vaccination.

#### **a) FMD serum provision to calibrate diagnostic test**

In response to the request of the Commission, the Biological Standard Commission agreed that the proposal to amend the *Terrestrial Manual* chapter on FMD to include the requirement that vaccine manufacturers provide, on request of the vaccine purchaser, post-vaccination sera produced during final product batch testing for potency for use in the calibration of locally used tests for measuring population immunity was scientifically sound and offered important practical implications when carrying out post-vaccination monitoring.

The Commission was informed that the Reference Laboratory experts would be requested to include suitable text in the *Terrestrial Manual* chapter. The Commission also proposed to include a remark suggesting that this serum could also be produced and distributed by OIE Reference Laboratories, while acknowledging the additional funding requirements of this request.

#### **b) Revision of the BSE chapter of the *Terrestrial Manual* to include available test to discriminate atypical from classical BSE**

The Commission was informed that experts from the OIE Reference Laboratories were already tasked with the revision of the *Terrestrial Manual* Chapter. It is expected to be presented for adoption in May 2016.

#### **c) Update on the proposal for a replacement international standard for bovine tuberculin**

The Commission was informed that the request for an *ad hoc* Group on a Replacement International Standard for Bovine Tuberculin was already endorsed by the Director General. The Group would include experts from the OIE Reference Laboratories, from industry and other stakeholders. The Commission would be duly informed on the outcome of the *ad hoc* Group meeting during its February meeting.

### **8.3. Common issues related to several Specialist Commissions**

#### **a) Update on the WAHIS harmonisation task, defining the term “events” and update on the annual report**

The Commission was informed on the progress made by an OIE internal taskforce on WAHIS Harmonisation, in charge of producing the OIE Notification Procedures which included the update of the current notification guidelines and harmonising the definitions with the Glossary of the *Terrestrial Code*.

The Commission acknowledged the revision of the annual report eliminating the list of non-Listed diseases, which was historically a joint WHO/FAO/OIE questionnaire. The list of zoonosis in the annual report was also updated.

## **9. Conferences, workshops, meetings**

### **9.1. Global conference on Biological Threat Reduction, Paris: June 2015**

The Commission was provided with an overview of the OIE Global Conference on Biological Threat Reduction held in collaboration with the WHO from 30 June to 2 July 2015. The Commission commended the organisation of the Conference and highlighted the high quality of participation. It was noted that the Conference resulted in 18 Recommendations – underpinning the importance of investments in infrastructure, the sharing of organisational resources, identifying areas of mutual interest with the intention to hold similar conferences to build on cooperation and engagement.

### **9.2. Rabies Global Conference. Geneva**

The Global conference on rabies is organised by WHO and OIE with the collaboration of FAO and with the support of GARC. It would take place at WHO Headquarters from 10 to 11 of December 2015. OIE Delegates from rabies endemic Member Countries, OIE Reference Centres, representatives from the Specialised Commissions and relevant international organisations which have an agreement with the OIE will be invited by the OIE. The main objective of the conference is to support the feasibility of eliminating dog-mediated rabies using existing tools.

### **9.3. Workshop on disease status recognition**

The Commission received feedback on three workshops organised to provide better understanding by Member Countries willing to prepare an application dossier for official status recognition and endorsement of an official control programme. Two countries who attended these workshops had already submitted applications with a noticeable improvement in the quality of their dossiers. The Commission was informed that other workshops were already planned to cover the remaining interested regions.

### **9.4. Workshop on Rift Valley fever, Djibouti**

The Commission was informed on the main outcomes of the workshop on Rift Valley fever that took place in Djibouti from 21-23 of April 2015. The meeting was organised under the GF-TADs umbrella with participants from countries from the Horn of Africa and the Arabic Peninsula. During the workshop the participants had the opportunity to discuss the implications of the new possibilities for safe trade included in the recently adopted *Terrestrial Code* Chapter on Rift Valley fever and also to discuss vaccine and diagnostic developments in the face of the increase risk of epidemics occurring.

## **10. Disease specific issues**

### **10.1. Classical Swine fever: Movement of pigs for immediate slaughter from a zone not free of CSF to one that is free**

The Commission discussed a Member Country's inquiry on pig movements for immediate slaughter from an infected to a free zone and agreed with the response provided by the OIE. It was agreed to request the opinion of the *ad hoc* Group at its 2015 meeting to assess if an amendment of the current chapter would be necessary. The Commission requested that the *ad hoc* Group discussed this issue together with other possible future amendments of the Chapter identified by the last *ad hoc* Group on African swine fever.

### **10.2. Foot and Mouth Disease. Movement of vaccinated animals to free zone where vaccination is not practiced**

The Commission discussed a Member Country's inquiry on the movement of previously vaccinated animals to a free country/zone where vaccination is not practiced under the condition that those animals had not been vaccinated for the past 12 months. The Commission noted that those animals would be in an environment where vaccination was practised which presents a different risk than in an environment where vaccination had ceased for more than 12 months. In addition, point 4e of Article 8.8.12. stated that no vaccinated animal should be introduced in a free country without vaccination, except if the movement was under the provisions of Articles 8.8.8. and 8.8.9. (direct for slaughter).

The Commission concluded that the current requirement not allowing vaccinated animals in an FMD free country or zone without vaccination should be maintained. Nevertheless, the Commission suggested that the *ad hoc* Group on FMD should provide further scientific justification to the Commission to substantiate that this provision was still scientifically sound.

#### **10.3. Paper on Rabies as threat to biodiversity by Working Group on Wildlife**

The Commission commended the authors of the paper on rabies and provided minor comments for their consideration. The Commission encouraged the publication of the paper.

#### **10.4. Bovine tuberculosis. Code provisions for a free country or zone**

The Commission considered the clarification requested by some Member Countries with regards the *Terrestrial Code* Chapter provisions for a free country. The Commission took note of the request and suggested to postpone the discussion to the next meeting when addressing the expected Member Countries' comments to the recently amended chapter circulated among Member Countries.

### **11. For the Commission information**

The Commission was updated on the following topics:

#### **11.1. Conclusions of IV international conference on bluetongue and related orbiviruses, Rome 2014**

The Commission considered the recommendations made by participants of the IV international conference on bluetongue and related orbiviruses. Special notice was taken of the recommendation to further characterise the biology and significance of newly discovered BTV serotypes (e.g. 25, 26, 27) and their animal-vector-host-virus interaction where horizontal (non-vector) transmission had been demonstrated.

The Commission acknowledged that this issued was already discussed in the *ad hoc* Group tasked with the harmonisation of some of the vector borne disease chapters of the *Terrestrial Code*. The Commission decided to include it in the agenda of its February 2016 meeting for further discussion.

#### **11.2. Update on the OFFLU strategy for monitoring global influenza diversity in wild birds**

The Commission was informed on the results of the teleconference organised by OFFLU to establish a strategy for monitoring global influenza in wild birds. The Commission took note that the chair of the Wildlife Working Group was part of this initiative and that this topic was included in the next agenda of the Working Group. The Commission requested an update on this issue during its next meeting.

#### **11.3. Proposal to create a non-tsetse transmitted African trypanosomosis (NTTAT) OIE network**

The Commission acknowledged and support the initiative of creating the NTTAT OIE network and request an update on this issue at its next meeting.

#### **11.4. Update on elimination of rinderpest virus material**

The Commission was informed on the results of the adoption of Resolution No. 25 at the 83rd General Session for the Designation of Facilities Holding Rinderpest Virus Containing Materials. The Commission was informed that FAO was still in the process of determining and completing an official procedure for approval of those facilities by its membership. The Commission was also informed that there was a pending application that has been reviewed and recommended for site inspection by the Joint FAO/OIE advisory Committee. However, due to the financial constraints of the facility, the site

inspection had not yet been arranged. Two other countries had inquired about applying for facilities with Rinderpest virus containing materials after the General Session. However, they had not yet submitted application dossiers for evaluation.

#### **11.5. Update on biological threat reduction issues**

The Commission was informed of the recent WHO-UN Office of Disarmament Affairs workshop in The Hague and the upcoming biological threat reduction-themed meetings in which the OIE will participate; including the G7 Global Partnership Working Group Meeting in Berlin as well as the United Nations 1540 Committee Meeting in Vienna.

### **12. Any other business**

#### **12.1. IFHA request on international horse movement**

The Commission took note of the recommendations of the International Federation of Horseracing Authorities made to the Director General in a letter dated on 4 February 2015. The Commission noted that some of the recommendations such as the updating of *Terrestrial Code* and *Terrestrial Manual* chapters and finalising the health certificate for HHP horses were already on the agenda of the Commission or close to be accomplished.

#### **12.2. Improve accessibility of Member Countries to *ad hoc* Group reports**

The Commission acknowledged the request of Member Countries to improve the accessibility to reports of *ad hoc* Groups for which the Commission is responsible. It was reiterated that all endorsed *ad hoc* Group reports were annexed to the Commission report and would therefore be in the public domain. Nevertheless, the proposal was supported to create a specific electronic link on the OIE website to ease access to these reports.

### **13. Programme and priorities**

#### **13.1. Review and update of the priority list**

The Commission reviewed and updated the priorities list and working programme for 2015–2016 taking in consideration the priorities identified by other Specialist Commissions.

### **14. Adoption of the report**

The Commission agreed to circulate the draft report electronically for comments before the final adoption.

### **15. Date of next meeting**

The next meeting of the Scientific Commission is scheduled for 8–12 February 2016.

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.../Annexes





## MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 7–11 September 2015

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### Agenda

1. Adoption of the agenda and appointment of rapporteur
2. Feedback from the 83rd General Session
3. Issues from the last meeting of the Scientific Commission
  - 3.1. Member Country comments received for SCAD consideration
4. *Ad hoc* and Working Groups
  - 4.1. Meeting reports for endorsement
  - 4.2. Planned *ad hoc* Groups and confirmation of proposed agendas
5. Official disease status
  - 5.1. Expert missions
  - 5.2. Update on official disease status BSE
  - 5.3. Update on situation of countries/zone with suspended disease status
  - 5.4. Annual reconfirmations of official status
  - 5.5. Revision of the Standard Operation Procedures for official disease status recognition
  - 5.6. The impact on disease status of the use of emergency vaccination in response to risk of incursion
6. FMD and PPR control strategies
  - 6.1. Peste de Petits Ruminants - Global Eradication Strategy
  - 6.2. Foot and Mouth Disease Global Control Strategy
7. OIE Collaborating Centres
  - 7.1. Follow up of the proposal for an OIE Collaborating Centre for Training Veterinary Officials, Diagnosing infectious Animal Diseases and Zoonoses, and for the Control of Veterinary Chemicals in Sub-Saharan Africa
8. Liaison with other Commissions
  - 8.1. Terrestrial Animal Health Standard Commission
  - 8.2. Biological Standards Commission
  - 8.3. Common issues related to several Specialist Commissions
9. Conferences, workshops, meetings
  - 9.1. Global conference on Biological Threat Reduction, Paris: June 2015
  - 9.2. Rabies Global Conference. Geneva
  - 9.3. Workshop on disease status recognition
  - 9.4. Workshop on Rift Valley fever, Djibouti
10. Disease specific issues

- 10.1. Classical Swine fever: Movement of pigs for immediate slaughter from a zone not free of CSF to one that is free
  - 10.2. Foot and Mouth Disease. Movement of vaccinated animals to free zone where vaccination is not practiced
  - 10.3. Paper on Rabies as threat to biodiversity by Working Group on Wildlife
  - 10.4. Bovine tuberculosis. Code provisions for a free country or zone
  - 11. For the Commission information
    - 11.1. Conclusions of IV international conference on bluetongue and related orbiviruses, Rome 2014
    - 11.2. Update on the OFFLU strategy for monitoring global influenza diversity in wild birds
    - 11.3. Proposal to create a non-tsetse transmitted African trypanosomosis (NTTAT) OIE network
    - 11.4. Update on elimination of rinderpest virus material
    - 11.5. Update on biological threat reduction issues
  - 12. Any other business
    - 12.1. IFHA request on international horse movement
    - 12.2. Improve accessibility of Member Countries to *ad hoc* Group reports
  - 13. Programme and priorities
    - 13.1. Review and update of the priority list
  - 14. Adoption of the report
  - 15. Date of next meeting
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## MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 7–11 September 2015

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**Rationale for the amendments to:**

**Model veterinary certificate for the international movement not exceeding 90 days  
of high health-high performance horse for competition or race**

In response to a Member Country's comment referring to equine piroplasmosis, the Commission reiterated that the biosecurity provisions addressed the risk of transmission by seropositive horses. It was acknowledged that the OIE standards did not request two different assays for the diagnosis of equine piroplasmosis and did not agree with a Member Country's proposal of prescribing two assays (IFAT and c-ELISA) for the diagnosis. The Commission made reference to Article 12.7.3. that requested treatment against ticks seven days prior shipment. The Commission agreed to remove the clause on "clinical signs of piroplasmosis on the day of examination" as it was already covered for all diseases in the clause V.1 of the Model veterinary certificate.

With regards to equine infections anaemia the Commission agreed with the opinion of a Member Country that the test should be performed within the 90 days prior to the shipment as stated in the specific *Terrestrial Code* chapter instead of 120 days. The text was modified accordingly.

The Commission confirmed that the provision of 15 days with no contact with other horses included in the draft certificate was consistent with the adopted Chapter 5.12. on model passport for international movement of competition horses.

In response to a Member Country's comment referring to the diseases included in the model certificate, the Commission reiterated that the model certificate covered the 6 priorities diseases for the HHP concept. Those six priorities diseases should be notifiable in the country wishing to implement the HHP concept. The choice of making other equine disease notifiable was a national prerogative.

The Commission acknowledged the request of one Member Country to review the *Terrestrial Code* Chapter 12.11. on Venezuelan equine encephalomyelitis but emphasised that it should not prevent the use of the certificate.

The Commission considered the testing requirements for glanders and the risk of asymptomatic carriers. In the absence of an OIE official disease status recognition for glanders, testing was required for HHP horses in countries self-declared free with the aim of establishing a baseline for the testing regime for the compartment. The Commission pointed out that in the case of a Member Country considered being non infected only one test (CFT) would be required.

The Commission noted the *Terrestrial Code* did not provide requirements to define a glanders free premise and confirmed that, in the case of non-free Member Countries, all horses in the premise must be subjected to a test according to Article 12.10.4.

The Commission agreed with a Member Country's opinion to remove requirements for transportation because they are already addressed in the section on biosecurity of the handbook.

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**MEETING OF THE OIE AD HOC GROUP ON  
INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT**

**Paris, 3-5 March 2015**

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**1. Welcome by the Chair and Introductions**

Dr Murray, Chair of the *ad hoc* Group (AHG), welcomed participants and observers on behalf of Dr Vallat. Dr Eloit, Deputy Director General, addressed the AHG on the 4<sup>th</sup> March and acknowledged the work that has been done by the AHG. She highlighted the need to develop improved approaches to advocacy and communication that will support the full adoption and successful implementation of the concept. She also stressed the need for closer relationships between the equine industries and the public sector at the national level.

In his opening remarks, Dr Murray recalled that the HHP concept provides a sound option for international horse movements. The choice is a business decision for industry, but the HHP concept provides real opportunities for developing regions with equestrian and racing interest to engage in international competitions using simplified but scientifically based certification arrangements.

Dr Murray informed the participants that a constructive FEI-IFHA meeting took place at the OIE on the 2<sup>nd</sup> March 2015 to discuss industry relevant aspects of the implementation of the HHP concept. The meeting was most positive. He thanked both organisations for the leadership being shown.

After introducing new participants and extending apologies for those who could not attend, he requested participants briefly introduced themselves.

**2. Acceptance of the Agenda**

The adopted agenda for the meeting is given in Appendix I and the list of participants in Appendix II.

**3. Records of previous meetings**

The minutes of the fourth meeting of the AHG (Paris, 2–4 June 2014) and the minutes of the meeting of a sub-group to the AHG (Paris, 23 – 25 July 2014) were approved.

**4. Presentation of the OIE Member Country comments on the revised *Terrestrial Code* Chapter 4.16 and the Model Health Certificate**

The revised *Terrestrial Code* Chapter 4.16 *High health status horse subpopulation* was circulated for Member Countries' comments with the September 2014 Code Commission report. The Model HHP Veterinary Certificate and the explanatory text "Guide to the Management of the high health status horse subpopulation and the HHP horse" could be found in Part B of this report, as attachments to the report of the sub-AHG on HHP certificate. Drs Thiermann and Bonbon presented the main comments received by some Member Countries in time for the February 2015 Code Commission meeting.

Some of the comments on the revised *Terrestrial Code* Chapter 4.16 questioned the generic purpose of this Chapter and regretted the lack of technical details provided. Only a few Member Countries commented on the Model Veterinary Certificate, but the comments received were supportive and constructive.

The Code Commission noticed that some of the Member Countries seem to have difficulties in linking the different HHP documents together. This is legitimate since the Model Veterinary Certificate they commented on is the “end product” of the HHP concept, while the supporting documentation (biosecurity guidelines, operationalisation guidelines are still in draft form and the database is not yet developed.

For the success of the HHP initiative the partnership between the Public Sector and the equine Industry would need to be strengthened at national levels. This should be one of the main goals of the upcoming activities, especially through appropriate communication activities.

Dr Barcos highlighted that horses may not be a priority for the Veterinary Authorities in some regions and that specific activities at regional level need to be identified to raise awareness on the initiative.

Dr Thiermann indicated that the revised *Terrestrial Code* Chapter 4.16 will be proposed for adoption at the 2015 General Session. The Model HHP Veterinary Certificate will be circulated for comments and might be proposed for adoption at the 2016 General Session. He explained the rationale for this process and suggested ways to improve understandings of the HHP concept.

Dr Murray, in summarising the discussion, said that, to support a clear and easy understanding of the full HHP concept, it would be best if supporting documents establishing the biosecurity requirements and the details for the operationalisation of the concept were made available before the next meeting of the Code Commission. Such documents would provide a link from the Chapter to the Certificate.

## **5 Review of actions arising and achievements**

Dr Münstermann presented an overview of the work completed since the last meeting.

Technical assistance was provided to countries that wished to establish an equine disease free zone (EDFZ) or that were interested in field testing the HHP concept (2014: Asian Games in September-October; OIE-FEI mission to Brazil for the Olympics in November; second visit to Azerbaijan for the establishment of an EDFZ in December).

The HHP concept was presented at various meetings and events in 2014 (OIE Regional Commission for Europe in September, Dubai regional OIE – FEI – IFHA conference in October, EU Reference Laboratory for equine diseases in October, FEI Veterinary Committee in November, Federation of Asian Veterinary Associations Congress in November, FEI General Assembly and FEI Regional Groups in December, IFHA International Movement of Horses Committee in December).

The Chair congratulated Drs Münstermann, and Dominguez and the AHG in general for their efforts in progressing the core work of the AHG.

## **6. Translation of general principles into guidance**

### **6.1. Report from the Technical meeting between FEI and IFHA**

The goal of the FEI-IFHA technical meeting that was held on the 2<sup>nd</sup> March was to discuss industry relevant implementation aspects of the HHP concept.

This first meeting was successful in reaching an agreement between FEI and IFHA on certain HHP requirements (e.g. on identification, traceability, certification of FEI veterinarians).



The Industry expressed the need for more detailed scientific guidance on some of the biosecurity requirements (e.g. separation of horses during the preparation period from other horses; distances between stable blocks etc) which they would be able to base their practical recommendations.

During this meeting, the need for a minor change in the Model Health Certificate was identified to better capture the completion of the 90 days preparation period. This will be provided as a comment on the Model HHP Health Certificate.

Another meeting between FEI and IFHA to finalise these discussions will be scheduled very soon.

Dr Murray acknowledged the strong commitment of the equine industry for the development and the success of the HHP initiative.

## **6.2. Discussion of the “Guide to the management of the high health status equine sub-population and the high health performance horse”**

This document had been produced after the last expert sub-group meeting in July 2014 and had been circulated to Member Countries together with the HHP Veterinary Certificate.

Drs Thiermann and Bonbon suggested that a reference should be made in this Guide to the *Terrestrial Code* Chapter 4.3 “Zoning and compartmentalisation” and Chapter 4.4 “Application of compartmentalisation”. This would especially clarify the potential consequences of disease incidents on the status of the compartment. Dr Bonbon recommended to restructure the Guide in time for inclusion into the February report of the Code Commission and to differentiate more clearly the process to qualify as a compartment and the subsequent process to certify HHP horses for travel.

It was once again highlighted that although specific requirements for qualification and certification are provided for six diseases only, all of the OIE listed diseases for equids are encompassed in the HHP concept (through the veterinary supervision aiming at ensuring that all of the horses of the compartment are free from clinical signs of disease). For the diseases other than the six diseases listed in the Certificate, the HHP requirement should not go beyond the *Terrestrial Code*’s provisions. However, any relevant amendment to the *Terrestrial Code*’s provisions identified by the AHG should be communicated to the Code Commission (see also point 13).

A correction must be introduced in the provisions applying to “countries not officially free from AHS”: the horses must **not** be vaccinated 40 days before the introduction into a vector proof stable.

The private veterinarian responsible for the veterinary supervision of the compartment is currently defined in the Guide as “registered with the FEI or IFHA (if appropriate) and preferably accredited for this purpose by the Veterinary Authority”. The participants agreed to strengthen the latter recommendation by removing the word “preferably”. Besides, a certification with the industry would be more appropriate than a registration. The HHP concept should be integrated into the training of these veterinarians by the Industry. The private veterinarians responsible for the veterinary supervision of the compartment would then be defined as certified with the FEI or IFHA and authorised for this purpose by the Veterinary Authority.

The Chair stated that ultimately this Guide should be agreed by the Industry and endorsed by SCAD so that it can be officially endorsed by the OIE and made available on the OIE website.

## **6.3. Discussion of the Model HHP Veterinary Certificate**

Only a few Member Countries commented on the Model HHP Veterinary certificate but the comments received were constructive. Many comments were on the Certificate’s footnotes. The footnote explanations should be incorporated directly into the text of the certificate or clarified in an accompanying document.

Dr Kettle noted that for ground transportation, a transit certificate would be needed. Dr Kettle will draft provisions for transit conditions that will ensure that the high health status of the HHP horses will be maintained during transit.

The provisions for testing for piroplasmosis were discussed. The original draft stipulates that the IFAT **and** the c-ELISA should be used to identify the serological status of the HHP horse (for information to the importing country). There was discussion on the feasibility of this provision, as some countries might not be able to carry out both tests. The weaknesses of both tests were alluded to and the preference of some countries to use the CFT also. The revised Certificate now stipulates to use IFAT **or** c-ELISA. Should the group be of differing opinion, the reasoning should be submitted as a comment to the Code Commission by August.

The options for issuance of the Certificate (currently presented as four tick boxes on the first page of the Certificate), should be more clearly described and explained in the accompanying documents.

#### **6.4. Discussion on the Biosecurity Guidelines for horses in the high health status horse subpopulation and for equestrian events**

Dr Dominguez presented the Biosecurity Guidelines. They are divided into two main sections. The first part presents general considerations related to biosecurity and equine health, while the second provides specific recommendations to ensure biosecurity at home stables, during transport and at the event for the HHP horses. It was agreed to remove the general section in order to focus more on the recommendations specific for HHP horses. It was noted that some of the specific recommendations are not detailed enough to allow a harmonised implementation of the HHP concept, and they will be further developed by an expert group (see 6.a Report from the Technical meeting between FEI and IFHA).

To facilitate the global understanding of the HHP concept by the different stakeholders, it was agreed to limit the number of HHP documents to three: the *Code* Chapter, the Model Veterinary Certificate and a “Handbook” that would join the HHP specific section of the Biosecurity Guidelines, and the current “Guide to the management of the high health status equine sub-population and the high health performance horse”.

The level of prescriptiveness of the biosecurity recommendations was discussed. It was agreed that the “should” was appropriate for most of the recommendations. However, a few biosecurity requirements might constitute imperative criteria to qualify as a compartment or to certify HHP horses; the present tense could be used to prescribe these requirements.

The compliance with all of the biosecurity recommendations will need to be recorded and audited.

### **7. The way forward for the EDFZ concept**

#### **7.1. Update on the recent EDFZ requests**

Azerbaijan wishes to establish a permanent EDFZ on the Absheron Peninsula for the purpose of hosting FEI competitions and racing events to which they would be able to invite European countries. A joint OIE-FEI mission team visited Azerbaijan in March 2014 and a follow up mission was carried out in December 2014. The mission’s assessment was overall positive and provided Azerbaijan with a detailed proposal on the way forward.

Turkmenistan wishes to establish an EDFZ and has requested an OIE technical assistance. The first step would be for Turkmenistan to be officially recognised free from AHS.

#### **7.2. Need for formal procedures for the establishment of an EDFZ**

A prototype framework for the establishment of an EDFZ was developed to provide guidance to Turkmenistan. It lists the different issues that need to be considered for the establishment of an EDFZ.

Dr Kettle noted that the prerequisites for the establishment of an EDFZ should be made more explicit (e.g. quality of the Veterinary Services, etc).

It was well noted that for the establishment of a permanent EDFZ, the constant compliance over time with the requirements would be crucial. A monitoring system and verification process should be implemented (as recommended in the prototype framework) and evidence for compliance would have to be made available to support the self-declaration. Dr Thiermann indicated that the maintenance of the EDFZ over time could be addressed in the OIE annual reports. The EDFZ self-declarations and all of the supportive information, including evidence for the maintained compliance over time, could be published on the OIE website.

Overall, the participants considered that the flexible but comprehensive approach proposed in the prototype framework was appropriate, since the establishment of an EDFZ should remain a customisable concept. The participants didn't see a need for more formal procedures (such as a *Code* Chapter). Based on the framework, the countries should customise a solution that would be convincing to partners.

### **7.3. Visit to Brazil to assess preparations for Olympic Games**

Following a request from the OIE Delegate for Brazil in August 2014, an OIE technical mission with the participation of the FEI was sent in November 2014 to assess and advise on preparations for the equestrian events at the Olympic Games, Rio2016, and test events in 2015. The Team was of the view that the temporary importation of horses to compete in Rio2016 Olympic, Paralympic and 2015 Test Events will present an extremely low risk of disease spread to the competing horses and the national herd, and enable their safe return to countries of origin. Specific recommendations for the way forward were provided by the mission. Brazil decided to use the HHP concept and applicable recommendations.

Dr Pozetti indicated that the health regulations applicable for the Test event and for the Olympic Games have not been published yet. Drs Münstermann, Mc Cormack and Pozetti will review the regulations and associated Health Certificate during this meeting and will provide final comments to MAPA. It was also noted that while horses should have been removed from the Deodoro complex in December to allow the site to achieve a biosecurity status preparatory to the test event in August 2015, this has not been achieved yet. Mr de Vos, Dr John McEwan and Dr Newton expressed strong concerns over these delays and that FEI would take up the issue with responsible authorities.

Dr Fuessel pointed out that four states (including Rio) are free from glanders but the rest of the Brazilian territory is infected, and EU importation from these states is suspended. Dr Fuessel advised that dispositions should be taken urgently to fully separate the Olympic site from the rest of the territory and request regionalisation, so that even if glanders was to be reported in the State of Rio, Brazil would still be able to claim that the Olympic site is glanders free.

Dr Murray reiterated the critical importance of this issue and, on the facts presented, the need for immediate action. He would seek to ensure the OIE Director General was aware of the situation.

### **7.4. EDFZ in the context of official country status for AHS freedom**

Under the HHP concept, individual horses from AHS endemic countries can qualify as HHP horse and be exported under specific requirements provided in the Model HHP Veterinary Certificate, in line with AHS *Code* Chapter provision 12.1.7 (3c).

However, in order to set-up an EDFZ for the purpose of hosting an event in an AHS endemic country, the country would need to follow the provisions of zoning as stipulated in the AHS *Code* Chapter 12.1.2 and submit a declaration of zonal freedom to the OIE. The EDFZ, stipulating freedom from other additional diseases, could be set up in this AHS free zone.

Given the difficulties to establish this AHS free zone in line with the requirements of a 100 km free surveillance zone, an AHS vaccine acceptable to most trading partners and allowing a DIVA strategy could significantly facilitate the movements of horses from endemic countries and could in the long term allow for the temporary movement of horses to South-Africa.

The Chair thanked Drs Bonbon and Thiermann for their clarifications on the applicability of OIE Standards to this matter.

## 8. **Terrestrial Animal Health Code revision for equine diseases**

During the fourth meeting of the AHG (June 2014), some needs for the revision or development of *Terrestrial Code* and *Terrestrial Manual* Chapters were identified. More recently, a letter from IFHA has reinforced these needs.

Dr Bonbon indicated that SCAD was requested to give consideration to the development of a *Terrestrial Code* Chapter on equine trypanosomiasis and has approved of it. An *ad hoc* Group will be established soon. He also recommended the AHG to always provide the scientific basis and evidence that support any request for revision to the *Terrestrial Code* or *Terrestrial Manual*.

Dr Bonbon indicated that the best way to suggest revisions would be for the Delegates or the Industry to submit these requests to the Director General (by the 1st of August).

## 9. **Communication**

Ms Sayed presented the result of a study that provides recommendations for a communication - public relations strategy and the measures necessary for the implementation of the HHP concept by the target publics: the crucial political stakeholders, government veterinary services, national equestrian federation members and the FEI national head veterinarians, among whom a questionnaire survey was carried out in 29 countries.

The survey findings confirmed the importance of communication measures to improve the target public's understanding and knowledge of the concept, particularly since a lack of communication between industry and government was perceived by both sectors.

The study demonstrated the high value of the communication measures already used, such as the government – industry workshops, which showed a significantly better understanding of the concept amongst the participants in areas where regional workshops had already taken place, as opposed to regions where one had not yet taken place.

The study highlighted the importance of the roles of the stakeholder organisations; the OIE, the FEI and the IFHA in creating a transparent, trustworthy and safe environment to facilitate concurrence between the public and private sector on the HHP concept's implementation.

The FEI and the OIE are developing communication plans for the HHP concept. Dr Kettle indicated that the IFHA was aware of the importance of developing communication activities for the Racing sector.

Dr Fuessel noted that online education platforms or online forums could be interesting channels of communication to educate on the HHP concept. Dr Barcos indicated that regional activities would be essential to raise awareness locally. Dr Newton stressed the importance of measuring the effectiveness of the communication activities.

Mr de Vos stated that the communication activities (especially the OIE-FEI-IFHA regional conferences) would have greater impact if they were to be implemented after the full definition of the technical details for the practical implementation of the concept.

It was agreed that suitable and committed 'equine liaison persons' within the veterinary services and/or national industries could play a critical role to raise awareness on the concept and for the government sector to better link and collaborate with the equine industry.

Dr Murray said that the 3 parties on the basis of this discussion, could now usefully finalise their strategies noting that there would be many common messages; and proffered the view that effective communication would be critical for understanding and implementing the HHP concept at the national level.

## 10. Research

Dr Dominguez presented the eight research projects identified on glanders, AHS and equine influenza. A tender will be launched in March. A selection committee will be appointed to award the contract(s).

Participants received a summary of each proposal in their folders. Dr Münstermann explained the wide consultation process with OIE Reference Laboratories, Government personnel and equine disease experts utilised to identify a number of proposals and the process of quality scrutiny that was employed in order to end up with the eight proposals presented to the AHG. She outlined the tender process.

- Glanders:
  - Validation study of a serological diagnostic assay with high specificity and sensitivity for glanders in equids
- Equine influenza:
  - Validation study on real time RT-PCR diagnostic assay(s) for equine influenza in horses
  - Evaluation of current equine influenza vaccination protocols prior to shipment, guided by the OIE standard
  - Evaluation of comparative performance of rapid antigen detection immunoassay kits for equine influenza
- AHS:
  - Evaluation on the availability and efficacy of AHS vaccines and vaccine candidates
  - Estimation of the equine population at risk of and to be protected against AHS by a DIVA vaccine
  - Validation study of a serological diagnostic assay for African horse sickness
  - Evaluation of vector protection methods during loading and transport of horses from AHS endemic countries

The AHG endorsed all eight proposals but identified the following order of priority:

### Priority proposals

- Validation study of a serological diagnostic assay with high specificity and sensitivity for glanders in equids
- Validation study on real time RT-PCR diagnostic assay(s) for equine influenza in horses
- Evaluation on the availability and efficacy of AHS vaccines and vaccine candidates
- Estimation of the equine population at risk of and to be protected against AHS by a DIVA vaccine;
- Validation study of a serological diagnostic assay for African horse sickness

### Proposals with less priority

- Evaluation of current equine influenza vaccination protocols prior to shipment, guided by the OIE standard
- Evaluation of vector protection methods during loading and transport of horses from AHS endemic countries

- Evaluation of comparative performance of rapid antigen detection immunoassay kits for equine influenza

Dr McEwen reminded the AHG that the FEI also contributed for research projects and wanted FEI to be considered as a full partner in the proposed research projects.

In the context of these research related activities of the project, Dr Münstermann mentioned the ongoing ring test for the validation of a rt-PCR ring test between OIE Reference Laboratories and some invited laboratories. A need for a workshop was identified to discuss the outcome of this ring test and to develop a way forward, as this exercise did not include all currently used PCR protocols and was also unable to compare all protocols included in the ring trial in each laboratory. Dr Fuessel supported the proposal to discuss the results and suggested to use the EU Reference laboratory network meeting for such a discussion. However, as this meeting takes place only in November, the OIE was requested to consider supporting an earlier discussion.

The Chair indicated that if sufficient funds were available, all projects could be funded; but if funding is limited, the preference should be given to the priority group of proposals. He expressed the hope that the OIE would commence the tender process as soon as practical.

## 11. Update on the project workplan

Dr Münstermann presented the project workplan. The FEI funding will support the project until April 2016. The IFHA funding, which has started on September 2014, will support the project until August 2019.

The development of standards and guidelines has been a continuous activity since the beginning of the project (new *Code* chapter(s), technical guidelines on the HHP concept, revision of the *Terrestrial Code* and *Terrestrial Manual*). PVS critical competencies for the veterinary certification of horse movements have been developed.

The FEI funding supports the organisation of OIE-FEI-IFHA regional conferences. It was noted that FEI wishes to wait for the practical implementation guidance of the concept to be finalised before organising new conferences (see 9. Communication). Mr de Vos pointed out that if some regional conferences were to be organised after April 2016 a “no cost extension” for the FEI funding might be considered.

In the regions where no regional conference has been organised so far (e.g. Africa, Europe), the organisation of a conference with the main purpose to raise awareness is agreeable to the FEI without waiting for more technical content to be finalised, if funding could be provided by the host country.

The Chair noted the comments and indicated the workplan would need to be updated on a regular basis to take into account for example, the new timing for the communication activities.

## 12. Future of the AHG

Dr Murray indicated that the AHG had completed its terms of references (principles of the HHP concept have been defined and adopted, Biosecurity Guidelines are about to be finalised, priority diseases for temporary movement of sport horses have been identified, needs for revision of the *Terrestrial Manual* and *Code* Chapters have been identified, research issues have been identified, a framework for the establishment of an EDFZ has been developed, and technical assistance has been provided to countries for the establishment of EDFZ).

The success of the work of the AHG will be measured by the future adoption of the concept and its successful implementation in the field.

Dr Murray informed that he had been advised that there was, in effect, no funding left for the organisation of further AHG meetings under the FEI contribution. As such he suggested that the Group should interact mostly electronically from now on. Dr Kettle indicated that if specific needs for an AHG meeting were to arise in the future, the IFHA might consider additional funding. Dr Newton noted the AHG may also seize the opportunity

to meet during events which most of the members of the AHG would attend, such as the Equine Infectious Diseases Conference that will be held in April 2016 in Argentina. Dr Cullinane suggested that a session of this conference could be dedicated to international horse movements.

### 13. Conclusions and resulting actions and recommendations

The outcomes of the Industry meetings to develop industry relevant aspects of the concept will be critical for the success of the HHP initiative. If the handbook supporting the operationalisation of the concept was to be finalised by August, it could then be circulated for Member Countries 'comments together with the Model HHP Veterinary Certificate.

Dr Münstermann and Dr Timoney will draft the terms of reference for a multidisciplinary experts group that would further define the biosecurity requirements on the basis of risk assessments, in order to provide a more detailed scientific guidance to the Industry. The AHG members are invited to manifest their interest in participating in such a group or to indicate any expert that would be relevant for this work.

Dr Kettle will draft a comment to address the transit conditions in the Model Health Certificate.

The data and all of the documents supporting the self-declaration (and maintenance) of an EDFZ should be made available on the OIE website.

For success of the test event and the Olympics in Brazil, it is critical (i) to regionalise the site as soon as possible, (ii) to publish the health regulations without further delay. The OIE Director General might bring these recommendations to the attention of Brazil.

A good communication on the HHP initiative will be critical for the future adoption of the concept. Communication activities will be increased, once the technical content of the concept will have been fully finalised, including the full definition of practical implementation of the concept by the Industry. The OIE and the equine industry will align their messages in order to foster collaborations between the public sector and the industry, at national levels.

The AHG may meet again in the future should specific needs arise at the determination of the Director General.

The request for revision of certain *Code* Chapters, as highlighted in previous AHG meetings and requested in the letter of IFHA to the OIE DG of 4.2.15 was reiterated to the attention of the Code Commission and SCAD:

- Review of *Terrestrial Code* Chapter 8.8 (Japanese encephalitis) and Chapter 12.4 (equine encephalomyelitis, Eastern and Western) to include text similar to that in Chapter 8.17 (West Nile Fever) "*Member Countries should not impose trade restrictions on dead-end hosts such as horses*"
- Testing for piroplasmosis (Article 12.7.2)
- Timing of the issuance of a health certificate (Appendix H of Chapter 5.12)
- Timing of equine influenza vaccinations of horses moving temporarily (Article 12.6.3)

Dr Murray thanked the participants for the contributions and progress that they had made in meeting the ToR; he acknowledged the significant support that the OIE has given to the Group; the major steps made by the Industry to take the concept forward; and the strong efforts that will now have to be made to implement the concept at national levels.

**14. Follow-up action**

- Establish an expert sub-group on industry specific biosecurity requirements (see 6a). Proposed timing: *end of July 2015*.
- Provide support to a Workshop to discuss the outcome of an rt-PCR Ring trial between OIE Reference Laboratories and invited labs to discuss the outcomes and the way forward (see 10). Proposed timing: *beginning of June 2015*.
- Organise an OIE *ad hoc* Group on equine trypanosomosis, incl. Surra. Proposed timing: *beginning of July 2015*.

**15. Finalisation and adoption of the draft report**

The Group agreed that the report would be subject to a period of circulation within the Group for comments. The report will be finalised through correspondence.

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.../Appendices



Appendix I

## MEETING OF THE OIE AD HOC GROUP ON INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT

Paris, 3–5 March 2015

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### Agenda

**Objectives of the Meeting:** discuss the outcomes and implications of member countries' comments of the AHG report; consider key documents including the HHP health certificate, operationalisation proposals, biosecurity guidelines and EDFZs; examine the *Terrestrial Code* and *Manual* and need for revisions; review the effectiveness of AHG work activities and as appropriate modify approaches; examine research and communication needs; and update the Workplan.

#### Tuesday, 3<sup>rd</sup> March 2015

9.30 – 13.00

- Welcome by the Chair, objectives of the meeting, apologies and introductions
- Acceptance of the Agenda
- Record of the forth meeting
- Presentation of the OIE member country comments, SCAD and Code Commission observations
  - Discussion on the consequences of the decision
- Review of actions arising and achievements

14.00 – 18.00

#### **Topic 1** *Translation of general principles into guidance*

Report from the Technical Meeting between FEI and IFHA

Discussion and revision of the following documents, in light of the technical recommendations:

- Operationalisation proposal
- HHP health certificate
- Revised Biosecurity Guidelines

#### Wednesday, 4<sup>th</sup> March 2015

9.00 – 13.00

#### **Topic 2** *The way forward for the EDFZ concept*

- Update on the recent EDFZ requests: Azerbaijan, Turkmenistan
- Discussion on the need for more formal procedures based on a draft prepared for Turkmenistan
- Report on visit to Brazil to assess preparations for Olympic Games
- Discussion on EDFZ in the context of official country status for AHS freedom
  - The case of African countries

14.00 – 18.00

#### **Topic 3** *Terrestrial Animal Health Code revision for equine diseases*

- View of SCAD to prepare a Surra chapter
- Is there a need for revision of other *Code* and *Manual* chapters (IFHA request)

#### **Topic 4** *Communication*

- Communication plan for the HHP project
  - Presentation of an integrated OIE – FEI communication plan
    - Background and development
    - Proposed elements of communication plan for FEI and OIE
  - Identification of Communication needs for IFHA

**Thursday, 5<sup>th</sup> March 2015**

9.00 – 13.00

***Topic 5 Research***

- General discussion on research priorities expressed by IFHA and FEI
  - Outline of research topics developed for the tender procedure
  
  - Update of the work plan
  
  - General discussion on
    - successes so far,
    - need to rebalance activities,
    - future of AHG and options for progressing its ToR
  
  - Conclusions
  - Recommendations
  - next meetings:
    - sub-group meetings
-

## Appendix II

**MEETING OF THE OIE AD HOC GROUP ON INTERNATIONAL HORSE MOVEMENT  
FOR EQUESTRIAN SPORT  
Paris, 3–5 March 2015**

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**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN ANIMALS  
Paris, 21 – 23 April 2015**

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**1. Opening**

The OIE *ad hoc* Group on Prioritisation of Diseases for which Vaccines could reduce Antimicrobial Use in Animals met from 21 to 23 April 2015 at the OIE Headquarters in Paris, France.

Dr Bernard Vallat, Director General of the OIE, welcomed the participants and noted the growing importance of antimicrobial resistance. He explained that the OIE as a science-based organisation was responsible for developing intergovernmental standards on animal health and welfare and advice on animal health matters. For the 'One Health' agenda of the FAO, OIE and WHO, antimicrobial resistance was selected as one of three Tripartite flagship topics. The OIE was very supportive to the WHO in the development of the Global Action Plan on antimicrobial resistance proposed for adoption to the World Health Assembly of the WHO in May of this year, and was pleased to note that its comments on the draft plan had been accepted and that its work been recognised in the document. As part of its contribution to the international efforts to fight against antimicrobial resistance, the OIE was committed to launch a global database to collect data on antimicrobial use in animals before the end of the year, acknowledging that it will be difficult for some countries to respond. Other OIE initiatives relevant to the fight against antimicrobial resistance include an initiative, in collaboration with the World Customs Organisation, to prevent counterfeit products and the OIE initiative to improve good governance of veterinary services through the PVS pathway, contributing to the availability of quality antimicrobials and their responsible use in animals. The *ad hoc* Group represented a new approach of the OIE to address requests from several countries and organisations for information on where to invest to reduce the use of antimicrobials in animals, especially in view of the projected production growth for poultry, pigs and fish, which is most likely to happen in intensive production settings with the accompanying challenges. The outcome of the Group's work should provide direction to policy makers on where to invest in research to reduce the need for antimicrobial use in animals with a focus on vaccines. The conclusion of the Group's work might be that there are already good vaccines that are not being used. In these cases the OIE would hope for direction on what actions would be necessary to improve utilisation of such vaccines. The WHO Global Action Plan makes provision for such an approach and the Group's work, through the participants' expertise, represented the OIE's contribution to this goal.

The participants highlighted the need to not only inform investors in research but also to inform the research community.

**2. Appointment of chairperson and rapporteurs, and adoption of the agenda**

The Group appointed Dr Cyril Gay as the chairperson of the meeting and Professor Peter Borriello agreed to act as rapporteur for the joint discussions, and for the subgroup focussing on terrestrial animal species; the discussion on fish would be reported by Dr Mylrea and Dr Berthe (president of the Aquatic Animal Health Commission).

The Agenda, adopted with minor changes, and the List of Participants are presented in Appendices I and II of this report, respectively.

### **3. Background to the meeting**

Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, provided a short introduction to the OIE, its mission, the current strategic plan, its standard setting and animal health reporting activities, and its approach to providing scientific advice. The work of this Group was part of the provision of scientific advice activities of the OIE, and is not related to its standard-setting activities. Both terrestrial and aquatic animals were considered.

The participants introduced themselves to the Group and presented relevant background information from their specific fields of expertise, and discussed commonalities for the two sectors.

### **4. Review and address the Terms of Reference for the *ad hoc* Group meeting**

The Group heard the background information presented by the participants and considered the draft Terms of Reference (attached in Appendix III of this report).

The Group noted that there was a lack of scientific research generated globally with the aim of understanding which antimicrobials are used in which animal groups, and for which diseases or syndromes they are prescribed. The background information, whilst helpful in providing some data, was generated to answer other scientific questions and did not fully address the scientific questions considered by the Group.

The Group agreed that in view of the current scale and the projected growth in production for aquaculture, poultry and swine, an initial focus on these production sectors was the highest priority.

Regarding aquaculture the Group noted that the current scale of fish farming and high antibiotic use, and projected growth of both, ruled that it should also be included. However, there is a range of different freshwater and marine farmed fish species with differences in scale of production and production methods. Particular species of fish were therefore identified on the basis of overall and projected contribution to antibiotic use. Although there was antibiotic use in shrimp, the absence of a classical immune system would not support vaccine development.

The Group did not consider it necessary to adjust the Terms of Reference for the meeting. However, the Group agreed that the focus of their activity were antibiotics (substances that destroy or inhibit growth of bacteria), not antimicrobials.

### **5. Development of a template and criteria for the ranking of diseases**

#### **5.1. General considerations**

Vaccination has had a profound impact on the prevention of infectious diseases, perhaps equivalent to the impact of good hygiene and of the use of antibiotics to treat bacterial infections.

Arguably, vaccines represent the single most cost-effective medical countermeasure that can be used to confront the threat of antimicrobial resistance. Their effectiveness in preventing diseases has been far-reaching, and could significantly reduce the need and use of antibiotics in animal agriculture.

It was acknowledged, however, that vaccines optimally fulfil their potential when used as part of an overall programme of infection prevention and infection control. Such a programme would be inclusive of veterinary oversight, good biosecurity and husbandry practices, quality feed, and improved diagnostics to help ensure pathogen specific, targeted treatment. All of the above, when implemented optimally, will result in reduced, as well as more appropriate, antibiotic use. In particular it was acknowledged that much first line treatment is currently empirical, based on experience and in response to syndromic indications, e.g. diarrhoea. Reduction of syndromic indications through better targeted, easy to use, potentially multivalent vaccines has the potential to reduce the need for use of antibiotics.

Although diagnostic tests are often available the effective application in aquatic animals is hampered by multiple factors. Diseases usually show few specific clinical signs. In addition, the observation of clinical signs is generally difficult because of limited access to visualise sick fish. The diagnosis of a primary pathogen is often difficult due to the rapid invasion by secondary pathogens. As a result there is a significant non targeted use of antibiotics. Therefore the availability of vaccines that are well targeted may not directly result in a reduction of antibiotic use without field data demonstrating their effectiveness as part of a comprehensive disease control programme.

Increasing highly efficient animal production and providing equitable availability of food to a rapidly rising human population, while reducing antibiotic use in animal production and maintaining a sustainable environment, represent a considerable global challenge. Vaccines, in enabling the production of healthy animals, have already played a key role in expanding intensive farming practices that are providing access to high quality animal protein to a growing world population.

The aim of reduction of antibiotic use in food animal production presents a huge opportunity for vaccinology. The challenge presented by highly adaptable bacterial pathogens and by the complexity of developing effective vaccines, including the difficulties of immunization of young animals, should not be underestimated.

The research to support the development of multivalent vaccines should potentially cover a broad range of issues and disciplines, including discovery of new aetiological agents for inclusion in such vaccines, and, to close the diagnostic gap, identification of improved surrogate markers of protective immunity. It should also include an understanding of the mechanisms of interference and diminished efficacy that can be a consequence of combined vaccines. Encouragingly, new technologies and a major shift on how we approach vaccine discovery research may provide new opportunities for addressing these challenges.

## **5.2. Development of the template**

The participants discussed in detail the development of a template and guiding criteria for the ranking of diseases for the purpose of stimulating research into new or better adapted vaccines with the aim to achieve a reduction in the use of antibiotics in animals.

The Group discussed that in many cases a reduction of antibiotic use in chickens, swine and fish could be achieved by effective vaccines against a viral or parasitic disease, as some of these pathogens provided opportunities for subsequent bacterial infections.

It was noted that for many candidate diseases there might be pathogens for which effective vaccines existed. However, the degree, breadth, or duration of protection afforded was not optimal, thus providing a barrier to uptake of the vaccine.

For other situations the Group discussed that existing vaccines might be based on outdated production technology or delivery technology that would benefit from research investment into vaccines more adapted to the challenges of modern animal production, particularly in the light of projected production increase.

The Group agreed that the focus had to be on identification of where a new or improved vaccine would have the maximum effect on reducing antibiotic use. In doing so, it did not capture in the report vaccine development or improvement needs that were not considered as reducing antibiotic use significantly.

## **6. Proposed chicken, swine and fish diseases where development or improvement of vaccines would have a high impact on antibiotic use**

### **6.1. Key principles adopted**

In order to facilitate identification of infections where new or improved vaccines would have the maximum potential to reduce antibiotic use, a number of key considerations were agreed and applied:

1. Identification of the most prevalent and important bacterial infections in chickens, swine, and identification of fish species that are commonly farmed and associated with high antibiotic use, and associated prevalent bacterial infections in those species.

2. Identification of common non-bacterial infections in chicken, swine and fish (e.g. protozoal, viral) showing clinical signs that trigger empirical antibiotic treatment (e.g. for diarrhoea) and which also result frequently in bacterial co-infection.
3. An assessment of antibiotic use in response to the syndromic indication or diagnosed disease. This was categorised as high, medium or low in the context of considered use compared with the total use of antibiotics in that animal species.
4. The availability of a vaccine(s), and if available, their effectiveness.
5. The potential for a new or improved vaccine to reduce the need for antibiotic treatment.

Factors, other than vaccine design, which influence utilisation of a vaccine were considered out of scope.

Also considered out of scope were autogenous vaccines, primarily because of lack of broad applicability across time and space, registration variability and the absence of key efficacy data.

It was accepted that unless effective vaccines are available and widely used, their impact on reducing antibiotic use would be diminished.

## 6.2. Limitations

As a consequence of adopting the above criteria it became evident that there were many data gaps. For example, a current list of all available vaccines that have marketing authorisation, amount of antibiotic use for different infections, and relative incidence of different infections worldwide are not available. The conclusions of the report are therefore based on considerations weighted mostly on available expert opinion.

Key references consulted during the discussions are listed in Appendix IV of this report.

## 6.3. Poultry diseases

The Group concluded that the considerations would be restricted to chickens as this species was farmed more globally than turkeys and dominated compared to other farmed avians (e.g. ducks, game birds). Within chickens there were differences in disease prevalence, vaccine availability and optimised delivery routes, and for broilers, breeders and layers the infections were therefore considered in this context. In total, two bacterial pathogens, *Escherichia coli* (*E. coli*) and *Clostridium perfringens* (*C. perfringens*), were identified where an improvement on the current vaccines would result in an important reduction in antibiotic use (Table 1). Despite the availability of vaccines, there is still high use of antibiotics in broilers, breeders and layers to treat a range of systemic diseases caused by *E. coli*, such as yolk sac infection (omphalitis), airsacculitis, cellulitis, salpingitis, and peritonitis. *E. coli* develop resistance to antibiotics and frequently on transferable elements, making it a high value target for improved vaccine coverage. An important limitation of the current vaccines is the degree of strain coverage, and issues of ease of delivery. A challenge is to produce a fully cross-protective vaccine that is easy to administer (e.g. aerosol) with minimal adverse effects. An additional general challenge is the production of vaccines with protective immunity in the very young chicken, partly due to presence of maternal immunity.

High antibiotic use for necrotic enteritis caused by *C. perfringens* Type A remains an issue. The duration of passive immunity induced by toxoid vaccines in layers is short lasting. There remains the need for a vaccine to achieve active immunity, particularly for broilers.

Coccidial infection predisposes to secondary bacterial infections (Table 1), and improvement in the degree of cross-protection of current vaccines would result in a decrease of secondary bacterial infection and consequently diminish use of antibiotics.



Regarding viral infections in chicken, it was recognised that several respiratory and enteric viruses may predispose to secondary bacterial infection, but the group considered both infectious bronchitis and Infectious Bursal Disease Virus (IBDV) in broilers to be particularly problematic in this context to a degree that resulted in a classification of at least medium use of antibiotics. Areas for improvement include the range of strain coverage (infectious bronchitis), maternal antibody interference, and the short window of opportunity to efficiently vaccinate (IBDV).

**Table 1: Infections where new or improved vaccines would significantly reduce the need for antibiotic use in chickens**

Key syndrome	Primary pathogen(s) (disease)	Antibiotic use	Commercial* vaccine exists	Major constraints to use of vaccine / vaccine development	Vaccine research priority
Systemic (Broilers)	<i>Escherichia coli</i> (Yolk sac infection, airsaccuinitis, cellulitis)	High	Yes	<ul style="list-style-type: none"> <li>• Omphalitis: secondary bacterial infection – not a disease one can immunize against</li> <li>• Strain coverage limited</li> <li>• Airsaccuinitis, cellulitis: vaccines available, e.g. live aerosol vaccine. However, Serotype coverage limited and field efficacy variable</li> </ul>	High
	<i>Infectious Bursal Disease virus</i> (secondary bacterial infections)	Medium	Yes	<ul style="list-style-type: none"> <li>• Issues with vaccine application</li> <li>• Short window of opportunity to vaccinate</li> <li>• Maternal antibody interference</li> </ul>	Medium
Systemic (Breeders, Layers)	<i>Escherichia coli</i> (airsaccuinitis, cellulitis, salpingitis and peritonitis)	High	Yes	<ul style="list-style-type: none"> <li>• Strain coverage limited</li> </ul>	High
Enteric (Broilers, Breeders, and Layers)	<i>Clostridium perfringens</i> , type A (necrotic enteritis)	High	Yes	<ul style="list-style-type: none"> <li>• Toxoid vaccine for layers providing only short-lasting passive immunity</li> <li>• Research needed to achieve active immunity.</li> <li>• Improved and/or more convenient (mass vaccination) vaccine needed for broilers</li> </ul>	High
	Coccidiosis (secondary bacterial infections)	High	Yes	<ul style="list-style-type: none"> <li>• Lack of cross-protection</li> <li>• Strains must be matched to infectious agent</li> <li>• Current vaccines are not attenuated and can produce low dose infection</li> <li>• Sub-unit vaccines have not been successful</li> </ul>	High
	<i>Infectious Bronchitis virus</i> (secondary bacterial infections)	Medium	Yes	<ul style="list-style-type: none"> <li>• Issues with strain matching and strain coverage</li> <li>• High mutation rate of virus</li> </ul>	Medium

\* does not cover autogenous vaccines

#### 6.4. Swine Diseases

Eight bacterial pathogens and three viral infections (resulting frequently in secondary bacterial infections) were identified where antibiotic use was high, and one (*Haemophilus parasuis* (*H. parasuis*)) where use was considered to be medium (Table 2).

For systemic and respiratory disease authorised vaccines are available in all but one case: pneumonic disease caused by *Pasteurella multocida* (*P. multocida*), though an effective toxoid vaccine for atrophic rhinitis exists. For the bacterial infections common limitations for existing *Streptococcus suis* (*S. suis*), *H. parasuis* and *Actinobacillus pleuropneumoniae* (*A. pleuropneumoniae*) vaccines are the range of pathogen strain coverage and degrees of cross-protection. For example, it would be useful to have a vaccine to protect against *S. suis* infections that, in addition to the current strain 2, also protected against other strains (e.g. 1 and 14). Further individual vaccine specific issues are the relatively poor

immunogenicity of existing *S. suis* vaccines (in common with other capsule based vaccines), and maternal antibody interference with the *H. parasuis* vaccine. For *Mycoplasma hyopneumoniae* (*M. hyopneumoniae*), the vaccine does not eradicate the pathogen and lung lesion formation is not completely prevented. Two common viral infections causing respiratory disease were identified where secondary bacterial infection and consequential antibiotic use were considered high. These were Porcine Reproductive and Respiratory Syndrome (PRRS) virus and Swine Influenza virus (SIV). For both, current constraints are strain coverage and sub-optimal cross-protection. Further, for PRRS the rate of virus mutation and potential vaccine effectiveness evasion may be a challenge. PRRS is an important contributor to the porcine respiratory disease complex. For SIV, there are issues of limited efficacy in piglets and vaccine associated adverse reactions, in particular enhancement of respiratory disease.

For enteric diseases, three key bacterial pathogens, *E. coli*, *Lawsonia intracellularis* (*L. intracellularis*) and *Brachyspira hyodysenteriae* (*B. hyodysenteriae*) were identified as being associated with high or moderately high antibiotic use. For *B. hyodysenteriae* associated dysentery, it was recognised that other *Brachyspira* spp. may also be aetiological agents (e.g. *B. pilosicoli*). This disease appears to be re-emerging following a long period of active control through changed husbandry practices. The reasons for the re-emergence are unknown. The fact that the genus is anaerobic with additional non-routine culture requirements, and that more than one species can cause disease, are issues that may complicate effective vaccine development. Although currently antibiotic use is not as high as for some of the other causes of swine enteric disease, it is a growing problem which is further complicated by emergence of resistance to antibiotics authorised for use in pigs.

Despite the availability of an effective *L. intracellularis* vaccine there are other limitations which may prevent more widespread adoption. These include the need for an antibiotic free window for vaccination (it is a live attenuated vaccine), and that in the face of increasing *Brachyspira* infection antibiotic coverage to deal with both pathogens would be more pragmatic. The development of a vaccine for *brachyspira* infection may further support uptake of the vaccine for *L. intracellularis*.

*E. coli* is a common cause overall for diarrhoea in swine, but particularly for weaners/finishers. Effective maternal vaccines which provide passive immunity to neonates exist, but for *E. coli* vaccines in weaners/finishers complications are maternal antibody interference and the relatively short window for induction of immunity.

Of the viruses that cause enteric disease in pigs, rotaviral infection was considered as a significant cause of empirical antibiotic use in response to diarrhoea. An authorised vaccine is available, however its adoption is limited and currently the reasons limiting wider adoption are unknown.

A common feature of respiratory and enteric infections in pigs is that despite the availability of authorised vaccines antibiotics are still frequently used to treat various pathogens. This indicates that research which addresses the current limitation of the vaccines and the need for improved diagnostics has potential to remarkably reduce the need for and use of antibiotics in pigs.

**Table 2: Infections where new or improved vaccines would significantly reduce the need for antibiotic use in swine**

Key syndrome	Primary pathogen(s) (disease)	Antibiotic use	Commercial* vaccine exists	Major constraints to use of vaccine / vaccine development	Vaccine research priority
Systemic (respiratory)	<i>Streptococcus suis</i>	High	Yes	<ul style="list-style-type: none"> <li>Strain coverage too narrow</li> <li>Lack of cross-protection</li> <li>Poor immunogenicity due to being a capsule based vaccine</li> </ul>	High
	<i>Haemophilus parasuis</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Serotype specific with variable cross-protection</li> <li>Maternal antibody interference</li> </ul>	Medium
Respiratory	<i>Pasteurella multocida</i> (for pneumonic disease)	High	No	<ul style="list-style-type: none"> <li>No vaccine with approved label claim for pneumonia (There is a vaccine for atrophic rhinitis)</li> </ul>	High
	<i>Mycoplasma hyopneumoniae</i>	High	Yes	<ul style="list-style-type: none"> <li>Does not completely prevent lung lesions</li> <li>Animals continue to shed pathogen</li> <li>Diagnostics not always accurately done</li> </ul>	Low
	<i>Actinobacillus pleuropneumoniae</i>	High	Yes	<ul style="list-style-type: none"> <li>Limited coverage</li> <li>Good immunity only if serotype specific</li> <li>Sub-unit vaccine which affords cross-protection</li> </ul>	High
	Porcine Reproductive and Respiratory Syndrome virus (secondary bacterial infections)	High	Yes	<ul style="list-style-type: none"> <li>Strain coverage limited</li> <li>High virus mutation rate</li> <li>Modest cross-protection</li> <li>Vaccine evasion</li> </ul>	High
	Swine Influenza Virus (secondary bacterial infections)	High	Yes	<ul style="list-style-type: none"> <li>Strain matching</li> <li>Vaccine-associated enhanced respiratory disease (VAERD)</li> <li>Lack of cross-protection</li> <li>Efficacy in piglets limited</li> </ul>	High
Enteric – neonatal	<i>Escherichia coli</i>	High for the syndrome, Low for <i>E. coli</i>	Yes	<ul style="list-style-type: none"> <li>Maternal vaccine provides effective lactogenic immunity</li> <li>Coverage of enterotoxigenic <i>E. coli</i> may occasionally need to be updated</li> </ul>	Low
Enteric (weaners/finishers)	<i>Escherichia coli</i>	High	Yes	<ul style="list-style-type: none"> <li>Maternal antibody interference</li> <li>Short window for induction of immunity</li> </ul>	High
	<i>Lawsonia intracellularis</i>	High	Yes	<ul style="list-style-type: none"> <li>Other pathogens in the syndrome (<i>Brachyspira</i>) not included</li> <li>Antibiotic-free window for vaccination required (live attenuated oral vaccine)</li> </ul>	Low (see also <i>Brachyspira</i> )
	<i>Brachyspira</i> spp <i>B. hyodysenteriae</i> , <i>B. pilosicoli</i>	Medium-high	No	<ul style="list-style-type: none"> <li>Low current research investment as changes in husbandry largely eliminated the disease</li> <li>Technical barriers to vaccine development</li> </ul>	High
	Rotaviruses (secondary bacterial infections)	High	Yes	<ul style="list-style-type: none"> <li>Reasons limiting wider adoption unknown</li> </ul>	High

\* does not cover autogenous vaccines

## 6.5. Fish Diseases

Aquaculture deals with a very large number of species (>200 species). According to latest FAO statistics (FishStat. 2015), global production of cultured aquatic animals is 72 million tonnes in 2013. Of this total, 57% were freshwater fish, which accounted for 38% cyprinids (mainly carps), 6% cichlids (mainly tilapias) and 1% freshwater salmonids (mainly trout and salmon smolts). Among the marine aquaculture production, 4% accounts for salmonids, while 3.2% accounted for other marine fish.

In keeping with the guiding criteria agreed by the Group, there was a focus on species that are most produced and in which antibiotic use is believed to be most used. Considering the current production statistics and future forecast, combined with experience and knowledge on the use of antibiotics in production systems, the following categorisation was considered important for the analysis: cyprinids (mainly carps), cichlids (mainly tilapias), freshwater salmonids, marine salmonids, other marine fish.

It was also noted that not all species will equally contribute to the continuing growth of aquaculture and efforts should be focused on those species that are likely to become dominant in the future considering the expected development of aquaculture; the likely predominance of tilapia was recognised, identifying this as a priority species to be addressed.

The Group recognised that in freshwater salmonids penetration of the different markets with a number of commercially available vaccines is limited. The significant registration and application costs limit their use because the majority of production systems are scattered production units producing low total biomass.

The Group noted the contrasting picture where the use of antibiotics in freshwater cyprinids per kilogram of biomass is less than in marine fish aquaculture, however the volume of freshwater cyprinid aquaculture is much greater than the volume of marine fish production. As a result the total antibiotic usage volume in cyprinid aquaculture on the global scale is high.

Fish are poikilothermic, cultured in different environments (covering a wide range of water temperatures and salinity), which has implications on the immunological response to vaccines. In fish, an additional constraint is that they are normally exposed to the pathogen before vaccination is technically possible. For example, hatcheries implement strategies for pathogen exclusion which often includes water treatment with antibiotics.

In some of the major fish species, there are practical constraints to the application of classical injectable vaccines in large numbers of individual fish. These constraints include the need to bring fish out of the water which requires handling and anaesthesia, skilled staff, dedicated equipment, and application costs. In addition, the procedure induces stress so when not carried out properly the procedure itself may be detrimental to individual fish. Because of these constraints the practice of mass vaccination has been almost exclusively applied to high value fish species. The Group recommended that research be undertaken to address the safe and affordable application of vaccination to large populations.

Oral and bath vaccination are available only to a limited extent because the protective immune response induced is of short duration and dosing is not as controllable as injectable vaccines. A recommendation is that research be undertaken to address the question of adjuvants in support of alternative application technologies.

In aquatic animals there is a general lack of registered, efficient anti-parasitic drugs. As a result parasitic infections are widespread which often result in secondary bacterial infections. Secondary bacterial infections also arise from viral and fungal infections, and stress resulting from handling fish (sorting, transport, vaccinating). Therefore, availability of vaccines for viral infections and improved management of parasitic infections would also likely reduce the need for antibiotics, in keeping with terrestrial animals.

Worldwide, commercial vaccines are available for 18 bacterial infections (Pridgeon and Klesius, 2012). The majority of these vaccines are commercially available in only a limited number of countries. Vaccination is a common practice for only a limited number of marine species e.g. salmonids, yellow tail and flounder, sea bass and sea bream. Among the freshwater species vaccination in tilapia is being introduced.

It was noted that reduction in the use of antibiotics in the Norwegian salmon industry as a result of the use of vaccines is a frequently used example. The Group also reviewed the success of the yellowtail industry in Japan where vaccination has also been successful in reducing use. The success of vaccination also depends on the broader context where it is applied. There are limitations in the extrapolation of these

examples to other countries where aquaculture is based on multi species, industry is scattered into small production units, and where new emerging bacterial diseases are common and require antibiotic use as first line management.

Table 3: Infections where new or improved vaccines would significantly reduce the need for antibiotic use in fish

Key syndrome or disease	Primary pathogen(s)	Antibiotic use	Commercial* vaccine exists	Major constraints to use of vaccine / vaccine development	Vaccine research priority
<b>Freshwater cyprinids</b>					
Systemic bacterioses	<i>Aeromonas hydrophila</i> and other species	High	No	• Disease is caused by a wide range of serotypes	High
Dermal bacterioses / red spot disease	<i>Pseudomonas</i> spp.	High	No	• Disease is caused by a range of species and wide range of strains and serotypes	High
Columnaris	<i>Flavobacterium columnare</i>	Medium	Yes	• Limited uptake by some countries for unknown reasons	Low
<b>Freshwater cichlids</b>					
Systemic/dermal bacterioses	<i>Aeromonas hydrophila</i> and other species	Medium	No	• Disease is caused by a range of species and wide range of strains and serotypes	Medium (not low because of projected increase in production)
	<i>Streptococcus iniae</i> , <i>S. agalactiae</i>	Medium	Yes	• Industry awareness of need is low (first vaccine only became recently available)	Medium
<b>Freshwater salmonids</b>					
Systemic bacterioses	<i>Aeromonas salmonicida</i> , <i>Yersinia ruckeri</i> , <i>Flavobacterium psychrophilum</i> , <i>Vibrio anguillarum</i>	Medium	Yes (multivalent, injectable)	• cost of vaccine is high relative to harvest value	Low
<b>Marine salmonids</b>					
Salmon Rickettsia Syndrome	<i>Piscirickettsia salmonis</i>	Medium	Yes	• Multivalent vaccine which provides low protection for <i>P. salmonis</i> compared to other pathogens included in the vaccine.	Unknown because the recent introduction of an oral monovalent vaccine booster may improve the level of protection
<b>Other marine fish</b>					
Systemic / dermal bacterioses	<i>Vibrio</i> spp., <i>Photobacterium</i> spp.	Medium	Yes	• Disease is caused by a wide range of serotypes • Industry awareness is low in some countries	High
	<i>Streptococcus</i> spp.	Medium	Yes	• Disease is caused by a wide range of serotypes • Industry awareness is low in some countries	High
<b>Catfish</b>					
Systemic	<i>Edwardsiella ictaluri</i> , <i>E. tarda</i>	Medium	Yes (for Channel catfish)	• Vaccines are not available for African catfish (an important farmed species) • Vaccines have very recently become available for Tra catfish and yet to be adopted by the industry	High (for African catfish)
Systemic	<i>Aeromonas hydrophila</i> and other species	Medium	No	• Disease is caused by a wide range of serotypes	High

\* does not cover autogenous vaccines

**7. Agree on an overall priority list of animal diseases where availability of vaccines could reduce the use of antimicrobials taking into account technical and financial constraints to vaccine usage**

The Group agreed that effective vaccines for the diseases listed in Table 1-3 could significantly reduce the use of antibiotics in swine, poultry, and fish farming. It was acknowledged that significant scientific and technical hurdles exist. However, an overarching investment in vaccine research could have a significant impact, particularly if the research addressed the following four priority gaps:

1. Maternal antibody interference
2. Cross-protection or inclusion of relevant strains in vaccine formulations
3. Occurrence of immunological interference in multivalent vaccines
4. Innovative delivery systems to enable mass-vaccination

**8. Any other issues**

The Group suggested that the report be distributed for consideration to funders of research, global animal health research organizations (e.g., STAR-IDAZ), and that global vaccine research networks be created to pull resources and expertise to address gaps for each of the priority diseases listed in Table 1-3..

**9. Finalisation and endorsement of the draft report**

The Group adopted the report.

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.../Appendices

Appendix I

**AD HOC GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN ANIMALS  
Paris, 21 - 23 April 2015**

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**Agenda**

1. Opening
  2. Appointment of chairperson and rapporteurs
  3. Background of the meeting
  4. Review and address the Terms of reference for the *ad hoc* Group meeting
  5. Refine template and criteria for the ranking of diseases
  6. Rank diseases for the three focus areas
    - a. Poultry diseases
    - b. Swine diseases
    - c. Fish diseases
  7. Agree on an overall priority list of animal diseases where availability of vaccines could reduce the use of antimicrobials taking into account technical and financial constraints to vaccine usage
  8. Any other issues
  9. Finalisation and endorsement of the draft report
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Appendix II

**AD HOC GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN ANIMALS  
Paris, 21 - 23 April 2015**

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**Terms of Reference**

**Background**

To address the threat of antimicrobial resistance, the WHO with the support of the OIE and FAO is drafting a Global Action Plan on Antimicrobial Resistance. In the development of this plan, the use of vaccines to prevent diseases and to reduce the prevalence of infections was considered as being one of the possible options to reduce the use of antimicrobial agents at the global level. The OIE has agreed to convene an *ad hoc* Group to identify animal diseases for which availability and use of vaccines could reduce the use of antimicrobial agents in animals as well as to make recommendations for targeted research programmes for improved and new vaccines.

**Purpose**

The *ad hoc* Group will provide guidance on prioritisation of diseases for which the use of already available and new vaccines could reduce antimicrobial use in animals, focussing at a first step on pigs, poultry and fish.

**Terms of Reference**

1. Consider diseases for which the availability and use of appropriate vaccines could reduce antimicrobial use in animals.
2. Rank bacterial diseases in terrestrial (pigs and poultry) and aquatic (fish) animals by animal group, which cause the highest use of antimicrobials in the animals concerned.
3. Refine the ranking by considering relevant factors impacting vaccine development, effectiveness or implementation of vaccination (examples could include but are not limited to the feasibility to develop vaccines, factors affecting the effectiveness of vaccines, such as number of bacterial strains, specific host immune reactions, general immune status related factors, or other factors that might reduce implementation of vaccination, such as current vaccine costs).

**Expected output of the *ad hoc* Group**

The development of a list of ranked priority diseases to guide research on vaccine development or improvement for terrestrial (pigs and poultry) and aquatic (fish) animals with the overall aim of decreasing the use of antimicrobial agents at the global level.

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Appendix III

**AD HOC GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN ANIMALS  
Paris, 21 - 23 April 2015**

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Appendix IV

**AD HOC GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN ANIMALS  
Paris, 21 - 23 April 2015**

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**REPORT OF THE OIE AD HOC GROUP ON  
PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME**

**Paris, 23-25 June 2015**

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A meeting of the OIE *ad hoc* Group on Porcine Reproductive and Respiratory Syndrome (PRRS) (hereafter referred to as the Group) was held at the OIE Headquarters in Paris from 23 to 25 June 2015.

**1. Welcome, adoption of the agenda, appointment of chairperson and rapporteur**

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Monique Eloit, Deputy Director General, welcomed the Group. She explained that the Scientific Commission for Animal Disease (Scientific Commission) and the Terrestrial Animal Health Standard Commission (Code Commission) agreed during their February 2015 joint meeting to request the OIE Director General to convene another meeting of the *ad hoc* Group to provide support in addressing Member Countries' comments on the *Terrestrial Animal Health Code (Terrestrial Code)* draft chapter 15.X. on Infection with PRRS virus.

Dr Eloit highlighted that the main objective of the meeting was to address scientific-related Member Countries' comments received by January 2015 on the draft *Terrestrial Code* Chapter.

She reminded the Group that the chapter was first drafted in 2013 and endorsed by both Scientific Commission and Code Commission and was circulated in 2014 among Member Countries that provided very valuable comments. Dr Eloit reminded the Group that PRRS was extensively discussed during the workshops organised in the framework of the last regional conference for Asia.

Dr Eloit informed the Group that new members of the OIE Specialist Commissions were elected during the 83rd General Session in May 2015 and took the opportunity to congratulate Dr Gideon Brückner and Dr Etienne Bonbon for being elected as the presidents of the Scientific Commission and Code Commission, respectively.

Dr Brückner reminded the Group that the inclusion of the *Terrestrial Code* Chapter on infection with PRRS virus was intended for facilitating safe trade among Member Countries and that the Chapter was drafted initially following the template and approach of the classical swine fever (CSF) Chapter which has been well accepted by OIE Member Countries and that the current Group should ensure consistency with the approach, especially when considering the role of wildlife in the epidemiology of the disease.

The Group adopted the proposed agenda for the meeting. The Group was chaired by Dr Howard Pharo, and Mr Torben Grubbe acted as rapporteur with the support of the OIE Secretariat.

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

**2. Update on the current situation of PRRS in the World**

The experts from China, Poland, South Africa and Chile provided updated information of the current situation of PRRS in their regions describing the spatial-temporal pattern of the disease and the impact of the infection in pig populations. Risk factors for introduction and spread as well as the measures of control and eradication implemented in their regions were also discussed.

The experts agreed that based on their experience and on current scientific literature, there was no evidence to suggest that meat, as defined in the *Terrestrial Code*, poses a risk for transmission of PRRS virus.

The role of wild and feral pigs in the epidemiology of the disease was also extensively discussed. It was agreed that, despite being susceptible to PRRS virus, they do not play a significant role in the epidemiology of the disease. Based on current knowledge of the epidemiology in wild and feral pigs, sporadic infections might have been a consequence of spill over from the domestic pigs but the disease was not known to be maintained in wild and feral pigs.

The Group considered the movement of live animals and semen as the relevant routes of transmission of PRRS virus for international spread.

### 3. Review and address Member Countries' comments on the draft chapter on infection with PRRS virus

The Group was provided with the Member Countries' comments on draft Chapter 15.X. on Infection with PRRS virus.

The Group agreed that PRRS has epidemiological particularities, such as infectivity, role of wildlife, risk factor pathways, etc. that differed from the epidemiology of CSF and that this should be reflected in the current draft chapter to avoid creating unnecessary barriers for international trade of animals and commodities.

The Group noted that in the *Terrestrial Code* chapters currently adopted there were several examples in which a case in a wildlife subpopulation would not preclude the Member Country from being considered as free from the disease for the purpose of the *Terrestrial Code*, assuming that appropriate biosecurity and surveillance measures were in place (e.g. CSF, AI).

The Group noted that several Member Countries made comments related to the terminology already included in the Glossary (e.g. fresh meat, quarantine station, biosecurity, stamping-out), and emphasised that Member Countries should refer to the Glossary<sup>1</sup> for clarification.

#### Article 15.X.1. General provisions

The Group noted that although the name of the disease refers to the presentation of clinical signs (syndrome), the chapter was intended to mitigate the risk of infection with PRRS virus also when trading live pigs or their products without apparent presence of clinical signs. This approach was consistent with other chapters of the *Terrestrial Code*.

In response to a Member Country's comment, the Group reiterated that as the definition of infection includes all virus strains (similar to the foot and mouth disease chapter of the *Terrestrial Code*), it was unnecessary to specify the two distinct genotypes of PRRS virus. The Group emphasised that for the purpose of this chapter, infection with PRRS virus includes all PRRS genotypes.

In response to several Member Countries' comments referring to the definition of infection, the Group noted that Article 15.X.1. provided four options for defining a PRRS infection and reiterated that the definition provided was consistent with other *Terrestrial Code* chapters (e.g. CSF, FMD). Therefore, the Group did not support the modification of the case definition proposed by some Member Countries. In addition, the Group clarified that a positive serological test alone would not be sufficient to conclude the presence of PRRS virus infection but should be subjected to further investigation in accordance with the recommendation under the surveillance articles of the chapter. The Group explained that the spread of a modified live PRRS vaccine strain from a vaccinated animal to an unvaccinated animal must be considered as an infection. Therefore, the isolation of any PRRS virus including vaccine-like virus in a non-vaccinated animal must be considered as an infection as per point 1 of this article as well as in the case of spread of this variant to a non-vaccinated pig (point 2).

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<sup>1</sup> Glossary of the *Terrestrial Animal Health Code* available on line at <http://www.oie.int/index.php?id=169&L=0&htmlfile=glossaire.htm>

In response to another Member Country's comment, the Group emphasised that there was insufficient evidence to consider that wild pigs play a significant epidemiological role in virus transmission. In addition, the Group considered that captive wild pigs were bred and reared in farms (not captured and farmed as suggested by a Member Country) and they were maintained separate from the wild population. In addition, the Group noted that captive wild animal was defined in the Glossary of the *Terrestrial Code* in terms of phenotype and not in terms of the source. The Group concluded that the chapter should focus only on domestic and *captive wild* pigs and not to any pig as suggested by the Member Country.

As a consequence of the above and consistent with the CSF and other chapters of the *Terrestrial Code*, the Group disagreed with the proposal to remove the paragraph indicating that a Member Country should not impose bans on trade in case of infection in wild or feral pigs.

The Group considered the comment suggesting the draft chapter be proposed for adoption only after the revision of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and referred this comment to the Code Commission.

#### **Article 15.X.2. Safe commodities**

The Group noted that the concept of safe commodities was defined in the 2015 version of the *Terrestrial Code* as "a commodity which can be traded without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation and regardless of the status of the country or zone of origin for that disease, infection or infestation."

The Group considered a Member Country's comment and reference to a scientific paper related to hides, skins and trophies<sup>2</sup>. The Group concluded that this reference did not provide scientific justification for removing hides, skins and trophies from the list of safe commodities. The Group considered that these commodities did not constitute a risk for PRRS transmission and therefore should be regarded as safe.

The Group extensively discussed the role of meat and meat products as defined in the *Terrestrial Code*. Considering the epidemiology of the disease, the Group concluded that these commodities should be considered as safe provided that they have been derived from pigs that have passed *ante-* and *post-mortem* inspections in accordance with Chapter 6.2. It was also noted that blood by-products were included in the definition of meat.

The Group could not support the proposal to remove meat and bone meal from the list of safe commodities. Not only were these products derived from potentially edible tissues and therefore considered meat, but also the standard process of production would inactivate PRRS virus. Based on the same argument, the Group agreed to include gelatine in the list of safe commodities as proposed by a Member Country.

Given the proposed definition of casings by the Code Commission which was circulated to Member Countries envisaging its adoption by the World Assembly of Delegates during the General Session in 2016, the Group considered it could be considered as safe commodity, for similar reasons.

#### **Article 15.X.3. Country, zone or compartment free from PRRS**

The Group agreed to differentiate the time requirement after the cessation of vaccination according to the type of vaccine used. In agreement with the proposal of a Member Country, it was decided to extend the waiting period without vaccination to two years when a modified live vaccine had been used to consider the risk of vaccine-strain virus transmission.

#### **Article 15.X.4. Recovery of free status**

The Group acknowledged the amendment to the definition of stamping out as adopted in May 2015. The term stamping out, as defined in the *Terrestrial Code*, implies the destruction of the carcasses with no possibility of commercialising the carcass for consumption. The Group noted that several Member Countries had eradicated

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<sup>2</sup> Hu S.P., Zhang Z., Liu Y.G., Tian Z.J., Wu D.L., Cai X.H., He X.J. (2013). Pathogenicity and distribution of highly pathogenic porcine reproductive and respiratory syndrome virus in pigs. *Transboundary. Emerging. Dis.*, **60**(4): 351-9.

PRRS by implementing a stand-still policy in the affected herds and sending all susceptible animals to slaughter for commercial use, combined with the implementation of strict biosecurity measures which include the cleaning and disinfection of the affected premises and enhanced surveillance. The Group amended the article to allow commercial slaughter when a Member Country implements the measures to recover its free status after an outbreak.

In response to another Member Country's proposal to extend the time before recovery of free status, due to immune suppression of infected pigs, the Group noted that the provisions of this article implied the destruction or slaughter of all infected and susceptible animals along with the implementation of appropriate biosecurity measures, thereby eliminating the source of virus. Therefore, it was not necessary to extend the time before recovery of free status.

The Group reiterated that a minimum of three months was necessary to allow the implementation of appropriate control measures and to ensure that surveillance was conducted to demonstrate freedom.

The Group decided to remove the option of using emergency vaccination to regain free status. The Group considered that international experience suggested that the use of inactivated vaccine was not ideal for emergency use because of insufficient efficacy for primary immunisation. Under these circumstances and considering the risk of spread related to the use of modified live vaccines, the use of emergency vaccination should not be considered by a country wishing to regain its previous free status in three months. The article was modified accordingly.

#### **Article 15.X.5. Recommendations for importation from countries, zones or compartments free from PRRS**

In response to a Member Country's comment on the time that animals should be kept in a free country, zone or compartment before being exported, the Group noted that this article entailed importation from countries, zones or compartments already free from PRRS as specified in article 15.X.3. Even when considering the eventual import of an infected animal, three months was considered to be sufficient to detect the introduction of PRRS virus, provided that appropriate surveillance was being carried out. This time period was also consistent with other chapters of the *Terrestrial Code*.

#### **Article 15.X.6. Recommendations for importation from countries or zones not free from PRRS**

##### For domestic and captive wild pigs for breeding or rearing

In response to a Member Country's comment, the Group discussed the common use of the term "isolation". The Group considered that, in this particular case, it referred to the separation from other pigs and not necessarily confinement in a quarantine station, and it could include the possibility of isolation on the premises of origin. The Group amended the text to clarify that isolation should include biosecurity measures, as defined in the Glossary of the *Terrestrial Code*.

The Group discussed the suggestion by a Member Country that additional measures should be warranted to manage the risk of infected animals which were no longer presented as seropositive but may still be harbouring the virus. The Group was not aware of any scientific evidence of persistently infected individual animals beyond the recognised potential harbouring the virus in the oropharynx. The Group was also not aware of any evidence that shedding may be reactivated in these animals. Therefore, the Group concluded that serological testing was the most appropriate tool for identifying infected animals in this context. The measures proposed for the demonstration of freedom in the herd of origin combined with pre-export isolation and testing were considered adequate.

The Group considered the proposal from a Member Country to require whole herd testing for the herd of origin in addition to testing in pre-export isolation. The Group considered that it was appropriate to introduce a provision for herd of origin freedom but not in a highly prescriptive way. The provision specified that pigs should be kept since birth or for at least three months prior to isolation in an establishment without any case of PRRS.

**Article 15.X.7. Recommendations for importation from countries or zones not free from PRRS**For domestic and captive wild pigs for slaughter

The Group took note of two comments proposing disinfection of transport vehicles from countries not free from PRRS and did not support the explicit mentioning of these requirements under the article. Furthermore, the Group mentioned that disinfection of the vehicles was implicitly stated in horizontal chapters (i.e. Chapter 7.3. of the *Terrestrial Code*). With regard to two other Member Countries' comments related to direct transport and immediate slaughter, the Group considered both terms were clear enough as used in other chapters of the *Terrestrial Code*. Several Member Countries also commented on the potential for contact with other pigs during transport, and for this reason the Group decided to include a provision that pigs should be transported with appropriate biosecurity measures.

**Article 15.X.8. Recommendations for importation of wild and feral pigs**

The definition of PRRS in article 15.X.1. makes it clear for the purposes of the *Terrestrial Code*, PRRS is considered to be an infection in domestic or captive wild pigs. Therefore, and considering that available information indicated that trade of wild and feral pigs may not be of sufficient magnitude to justify trade recommendations in the *Terrestrial Code*, the Group proposed to delete the article as suggested by a Member Country's comment.

**Article 15.X.9. Recommendations for importation from countries, zones or compartments free from PRRS**For semen of domestic and captive wild pigs

The Group noted comments from two Member Countries and concluded that as this article refers to free countries, zones or compartments, the inclusion of an extended period of observation for clinical signs subsequent to the collection of the semen was unnecessary.

**Article 15.X.10. Recommendations for importation from countries or zones not free from PRRS**For semen of domestic and captive wild pigs

The Group acknowledged several Member Countries' comments that monthly testing of all boars in the artificial insemination centre may not be feasible, from a management and welfare perspective, and considered that the same level of certainty could be reached by other testing regimes. The Group suggested that samples be taken and tested on a monthly basis from a statistically significant number of boars to demonstrate absence of infection.

With regard to a Member Country's comment on the evidence of PRRS, the Group decided to clarify it by using the term "case" that was already defined in the *Terrestrial Code*.

The Group recommended that the Code Commission explicitly elaborates on the obligation to have an early detection system for all relevant swine diseases including PRRS in Chapter 4.5. of the *Terrestrial Code*.

Given the multiple levels of testing, the Group concluded that additional post-collection testing was not warranted, and not feasible in the majority of the circumstances since a significant portion of trade was in fresh semen.

With regard to a Member Countries' comment on point 1) b), in the case of a recent incursion, the Group considered that it was possible in a small *artificial insemination centre* that all boars could be seronegative despite being at very early stages of viremia. The reference provided by the Member Country demonstrated that at early stages of infection semen could be PCR negative while serum could be PCR positive<sup>3</sup>. In this situation, the serological test of all boars would rule out the presence of virus in all situations except for very recent incursions. The Group agreed that the scientific reference showed that PCR testing of serum was more sensitive than PCR testing of semen at an early stage of infection and amended the text accordingly.

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<sup>3</sup> Reicks D., Muñoz-Zanzi C., Mengeling W., Jane Christopher-Hennings J., Lager K., Polson, D., Dee S. and Rossow, K. (2006) Detection of porcine reproductive and respiratory syndrome virus in semen and serum of boars during the first six days after inoculation. *Journal of Swine Health and Production* — Volume 14, Number 1

**Article 15.X.11. Recommendations for importation of *in vivo* derived embryos of domestic and captive wild pigs**

In response to a Member Country's comment, the Group agreed to delete the phrase "regardless of the PRRS status of the country of origin" and separate the article into two: i) Recommendations for importation of *in vivo* derived embryos of domestic and captive wild pigs from countries, zones or compartments free from PRRS and ii) Recommendations for importation of *in vivo* derived embryos of domestic and captive wild pigs from countries or zones not free from PRRS. In addition, the Group took into account the comment from a Member Country to consider the risk of infection derived from semen and included the reference to the provisions of Chapter 4.7. and 4.9. in order to improve clarity of the article.

The Group further justified the amendments with reference to Chapter 4.7. of the *Terrestrial Code*; PRRS was listed in Category 3 as a disease for which preliminary evidence indicates that the risk of transmission was negligible, but for which additional *in vitro* and *in vivo* experimental data would be required to substantiate the preliminary findings. If experimental data demonstrates that embryos do not pose a risk, this article would need to be revised.

Based on several Member Countries' comments, the Group added the serological testing provisions of donor females from countries or zones not free from PRRS and aligned the text in accordance with the recommendations for importation of live animals.

The Group disagreed with a Member Country's suggestion to delete the article and recommended the maintenance of effective measures for trade of embryos.

**Article 15.X.12. Recommendations for importation of fresh meat of domestic and captive wild pigs**

In response to Member Countries' comments, the Group finally noted after extensive discussion, that there had not been any evidence since the last meeting of the Group in July and October 2013 that meat posed a risk to international spread of PRRS virus, and the only existing studies that the Group were aware of were performed in highly artificial settings that did not reflect the field environment.

The Group considered whether there was scientific justification for maintaining a requirement to exclude lymphoid tissue of the head and neck, and thoracic and abdominal viscera. The Group noted and discussed in detail that despite the already existing trade patterns involving vast quantities of meat without any measures imposed, there had been no new evidence to suggest that PRRS virus spreads internationally through meat, includes all edible tissues of pigs. The Group further discussed and noted the low likelihood of exposure from importing and feeding of raw meat while taking into account the conditions and time taken for virus degradation and concluded that the risk was negligible.

Therefore, the Group concluded that meat including fresh meat and meat products derived from pigs (as defined in the *Terrestrial Code*) that has passed ante-and post-mortem inspection should be considered as safe, and consequently the Group decided to delete the article.

Whilst acknowledging the initial request by Member Countries to draft a chapter on PRRS mainly due to the emergence of new high pathogenic strains and the concern that the new strains may behave epidemiologically in a different manner, the Group was not aware of any significant change in the epidemiology of virus transmission. Therefore, the Group concluded that the existence of new strains of PRRS virus did not warrant further measures to be applied to meat.

**Article 15.X.13. Recommendations for importation of fresh meat of wild and feral pigs**

The Group agreed to delete the article based on the above-mentioned rationale used for the deletion of the article on the recommendations for importation of meat of domestic and captive wild pigs.



**Article 15.X.14. Recommendations for importation of offal**

The Group considered the comments made by several Member Countries and decided to delete the article as offal was included in the *Terrestrial Code* definition of meat.

**Article 15.X.15. Introduction to surveillance**

For the purpose of the chapter and in accordance with the definition, the aim of surveillance was to demonstrate freedom in domestic and captive wild pigs, and not in wild and feral pigs as they do not play an epidemiologically significant role in PRRS virus transmission.

In response to a Member Country's comment, the Group agreed to include the role of pig-to-pig contact as source of infection, being one of the specific characteristics of PRRS epidemiology.

The Group agreed with a Member Country's comment with regard to aerosol transmission of PRRS virus and amended the text accordingly.

**Article 15.X.16. General conditions and methods for surveillance**

The Group considered Member Countries' comments proposed for improvement of clarity and made appropriate amendments.

**Article 15.X.17. Surveillance strategies**

The Group could not support a Member Country's comment and stated that it was not aware of any situation where serological surveillance in the wild pig population had been a more efficient and effective surveillance methodology than in the domestic and captive wild pig population. The Group emphasised that serology should be used in an unvaccinated population, and thus decided to leave the text as it was. However, the Group mentioned that the current text did not preclude Member Countries from implementing surveillance in the susceptible subpopulation based on the epidemiological characteristics of the country.

In response to a Member Country's comment on virological surveillance, the Group amended the text to include, as one of the purposes, to monitor at risk populations and to follow up positive serological results in alignment with the *Terrestrial Code* Chapter on infection with CSF virus.

The Group made a remark in the text to indicate that young unvaccinated animals with no maternal antibodies could be targeted by serological surveillance for the aim of early detection.

**Article 15.X.18. Additional surveillance requirements for recovery of free status**

The Group reiterated that, while wild or feral pigs may not be the priority target subpopulation for surveillance to recover free status, this recommendation would not preclude Member Countries from implementing surveillance in the susceptible subpopulation that they consider as appropriate.

**4. Finalisation and adoption of the draft report**

The Group reviewed and finalised the draft report provided by the rapporteurs.

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.../Appendices

Appendix I

**AD HOC GROUP ON PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME  
Paris, 23-25 June 2015**

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**Agenda**

1. Welcome, adoption of the agenda, appointment of chairperson and rapporteur
  2. Update on the current situation of PRRS in the World
  3. Review and address Member Countries' comments on the draft chapter on infection with PRRS virus
  4. Finalisation and adoption of the draft report
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Appendix II**AD HOC GROUP ON PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME**

Paris, 23-25 June 2015

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## MEETING OF THE OIE *AD HOC* GROUP ON BIOSECURITY FOR THE HHP CONCEPT

Paris, 28 – 29 July 2015

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### 1. Welcome and Introductions

Dr Münstermann welcomed the Expert Group on Biosecurity for the High Health High Performance (HHP) concept. She introduced the terms of reference of the *Ad hoc Group* and requested the participants' expertise for the revision and approval of the HHP handbook.

This handbook is intended for the information of the Veterinary Services and the Delegates on the HHP concept and will serve as a reference for the Horse Industry (IFHA and FEI) to develop "operational manuals" for the use by the stakeholders of the private sector.

Dr Bernard Vallat joined the meeting to thank the participants for their support for the project. He provided a brief history of the HHP concept and explained that the HHP handbook approved by the *Ad hoc Group* would be submitted to the OIE Scientific Commission for its consideration at its September meeting.

It was agreed that Dr Münstermann would chair the meeting and that Dr Termine (FEI) would write the minutes.

As an introduction, Dr Münstermann presented an overview of the OIE, outlining the roles of the Scientific Commission, the Working group and the Terrestrial Animal Health Code Commission. She also explained the concept of zoning, compartmentalisation and their integration into the HHP concept.

The Agenda, the Terms of reference and the List of participants are presented in Appendices I, II and III, respectively.

### 2. Review of the Handbook for the management of HHP

#### 2.1. General issues

The level of prescriptiveness of the HHP biosecurity recommendations was discussed. It was suggested to replace 'should' with 'must' in the text. Dr Münstermann advised that 'must' was a prescriptive term that remains unused in OIE documents, and that the guidance of the OIE Scientific Commission should be sought on this issue.

The participants discussed the opportunity of a transition period before the Member Countries adopt the HHP requirements in their national legislation during which the HHP requirements for Certification could be slightly adjusted by the exporting/importing countries to make them compatible with their current legislation. Dr Münstermann advised that the guidance of the OIE Scientific Commission should also be sought on that matter.

The scope of a veterinary "examination" compared to a veterinary "inspection" of the horses was discussed and clarified.

The overall structure of the handbook was questioned. The description of the HHP biosecurity guidelines follows the cycle of a HHP journey. Considering that similar requirements have to be met at different stages of the HHP concept, the participants advised that the handbook could be restructured to avoid unnecessary repetitions.

Lastly, a recurring suggestion throughout review of the handbook included the consistency of use of 'cleaned', 'disinfected' and 'sanitised'.

## 2.2. Detailed content

### ▪ *Preamble*

The participants highlighted that in addition to biosecurity measures protecting travelling horses, the countries that the horses were travelling to would also be protected.

### ▪ *Part 1– The HHP concept*

#### **Summary**

Discussion of the flow chart representing the stepwise implementation of the concept resulted in suggestions of a circular flow chart incorporating the horse's return to the home compartment following a 90 day travel period. Additional suggestions were made involving a legend, indication as to when HHP status is maintained and addition of 'isolation' in the relevant parts of the graphic.

#### **Section 1.2 – Stepwise implementation**

The duration of the qualification period was discussed. It was suggested that an explicit reference to the *Code* Chapter 12.5 that defines a 90 days period for the temporary importation of horses as a requirement for Equine infectious anemia (Chapter 12.5) could be made.

It was mentioned that some horses may wish to lose their HHP status after attending an HHP event in which case the national health conditions for re-entry after temporary exports would then apply.

It was suggested that the requirements for the HHP stables for temporary residence (lay over points and event venues) should be emphasized (i.e. biosecurity requirements similar to those applicable to home stables and approval by the Veterinary Authority).

#### **Section 1.3 – Roles and responsibilities**

It was noted that the acronym 'PR' ("Person Responsible") that in the handbook designated the person made responsible for a compartment introduced some confusion with the PR designated in the sport's regulations. The participants recommended a different acronym should be used.

It was proposed that the role of the Veterinary Authority in controlling, and if appropriate, suspending a HHP status should be highlighted

It was recommended that an addition should be made to Section 1.3.5 on transport to include transport by sea.

### ▪ *Part 2– Biosecurity guidelines for the management of the subpopulation*

#### **Section 2.1.1 – Compartment construction**

Discussion took place on the separation distances between a compartment and other stable units containing equids that don't have an equivalent health status. The participants concluded that specific figures were rarely referred to and the term 'functional separation' according to the disease of concern would be appropriate. The compartment should be physically separated from other stables.

The participants noted that vehicle access should be addressed to prevent horses from passing others for loading.

Following a discussion concerning isolation stables, the participants concluded that a specific isolation area for HHP horses was required which should be separated from non-HHP isolation stables. It was noted that isolation facilities and dedicated treatment boxes at events were also to be addressed and that a protocol for the treatment of HHP horses at veterinary clinics was required.

#### **Section 2.1.2 – General management of the compartment**

The frequency of disinfection of stables was discussed. The participants agreed that disinfection should occur between horses occupying stables, but was not required for the duration of the same horse occupying the stable.

#### **Section 2.1.3 – Prevention of disease introduction in the compartment**

It was noted that clarification was required concerning the disinfection of vehicles transporting HHP horses. The participants recommended that vehicles should be disinfected prior to carrying HHP horses.

#### **Section 2.1.4 – Health supervision of horses in the compartment**

The participants recommended that body temperature of horses should be taken twice daily to ensure the detection of transient pyrexia, should it occur. They recommended that temperatures of above 38.5°C should be reported to the RV.

The participants advised that in the event of horses requiring surgery, the facility should be adequate for horses to maintain their HHP status (i.e. HHP stables).

#### **Section 2.1.5 – Departure of HHP horses to attend an event**

It was highlighted that under certain circumstances the responsible veterinarian could be the official veterinarian

The participants suggested that clarification was required regarding whether a country must permit entry for a horse of HHP status.

#### **Section 2.2.1 – Transportation planning**

It was agreed that the transporter should be responsible for submitting the route to the veterinary authority of the exporting country for approval prior to certification. The transporter should also be responsible for presenting a contingency plan and the veterinary authority should be notified of any issues arising during transport.

#### **Section 2.2.2 – Transport**

The participants suggested that it should be added that horses should not travel for longer than permitted as stated by national animal welfare legislation.

They also indicated that the groom should be highly experienced and preferably a professional flying groom. The transportation of horses by sea, boat and rail is also to be included.

#### **Section 2.3 - Biosecurity guidelines at an equestrian event**

It was agreed that the biosecurity guidelines required basic inclusions to cover events that horses may attend during the preparation period. Event managers should be responsible for implementing relevant biosecurity precautions.

Criteria should be defined to determine which events horses may attend during the preparation period.

A common theme was to ensure biosecurity signs at an equestrian event were translated into a variety of relevant languages.

### **Section 2.3.3 – Event facilities**

The participants suggested that the possibility of using fencing around a HHP stable should be included. They indicated that clarity was required concerning stabling based on risk (e.g. country of origin, health status and horses testing positive to piroplasmosis).

### **Section 2.3.5 – Veterinary inspection on arrival at an event**

It was proposed that HHP horses may enter the compartment at events without undergoing an examination on arrival first; however, the examination must be carried out as soon as possible afterwards and that a functional separation of horses should be constantly ensured at events. It was recommended that non-HHP horses should undergo examination on arrival, prior to entering the event's stabling areas.

## **3. Strategies for use of the HHP concept**

The recommendations of the expert group were sought on the requirements to be applied to:

- The introduction of new horses into a compartment, including during the preparation period;
- The removal of horses from a compartment, including during the preparation period;
- The perpetuation of the HHP system once one cycle of travel has been completed (i.e. maintenance of a qualified subpopulation).

### **3.1. New entrants**

The participants recommended that new entrants could be introduced into a compartment, including during the preparation period, provided they originate from a country of the same health status as the country of the compartment under preparation. They should undergo the same testing and vaccination as resident horses before entering the compartment. Within the compartment, they should be isolated from the other horses for at least 2 weeks. Thereafter they need to finalise their full preparation period.

### **3.2. Removal**

If a sick horse was to be removed from a compartment including during the preparation period, the participants advised that strict biosecurity should be maintained until an investigation is performed and a diagnosis is made. The consequences of the incident for the rest of the compartment should depend on the disease of concern. Once the compartment is cleared from the disease of concern, the preparation period would continue (without resetting the 90 days period).

### **3.3. Maintenance**

For the perpetuation of the HHP system once one cycle of travel has been completed, the group recommended the following requirements:

- a minimum of an annual audit of the subpopulation by the Veterinary Authority;
- annual retesting and regular revaccination of all horses in the subpopulation (i.e. annual retesting for equine infectious anaemia and glanders (in countries of unknown health status) and vaccination maintained valid for equine influenza and Venezuelan equine encephalomyelitis);
- specific tests, vaccination, isolation periods before travel as to meet the requirements of the Model HHP Veterinary Certificate.



#### **4. Conclusions**

Dr Münstermann thanked the participants for their contributions.

#### **5. Follow-up action**

Produce a revised version of the Handbook that will circulate within the Group for comments and finalised through correspondence. - *Proposed timing: August 2015.*

Consult the OIE ad hoc group on international horse movement for equestrian sport and the Scientific Commission on the proposed strategy for the maintenance of a high health status subpopulation - *Proposed timing: August 2015.*

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON BIOSECURITY FOR THE HHP CONCEPT**

**Paris, 28 – 29 July 2015**

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**Agenda**

1. Welcome and Introductions
2. Review of the Handbook for the management of HHP
  - 2.1. General issues
  - 2.2. Detailed content
3. Strategies for use of the HHP concept
  - 3.1. New entrants
  - 3.2. Removal
  - 3.3. Maintenance
4. Conclusions
5. Follow-up action

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Appendix II**MEETING OF THE OIE AD HOC GROUP ON BIOSECURITY FOR THE HHP CONCEPT****Paris, 28 – 29 July 2015**

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**Terms of Reference**

Within the framework of the activities undertaken by the *ad hoc* Group on International Sport Horse Movement, draft Biosecurity Guidelines were developed to guide the practical implementation of the HHP concept at the home stable, during transport and at event venues.

In order to progress the work these draft Guidelines need to be further developed in specific areas critical for the establishment and maintenance of the HHP status.

It is for this reason, that the following Terms of Reference are proposed to guide the work by this specific expert group:

- Infrastructure specifications and biosecurity measures to establish and maintain a compartment
  - Construction standards
  - Physical separation and barriers including functional separation
  - Entry control for people, other animals, vehicles
  - Delivery of feed, bedding, other supplies
  - Disposal of manure and waste
  - Disinfection and cleansing
  - Storage of equipment and material, feed and veterinary products
  - Water supply
  - Ventilation
  - Insect, rodent and wild bird control
- Vector protection
  - At home stable, during transport, at events
- Contingency planning during transport
- Procedures to be followed for the permanent removal of horses from the population
- Conditions for new entrants
  - During the qualification period
  - In a qualified stable
- Measures to maintain HHP stable and horse status
  - Continued maintenance of biosecurity conditions
  - Frequency of retesting/revaccination
- Validation of the existing principles of the Biosecurity Guidelines
- Identification, consideration and development of additional measures as warranted

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Appendix III**MEETING OF THE OIE AD HOC GROUP ON BIOSECURITY FOR THE HHP CONCEPT****Paris, 28 – 29 July 2015**

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**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE**  
**Paris, 25 – 27 August 2015**

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**1. Opening and background information**

The OIE *ad hoc* Group on Antimicrobial Resistance (further referred to as 'the Group') met from 25 to 27 August 2015 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. She pointed out that the meeting would be organised in two parts. The first part would be dedicated to finalise the template and instructions developed for the OIE Member Countries to report, to the OIE, data on the use of antimicrobial agents in animals, as well as to propose a draft cover letter to be sent with these documents to OIE Delegates. The second part would be dedicated to review comments of OIE Member Countries at the 80<sup>th</sup> General Session on Chapter 6.7. of the *Terrestrial Animal Health Code (Terrestrial Code)* on "Harmonisation of national antimicrobial resistance surveillance and monitoring programmes" to select veterinary pathogens for surveillance. It was also proposed to review definitions of the critical terms used in the chapters related to antimicrobial resistance and the use of antimicrobial agents. She highlighted the importance of the Group in the future to follow up the work of the OIE in collecting data on the use of antimicrobial agents in animals worldwide. Finally she informed the participants that a presentation on WHONET Software would be given by Dr John Stelling (WHO Collaborating Centre for Surveillance of Antimicrobial Resistance), Thursday 27 August, noon.

Dr Awa Kane provided an overview of the FAO<sup>1</sup>/OIE/WHO<sup>2</sup> Tripartite activities regarding antimicrobial resistance and on the World Health Organization's Global Action Plan for Antimicrobial Resistance. She noted that each country within their action plan is requested to have activities at the human/animal interface, and that the data collection on the use of antimicrobial agents in animals should be included in the National Action Plans.

**2. Appointment of chairperson and rapporteur, and adoption of the agenda**

The meeting was chaired by Dr Herbert Schneider, Dr Carolee Carson acted as rapporteur for the discussions related to the OIE global database on the use of antimicrobial agents in animals and Dr Chris Teale acted as rapporteur for the discussions related to the *Terrestrial Code*.

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

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1 FAO: Food and Agriculture Organization of the United Nations

2 WHO: World Health Organization

### 3. Presentation on the responses received from selected countries from the Africa and Middle East regions consulted on the OIE template for the collection of data on the use of antimicrobial agents

The data collection template, the accompanying guidance for completion and an annex to assist in necessary calculations were presented and discussed with the OIE National Focal Points for Veterinary Products in the Americas, Europe and Asia-Pacific regions in the frame of the third cycle of training seminars for the Focal Points for Veterinary Products. However, this training cycle had already been completed for Africa and the Middle East and there was no possibility for formal interaction with the Focal Points of these two regions.

To ensure that the concept and the templates were also acceptable to these regions before starting the collection of data on antimicrobial use in animals at the end of 2015, the documents were sent to a selected number of Member Countries in Africa and the Middle East. The aim was to get their feedback on the clarity of the questionnaire.

Few of the consulted Member Countries provided detailed responses. However, the respondents indicated that the data collection template and the accompanying instructions were clear. One country attempted to populate the template with data and encountered challenges with the calculations required.

Based on the responses received from selected countries, the Group noted the technical complexity of this project and highlighted to the OIE the need for dedicated human resources to manage the project.

The Group was informed that the upcoming training (first of the fourth cycle) to be held in December 2015 in Uganda for the OIE National Focal Points for Veterinary Products, will provide the opportunity to seek additional input and to train the Focal Points to support their Delegates in completing the template.

### 4. Finalisation of the OIE data collection template and the accompanying instructions

The Group reviewed the draft template and instructions developed for the OIE Member Countries to report data on the use of antimicrobial agents in animals. The Group recognised that this project will develop and progress over time including the amount and type of data reported and that this should be clearly indicated. Therefore the Group suggested that current activities be designated as 'Phase I'.

#### Guidance for the completion of the OIE template

The Group discussed the text proposed for the Guidance document and noted that in the introduction the personalised email addresses would be replaced by a generic email address.

The Group noted that the wording in respect to the 'year of data collection' in the Guidance needs to be harmonised with the preferred wording in the Template.

The Group included the following definitions for clarity: "veterinary medicinal product containing antimicrobial agent(s)", "active entity", and "chemical compound as declared on the product label".

The Group agreed to reflect any subsequent change in the annex and template in the Guidance.

#### Annex to the Guidance

The Group emphasised that this document was a technical document providing guidance on the calculations necessary in the context of reporting quantities of antimicrobial agents used in animals.

- A new introduction to the Annex was drafted for review by the Group as agreed at the December meeting. The Group suggested additional changes such as replacing 'moiety' by 'entity' and keeping 'moiety' in brackets. The first paragraph was moved further down for better flow of the document.

- The Group discussed that product labels might not actually include the active entity, but rather the whole chemical compound. Hence, it may not be practical for all countries to report active entity. In consequence the document was restructured into calculations that are always necessary for reporting quantities of antimicrobial agents for bulk quantities (section 1) and veterinary medicinal products (section 2), and further optional calculations necessary for transforming amounts of the whole chemical compound into amounts of active entity (section 3). The Group suggested that countries include a description of the data they provided for prodrugs and long-acting products. This resulted in additions to the Guidance and Template to clarify any calculations countries have performed.

As per Group discussion, the Guidance document will include the following statement *that while reporting the active entity is preferred, information on the entire chemical compound as declared on the product label will be acceptable.*

- In the Annex, regarding long acting forms and prodrugs, the Group decided to include values consistent with what the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) is using at this point in time. The text will be revised to indicate that the ESVAC values were used as a starting point. These values can be updated based on future technical discussions. The whole section was moved to the new section 3 on optional calculations.

#### Template

- Changes were implemented as agreed at the December meeting. Changes were aimed at simplifying the information requested. The Group supported these changes.
- For each Reporting Option, a free text field was added for the collection of information on any additional calculations applied to the data for the purpose of converting to active entities. Corresponding descriptions were introduced in the Guidance document.

#### Cover letter to accompany the OIE Template, the Guidance document and its Annex

- The Group assisted in drafting the project cover letter to be signed by the OIE Director General for the first round of data collection, highlighting the link to previous OIE activities and the Global Action Plan on Antimicrobial Resistance.

### **5. Further development of the denominator and OIE reporting formats**

Dr Carolee Carson and Dr Don Prater presented on demographics, weights and options for data reporting.

Dr Paula Caceres, Head of the World Animal Health Information and Analysis Department, attended the discussion.

The name of the denominator (the multiplication of the animal demographic data by the standard animal weight) has yet to be decided. One option is 'biomass adjusted by populations and weights'.

#### Discussion of demographic data

There has been much revision of the WAHIS data requested of Member Countries for animal population numbers over the past months. These revisions will result in data that better suit the needs for reporting data on antimicrobial agents used in animals. The Group suggested harmonising the Template request for information on food-animal species with what is being requested via WAHIS.

The Group noted that the timing of the availability of the numerator (data on antimicrobial agents used in animals) and denominator data in the future may be well aligned.

#### Discussion of standard animal weights

The Group suggested discussing standard weights for the different animal production classes at the next meeting. In particular, consideration needs to be taken of regional variation of weights for select animal species.

#### Discussion of Reporting Formats

The Group discussed in depth possible reporting options and noted that some general principles could be established in advance.

The Group discussed having a section in the report to describe data quality. The chosen terminology labelling this section may need revisiting for better clarity, but this section would include whether the data on antimicrobial agents was derived from import information or was an extrapolation, etc.

There was a discussion that since the revised WAHIS data will be available in February 2016 (2015 annual population data), then demographic information would be applied to the 2015 data on antimicrobial agents used in animals. This could be designated as a key component of 'Phase II' for development of analysis and reporting.

#### Presentation of findings from a past OIE survey

Dr Gerard Moulin presented the OIE survey conducted in 2012 for the purpose of identifying general reporting principles applicable to data on antimicrobial agents used in animals.

The Group discussed the possibility of generating similar outputs formats to those presented in the analysis of the OIE survey in 2012; with the benefit of highlighting overall progress over time and advancement of the complementary antimicrobial use survey activities.

The Group highlighted that there are methods of reporting the data, which do not reveal the country of origin, similar to how the data were presented from the OIE survey.

Related to the data requested in the different Reporting Options, outputs from the OIE template could be created on antimicrobial class, route of administration, therapeutic/growth promotion use, and by terrestrial/aquatic animal species.

The Group discussed including data on the most frequently reported antimicrobial agents by region.

The Group discussed the value in having *Recommendations for Improvements* as a section in the report. This could be linked to future capacity-building funding opportunities. The purpose would be to help countries improve their national systems to build a better global system.

The Group discussed reporting information arising from the *Administrative Information* table in the template. In some cases, this information could be presented globally, rather than regionally. However, regional stratification of data might readily identify future capacity-building needs. Trends in the *Administrative Information* may be very useful to report, such as the number of countries using *Reporting Option 3* and details on changes in the source of the data.

## **6. Chapter 6.7. on “Harmonisation of national antimicrobial resistance surveillance and monitoring programmes”: Selection of animal pathogens for surveillance**

Prof. Peter Borriello provided an update on an initiative he has been leading on the surveillance of resistance in animal pathogens at the European level.



The Group noted comments received for the Chapter 6.7. of the *Terrestrial Code* on Harmonisation of national antimicrobial resistance surveillance and monitoring programmes. These comments requested to keep the table with the examples of animal pathogens and also to take into consideration more animal pathogens.

The Group noted a similar discussion during the development of the chapter 6.4. of the *Aquatic Code* on Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals that highlighted a similar need for the identification of pathogens of aquatic animals.

The Group agreed that more information on surveillance of antimicrobial resistance in animal pathogens was important and therefore that the OIE should take a lead role in this. The Group noted that other global efforts also identified the importance of resistance in animal pathogens. The Group was also of the opinion that these other efforts would be well supported by the OIE in developing further resources on prioritisation of antimicrobial resistance in veterinary pathogens and testing.

The Group proposed that the chapters 6.7. of the *Terrestrial Code* and 6.4. of the *Aquatic Code* be reviewed to include additional criteria for the selection of animal pathogens for antimicrobial resistance surveillance and, potentially, with a reference to specific pathogens, either in the chapter or in a separate document. The Group discussed the possibility to develop a separate document that would identify list(s) of animal pathogens, as a stand-alone document similar to the OIE List of antimicrobial agents of veterinary importance.

The Group also proposed to take the animal pathogen table (previously included in Chapter 6.7 and displayed below) as a starting point.

***Examples of animal bacterial pathogens  
that may be included in resistance surveillance and monitoring***

Target animals	Respiratory pathogens	Enteric pathogens	Udder pathogens	Other pathogens
Cattle	<i>Pasteurella</i> spp.	<i>Escherichia coli</i>	<i>Staphylococcus aureus</i>	
	<i>Haemophilus somnus</i>	<i>Salmonella</i> spp.	<i>Streptococcus</i> spp.	
Pigs	<i>Actinobacillus pleuropneumoniae</i>	<i>Escherichia coli</i>		<i>Streptococcus suis</i>
		<i>Brachyspira</i> spp.		
		<i>Salmonella</i> spp.		
Poultry				<i>Escherichia coli</i>
Fish				<i>Vibrio</i> spp.
				<i>Aeromonas</i> spp.

The Group proposed that the following criteria could be considered for prioritisation of animal pathogens for antimicrobial resistance surveillance:

- Animal health and welfare;
- Impact on food security and on production (economic importance of associated diseases);
- Implication of antimicrobial resistance in the pathogen on therapeutic options in veterinary practice;
- Bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);
- Existence of quality assurance programs or other pathogen reduction options that are non-antimicrobial (vaccines);
- Existence of susceptibility testing methodologies for the pathogen.

## 7. Definitions

The Group reviewed the definitions previously proposed for inclusion in the Glossary of the *Terrestrial Code* during the meeting held from 2 to 4 July 2012:

- Therapeutic use,
- Non-therapeutic use,
- Regulatory authority,
- Good manufacturing practices, and
- Veterinary medicinal products.

The Group took note of the current existence of definitions in the Glossary of the *Terrestrial Code* for *Good manufacturing practice* and *Veterinary medicinal product*.

The Group agreed with the Terrestrial Animal Health Code Commission that a definition of Regulatory Authority was included in the broader concept of *Competent Authority* defined in the Glossary of the *Terrestrial Code*.

With regards to the definition of the terms “Therapeutic use” and “Non-therapeutic use”, the Group noted that, while important, these terms were only used in Chapter 6.8. of the *Terrestrial Code* on “Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals”. The Group therefore proposed, as was done for Chapter 6.3. of the *Terrestrial Code* on “The control of hazards of animal health and public health importance in animal feed”, to include an article providing the definitions of these two terms at the beginning of the Chapter 6.8. The Group also proposed a change in the definition of “Non-therapeutic use”. The definitions as agreed by the Group are the following:

*Therapeutic use*: administration of an antimicrobial agent to animals to either prevent, control or treat infection or disease.

*Non-therapeutic use*: any usage of an antimicrobial agent in animals that is not a therapeutic use.

## 8. Work plan

The Group proposed the following short-term work plan for activities on the database:

1. October 2015: OIE data collection template and the accompanying instructions with a cover letter sent by the OIE Director General to all the OIE Member Countries
2. Mid December 2015: Deadline to receive the completed template from the OIE Member Countries.
3. Next meeting of the *ad hoc* Group on Antimicrobial Resistance from 19 to 22 January 2016. The purpose of the meeting will be to discuss the results from this first collection of data and make recommendations for the next steps.
4. Meeting of the *ad hoc* Group on Antimicrobial Resistance during the summer 2016 to prepare the second phase of the collection of data on the use of antimicrobial agents.

## 9. Adoption of report

The Group adopted the report.

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.../Appendices

Appendix I

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

**Paris, 25 – 27 August 2015**

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**Agenda**

1. Opening and background information
  2. Appointment of chairperson and rapporteur, and adoption of the agenda
  3. Presentation on the responses received from selected countries from the Africa and Middle East regions consulted on the OIE template for the collection of data on the use of antimicrobial agents
  4. Finalisation of the OIE data collection template and the accompanying instructions
  5. Further development of the denominator and OIE reporting formats;
  6. Chapter 6.7. on “Harmonisation of national antimicrobial resistance surveillance and monitoring programmes”: Selection of veterinary pathogens for surveillance
  7. Definitions
  8. Work plan;
  9. Adoption of report
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Appendix II**MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE****Paris, 25 – 27 August 2015****List of Participants****MEMBERS**

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## Appendix III

## Annex to the Guidance for Completing the OIE template for the collection of data on Antimicrobial Agents used in Animals:

### Considerations on converting content of antimicrobial active ingredients in veterinary medicines into kilograms

#### Calculating the quantities to report in kilogram (kg)

Data on antimicrobial agents intended for use in animals comes in different forms. The OIE template for the collection of data on antimicrobial agents used in animals (OIE template) is designed to collect data on the amounts of chemical compound as declared on the product label. The information may vary, ranging from bulk quantities of antimicrobial agents to numbers of packs of a veterinary medicinal product. The content of antimicrobial agents in such products can be stated in a number of possible ways. It will be necessary, where appropriate, to calculate the required data to populate the OIE template.

Detailed instructions are provided to harmonise some aspects of data reporting:

- Transformation of bulk quantities ([Section 1](#)); use this section if you need to convert quantities of raw material, e.g. from import data into the required format.
- Data on veterinary medicinal products ([Section 2](#)), including conversion from International Units (IU) to kg (section 2. (ii))
- Recommendations are made in [section 3](#) for further optional conversions, aimed at achieving refined reporting of active entities, the ultimately desired format. If such calculations are made, they should be reported in the OIE template in the free text field provided on the sheets for Reporting Option 1, 2 and 3.

The following abbreviations and symbols will be used:

Symbol/abbreviation	Explanation
Strength	amount of antimicrobial agent per unit of veterinary product
% w/v	per cent weight per volume
mg	milligram
g	gram
kg	kilogram
t	ton (metric)
ml	millilitre
l	litre

#### 1. For data on bulk quantities

Such information is usually sourced from customs, import or other bulk trading. It will likely come as a weight in a number of possible units (e.g. metric tons) of chemical compound and needs to be converted to kg. When conversion into kg is necessary, follow the steps below. If additional conversion factors are needed, please contact the OIE at [oieaudatabase@oie.int](mailto:oieaudatabase@oie.int).

**Step 1:** Multiply the amount of antimicrobial agent, i.e. the chemical compound as declared on the product label with the appropriate conversion factor from the table 1 below.

$$\text{Antimicrobial agent (kg)} = \text{antimicrobial agent (unit Z)} \times \text{conversion factor}$$

Table 1: Converting weight units into kg

Unit reported (unit Z)	Conversion factor to kg (for multiplication)
Metric ton	1000
Imperial ton (long)	1016
Imperial ton (short)	907.18
Stone (Imperial)	6.35
Imperial Pound	0.4536
Ounce	0.0283

## 2. For data on veterinary medicinal products

For veterinary medicinal products containing antimicrobial agents, data on quantities sold is likely to be available as numbers of packages of product sold, with each package containing a specified quantity of medicinal product with a specified amount of antimicrobial agent. In such cases, the amount of antimicrobial agent (chemical compound as declared on the product label) per package needs to be calculated first, and subsequently the result needs to be multiplied with the number of packages of the presentation sold to obtain the overall amount of antimicrobial agent, which should be reported in kg.

The most common ways to indicate the content of the antimicrobial agent(s) of a veterinary medicinal product are:

- (i) Strength in mg or g of the active ingredient per volume or weight or other unit, (for example: ml, l, kg, tablet),
- (ii) Strength in International Units (IU) per weight, volume or other unit,
- (iii) Strength in per cent (%) weight per weight (w/w) or weight per volume (w/v).

Each situation requires a different kind of mathematical conversion.

### 2. (i) – content of antimicrobial active ingredient (antimicrobial agent) stated in milligram per volume or weight or other unit (for example millilitre, litre, kilogram, tablet) of content

Step 1: Calculation of the content of antimicrobial agent per package

Multiply the amount of antimicrobial agent (chemical compound as declared on the product label) per unit of content, that is, the strength of the product, with the total number of units contained in the package

$$\begin{aligned} &\text{Content of antimicrobial agent per package} \\ &= \text{Strength (amount antimicrobial agent per unit)} \times \text{number of units per package} \end{aligned}$$

*Example A:*

Tiamulin 100 g/kg premix for medicated feeding stuff; package sizes: (a) 1 kg, (b) 5 kg and (c) 20 kg

Calculation of content of antimicrobial agent, tiamulin, per package:

- (a)  $\text{Pack content} = 100 \text{ g/kg} \times 1 \text{ kg} = 100 \text{ g}$
- (b)  $\text{Pack content} = 100 \text{ g/kg} \times 5 \text{ kg} = 500 \text{ g}$
- (c)  $\text{Pack content} = 100 \text{ g/kg} \times 20 \text{ kg} = 2000 \text{ g}$

*Example B:*

Tetracycline intrauterine tablet containing 2000 mg tetracycline hydrochloride per tablet; package sizes: (a) carton with 1 blister of 5 intrauterine tablets, (b) carton with 4 blisters of 5 intrauterine tablets each (20 tablets), (c) carton with 20 blisters of 5 intrauterine tablets each (100 tablets).

Calculation of content of antimicrobial agent, tetracycline, per package:

- (a)  $\text{Pack content} = 2000 \text{ mg} \times 5 = 2 \text{ g} \times 5 = 10 \text{ g}$
- (b)  $\text{Pack content} = 2000 \text{ mg} \times 20 = 2 \text{ g} \times 20 = 40 \text{ g}$
- (c)  $\text{Pack content} = 2000 \text{ mg} \times 100 = 2 \text{ g} \times 100 = 200 \text{ g}$

*Example C:*

Tilmicosin 300 mg/ml solution for injection for cattle; package sizes: containers of 100 ml and 250 ml; packs of (a) 6, (b) 10 and (c) 12 units of 100 ml and 250 ml.

Calculation of content of antimicrobial agent, tilmicosin, per package:

$$\begin{aligned}
 & \text{(a) Container content} = 300 \text{ mg/ml} \times 100 \text{ ml} = 30000 \text{ mg} = 30 \text{ g} \\
 & \text{Pack content:} \quad \begin{aligned} & \text{(a) } 6 \times 30 \text{ g} = 180 \text{ g} \\ & \text{(b) } 10 \times 30 \text{ g} = 300 \text{ g} \\ & \text{(c) } 12 \times 30 \text{ g} = 360 \text{ g} \end{aligned} \\
 & \text{(b) Container content} = 300 \text{ mg/ml} \times 250 \text{ ml} = 75000 \text{ mg} = 75 \text{ g} \\
 & \text{Pack content:} \quad \begin{aligned} & \text{(a) } 6 \times 75 \text{ g} = 450 \text{ g} \\ & \text{(b) } 10 \times 75 \text{ g} = 750 \text{ g} \\ & \text{(c) } 12 \times 75 \text{ g} = 900 \text{ g} \end{aligned}
 \end{aligned}$$

- Step 2: Sum up the antimicrobial agent contained in all presentations and packages sold  
Convert all contents of antimicrobial agent calculated under step 1 to the same weight unit and add up the total
- Step 3: If necessary: convert the total sum of antimicrobial agent contained in all packages of all presentations sold to kg  
Multiply the result from step 2 with an appropriate conversion factor to achieve the result in kg

**2. (ii) – content of antimicrobial agent (chemical compound as declared on the product label) in International Units (IU) per weight, volume or other unit (for example millilitre, litre, kilogram, tablet) of content**

Where the strength of the antimicrobial agent in the veterinary medicinal product is stated International Units (IU) per unit of finished product, an additional conversion step is necessary to obtain results in mg, g, or kg. Table 2 is used to convert content of antimicrobial agents declared in IU on the product label into mg for reporting to the OIE: either divide the total number of IUs of an antimicrobial agent by the value in the column 'International Units (IU) per mg' for this agent in table 2, or, if multiplication is preferred, multiply the total number of IUs with the conversion factor listed for the agent. To convert mg values into kg, please multiply the result of the conversion with  $1 \times 10^{-6}$  equalling 0.000001.

For some antimicrobial agents in veterinary medicinal products, the IU content or strength may be stated in respect to the active entity rather than to the chemical compound actually included; for example: a product may contain penethamate hydroiodide, or procaine benzylpenicillin, but the stated strength in IU refers to benzylpenicillin (product X containing penethamate hydroiodide, equivalent to xx IU benzylpenicillin, or, product Y containing procaine benzylpenicillin, equivalent to yy IU benzylpenicillin). For such cases, use the conversion factor for the relevant active entity listed in table 2 (in the examples used: benzylpenicillin). To convert mg values into kg, please multiply the result of the conversion with  $1 \times 10^{-6}$  equalling 0.000001.

If additional conversion factors are needed or have been used, please contact the OIE at [oielaide@oie.int](mailto:oielaide@oie.int).

**Step 1: Calculating the content of antimicrobial agent per package in IU**

Multiply the amount of IU antimicrobial agent per unit of content with the total number of units contained in the package

$$\begin{aligned}
 & \text{Content of antimicrobial agent per package in IU} \\
 & = \text{Strength (amount IU antimicrobial agent per unit)} \times \text{number of units per package}
 \end{aligned}$$

**Step 2: Converting the content of antimicrobial agent per package in IU into mg**

$$\begin{aligned}
 & \text{Content of antimicrobial agent per package in mg} \\
 & = \text{Content of antimicrobial agent in IU} \times \text{conversion factor}
 \end{aligned}$$

Steps 3-4: Follow steps 2-3 described for (i)

**Table 2:** Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant active entities, based on the ESVAC conversion factors<sup>3</sup>

Antimicrobial agent in the veterinary medicine	Antimicrobial active entity for reporting to OIE	International Units per mg	Conversion factor to mg for multiplication
Bacitracin	Bacitracin	74	0.013514
Benzylpenicillin (penicillin G)	Benzylpenicillin	1666.67	0.0006
Chlortetracycline	Chlortetracycline	900	0.001111
Colistin methane sulfonate sodium (colistimethate sodium INN)	Colistin	12700	0.000079
Colistin sulfate	Colistin	20500	0.000049
Dihydrostreptomycin	Dihydrostreptomycin	820	0.00122
Erythromycin	Erythromycin	920	0.001087
Gentamicin	Gentamicin	620	0.001613
Kanamycin	Kanamycin	796	0.001256
Neomycin	Neomycin	755	0.001325
Neomycin B (Framycetin)	Neomycin B (Framycetin)	670	0.001492
Oxytetracycline	Oxytetracycline	870	0.001149
Paromomycin	Paromomycin	675	0.001481
Polymyxin B	Polymyxin B	8403	0.000119
Rifamycin	Rifamycin	887	0.001127
Spiramycin	Spiramycin	3200	0.000313
Streptomycin	Streptomycin	785	0.001274
Tobramycin	Tobramycin	875	0.001143
Tylosin	Tylosin	1000	0.001
Tetracycline	Tetracycline	950	0.001

**2. (iii) – content of antimicrobial agent (chemical compound as declared on the product label) in per cent (%) weight per weight (w/w) or weight per volume (w/v) of content**

The amount of antimicrobial agent contained in a veterinary medicine concerned may be stated in per cent weight per weight (% w/w) (example 1: product X contains tylosin 100% w/w or, example 2, product Y contains amoxicillin 22.2 % w/w) or in per cent weight per volume (% w/v) (example: product Z contains procaine benzylpenicillin 30% w/v). Such figures first need to be converted into mg/g, g/g, or mg/ml, followed by the calculations described under (i).

**Converting % w/w:** Conversion calculations are performed by relating the content of antimicrobial agent to 1 g of the finished product. Divide the percentage value by 100 to obtain the amount of antimicrobial agent in g per g finished product.

$$\text{value antimicrobial agent in g per gram finished product} = \frac{\frac{\text{value (\%)}}{100} \times g}{1 \text{ g (finished product)}}$$

Example 1: Product X containing 100% w/w tylosin will contain  $100/100 \times g = 1 \text{ g}$  tylosin per g finished product.

Example 2: Product Y containing 22.2% w/w amoxicillin will contain  $22.2/100 = 0.222 \text{ g}$  amoxicillin per g finished product.

Continue with Steps 1-3 of (i)

**Converting % w/v:** Conversion is based on the assumption that 1 ml of the products weighs 1000 mg. Multiply the percentage value with 10 to obtain the content in mg/ml.

$$\text{value antimicrobial agent in g per ml finished product} = \frac{\text{value (\%)} \times 10 \times \text{mg}}{1 \text{ ml (finished product)}}$$

Example: Product Z containing 30% w/v benzylpenicillin will contain  $(30 \times 10 \times \text{mg})/1\text{ml}$ , equal to 300 mg/ml benzylpenicillin.

<sup>3</sup> [http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500189269](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269)



Continue with Steps 1-3 of (i)

### 3. Additional recommendations for further conversions of quantities of antimicrobial agents

For pragmatic reasons the OIE accepts the reporting of antimicrobial agents in amounts of chemical compound as declared on the product label of the veterinary medicinal product. However, OIE Member Countries may wish to carry out further calculations to report amounts of active entity. If such further calculations are carried out, please describe them in the OIE template.

(i) Calculating the total amount expressed in weight of chemical compound as declared on the product label of a veterinary medicinal product into antimicrobial active entity (e.g. salt into base)

This step may be carried out once the steps described in section 1 or section 2. (i) have been completed.

As an example, for the antimicrobial agent tiamulin that is often available in the form of tiamulin hydrogen fumarate (the chemical compound as declared on the product label), the conversion formula to tiamulin (the active entity) would be:

Salt (including base): Tiamulin hydrogen fumarate MW 609.8  
 Base: Tiamulin MW 493.7  
 Conversion factor = MW base/MW salt (including base) = 0.81

Multiply the final result in kg obtained by following steps 1 to 3 with the appropriate conversion factor

$$\text{Content of active entity (kg)} = \text{Content of chemical compound as listed on the label (kg)} \times \text{conversion factor}$$

(ii) The antimicrobial agent is in the form of a prodrug, expressed in weight

Where the antimicrobial agent contained in the veterinary medicinal product is a long-acting salt (example: benethamine benzylpenicillin) or a pro-drug (example: penethamate hydroiodide) and the content is stated in weight in reference to the actual chemical compound (example: product x contains 500 mg/ml benzylpenicillin benzathine), an additional conversion step as described below is needed to calculate the amount of active entity. When the antimicrobial agent is described in reference to the active entity (example: product y contains cloxacillin benzathine equivalent to 500 mg cloxacillin activity) the conversion using a prodrug conversion factor described below is not necessary.

Taking the prodrug conversion factors used by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) program managed by the European Medicines Agency, as a starting point, table 3 lists the suggested conversion factors for relevant long-acting salts and prodrugs. The amount of the actual chemical compound as declared on the product label (example: benzylpenicillin benzathine) needs to be multiplied with the prodrug conversion factor to obtain the corresponding amount of the active entity (example: benzylpenicillin).

If additional conversion factors are needed or have been used, please contact the OIE at oieadatabase@oie.int.

**Table 3:** Conversion of content stated in mg, g or kg of long-acting salts and prodrugs of antimicrobial agents in the veterinary product into corresponding mg, g or kg antimicrobial active entity for reporting to the OIE, based on the ESVAC conversion factors<sup>4</sup>

Antimicrobial agent (prodrug)	Active entity	Prodrug conversion factor for multiplication
Benethamine benzylpenicillin	Benzylpenicillin	0.65
Benzathine benzylpenicillin	Benzylpenicillin	0.39
Cefapirin benzathine	Cefapirin	0.41

<sup>4</sup> [http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500189269](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500189269)

Antimicrobial agent (prodrug)	Active entity	Prodrug conversion factor for multiplication
Cefalexin benzathine	Cefalexin	0.36
Cloxacillin benzathine	Cloxacillin	0.43
Oxacillin benzathine	Oxacillin	0.69
Penethamate hydroiodide	Benzylpenicillin	0.63
Procaine benzylpenicillin	Benzylpenicillin	0.61

Step 1–3: As described in section 2. (i)

Step 4: Multiply the final result in kg obtained by following steps 1 to 3 with the appropriate conversion factor listed in table 3

$$\begin{aligned}
 & \text{Antimicrobial agent (active entity)(kg)} \\
 &= \text{antimicrobial agent (chemical compound as declared on the product label)(kg)} \\
 & \quad \times \text{prodrug conversion factor}
 \end{aligned}$$

For bulk quantities of antimicrobial agents in form of prodrugs, the additional step 2 described below should be applied after the calculations described in section 1.

Step 2: If the antimicrobial agent is a long-acting salt or prodrug listed in table 3 above, additionally multiply with the corresponding conversion factor.

$$\begin{aligned}
 & \text{Antimicrobial agent (active entity)(kg)} \\
 &= \text{Step 1 antimicrobial agent (chemical compound as declared on the product label) kg} \\
 & \quad \times \text{prodrug conversion factor}
 \end{aligned}$$


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## Appendix IV

## Guidance for completing the OIE template for the collection of data on antimicrobial agents used in animals

### Contents

<b>Introduction .....</b>	<b>83</b>
<b>Introducing the individual sheets of the OIE template for the collection of data on antimicrobial agents used in animals .....</b>	<b>84</b>
<b>Required information and choices for reporting .....</b>	<b>84</b>
<b>Baseline information .....</b>	<b>85</b>
<b>Reporting option 1 (overall amount sold for / used in animals by antimicrobial class, with the possibility to separate by type of use) .....</b>	<b>85</b>
<b>Reporting option 2 (overall amount sold for / used in use animals by antimicrobial class, with the possibility to separate by type of use and species group) .....</b>	<b>85</b>
<b>Reporting option 3 (overall amount sold for / used in animals by antimicrobial class, with the possibility to separate by type of use, species group and route of administration) .....</b>	<b>85</b>
<b>Guidance notes on the data to be provided in the OIE template .....</b>	<b>85</b>
<b>Explanation of terms used in the context of the OIE template and related documents .....</b>	<b>85</b>
<b>Baseline information .....</b>	<b>87</b>
<b>Classes of antimicrobial agents for reporting .....</b>	<b>89</b>
<b>Reporting options 1, 2 and 3: Reporting quantities of antimicrobial agents .....</b>	<b>90</b>
<b>Reporting option 1, 2 and 3: Differentiation by type of use .....</b>	<b>91</b>
<b>Reporting option 2 and/or 3: Differentiation by animal species group .....</b>	<b>91</b>
<b>Reporting option 3: Differentiation by routes of administration .....</b>	<b>91</b>
<b>Calculating the quantities to report in Reporting options 1, 2 and 3 .....</b>	<b>92</b>

### Introduction

The OIE proposes to collect data on antimicrobial agents used in animals from OIE Member Countries implementing Chapters 6.8. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals of the OIE *Terrestrial Animal Health Code* and 6.3. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals of the OIE *Aquatic Animal Health Code*, and to contribute to the global effort against antimicrobial resistance.

Member Countries differ in the degree to which they collect, collate and publish data on antimicrobial sales or use in animals and also in the degree to which they can stratify the quantities of antimicrobial agents used in animals or used in different animal species.

Through this initiative, by means of a specific template (OIE template), the OIE seeks to collect data on antimicrobial agent use in animals from all OIE Member Countries in a harmonised way. Using a phased approach, the OIE will initially focus on **sales**<sup>5</sup> of antimicrobial agents destined for use in animals as an indicator of actual use. All antimicrobial agents destined for use in animals and listed in the OIE List of antimicrobial agents of veterinary importance<sup>6</sup>, plus certain antimicrobial agents only used for growth promotion should be reported. The exceptions are ionophores, which are mostly used for parasite control and therefore need not be reported as antimicrobial agents. The OIE places highest priority on food-producing animals, however data on all animals may be reported. Reporting will occur at antimicrobial class and, on one occasion, at sub-class level.

For the purpose of reporting data on antimicrobial quantities (amounts sold or imported for use in animals expressed in kg antimicrobial agent (chemical compound as declared on the product label) that is to be calculated from the available information as explained in the annex to this guidance document), animals are grouped into 'all animal species', 'all food-producing animals', 'terrestrial food-producing animals', and 'aquatic food-producing animals'.

Further refinement of the OIE collection of data on antimicrobial sales or use in animals is anticipated in the light of the experience gained with the utilisation of the OIE template and additional changes will be necessary as Member Countries capabilities of reporting stratified data develop.

For questions on the OIE template please contact the OIE at [oielatabase@oie.int](mailto:oielatabase@oie.int).

## Introducing the individual sheets of the OIE template for the collection of data on antimicrobial agents used in animals

### *Required information and choices for reporting*

As noted before, OIE Member Countries differ in the degree to which data on antimicrobial sales for use in animals is accessible and in the degree to which the quantities of antimicrobial agents used in animals can be further differentiated, for example by species. Therefore, three different reporting options are proposed.

There are four worksheets in the OIE template (four tabs at the bottom of the Microsoft excel file) labelled 'Baseline information', 'Reporting option 1', 'Reporting option 2', and 'Reporting option 3'.

**All OIE Member Countries** should complete the sheet **Baseline information**. On this sheet, some fields are formatted in *italics and grey*; these fields are optional, but Member Countries are encouraged to provide information to the greatest extent possible. Subsequently, and in accordance with the level of detail for data on antimicrobial agents used in animals available in the reporting country, either the sheet labelled **Reporting option 1** or the sheet labelled **Reporting option 2** or the sheet labelled **Reporting option 3** should be completed – only one of the three Reporting options should be selected.

<sup>5</sup> 'Sales' in the context of the OIE data collection on antimicrobial agents used in animals should be interpreted to include data on import of antimicrobial agents for use in animals.

<sup>6</sup> [http://www.oie.int/fileadmin/Home/eng/Our\\_scientific\\_expertise/docs/pdf/OIE\\_list\\_antimicrobials.pdf](http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_antimicrobials.pdf)

**Baseline information**

This sheet collects administrative information relevant to the data collected with this template. It should be completed by **all OIE Member Countries**.

At the bottom of this sheet a matrix is provided to help OIE Member Countries decide which Reporting option to complete next.

**Reporting option 1 (overall amount sold for / used in animals by antimicrobial class, with the possibility to separate by type of use)**

The form **Reporting option 1** is designed for the reporting of data on amount or type of antimicrobial agents used in all animals and accommodates reporting with only limited additional differentiation. Data may be reported overall for all animal species, but can be separated by antimicrobial class and possibly by type of use (therapeutic use, including prevention of clinical signs, or growth promotion use; see definitions below). If you know which classes of antimicrobial agents are used in animals in your country, but not how much is sold, you can still use this sheet. Instead of a number, please enter three dots, <...>, in the table.

**Reporting option 2 (overall amount sold for / used in use animals by antimicrobial class, with the possibility to separate by type of use and species group).**

If the data can be differentiated by use in all food-producing animals, and / or by use in terrestrial and aquatic food-producing animals, **Reporting option 2** is the appropriate choice. Further differentiation by antimicrobial class, therapeutic use, including prevention of clinical signs, or growth promotion use is possible.

**Reporting option 3 (overall amount sold for / used in animals by antimicrobial class, with the possibility to separate by type of use, species group and route of administration).**

If the data can be differentiated by route of administration, **Reporting option 3** is the appropriate choice. Further differentiation by antimicrobial class, use in food-producing species and, where possible, by use in terrestrial and aquatic food-producing species as well as therapeutic use, including prevention of clinical signs, or growth promotion use is possible.

**Guidance notes on the data to be provided in the OIE template****Explanation of terms used in the context of the OIE template and related documents**

A number of terms require definition of their use in the context of the OIE template, in order to ensure a harmonised approach to data collection.

**Active entity:** Antimicrobial agents (see definition below) are chemical compounds that can come in various forms. In order to render an antimicrobial agent suitable for use in a veterinary medicine, or to achieve desirable pharmacokinetic or organoleptic properties, antimicrobial agents can exist as different salts or esters or other chemical compounds. The **active entity** is the part of the chemical compound responsible for the antimicrobial action. The name used to refer to an antimicrobial agent listed on the OIE List of antimicrobial agents of veterinary importance is generally identical to the **active entity** of that agent.

**Antimicrobial agent:** As defined in the glossaries of the *OIE Terrestrial Code* and the *OIE Aquatic Code*, this means a naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms) at concentrations attainable in vivo. Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition. In the context of the OIE template, this term is being used as a general reference to substances with antimicrobial activity.

**Antimicrobial classes for use in animals:** Any antimicrobial agent belonging to the antimicrobial classes listed on the *OIE List of antimicrobial agents of veterinary importance* is included. In addition, antimicrobial agents used exclusively for growth promotion are also included. With the exception of ionophores, which are mostly used for parasite control, all uses of these substances should be reported, whether the antimicrobial agents are categorised as veterinary medicines or not.

**Chemical compound as declared on the product label:** As explained for active entity, an antimicrobial agent may exist in the form of various chemical compounds. For example, benzylpenicillin (the active entity) the sodium, potassium, procaine, benzathine or benethamine salts, and the prodrug penethamine hydroiodide are used in veterinary medicine. In consequence they may be traded as bulk products or be included in veterinary medicinal products containing antimicrobial agents (see explanation below). The term **chemical compound as declared on the product label** refers to the substance as it is reported on the label of a veterinary medicinal product or a bulk container or in the information provided to customs. This may be either the active entity (e.g. benzylpenicillin) or the complete chemical compound (e.g. sodium benzylpenicillin).

**Growth promotion, growth promoters:** In line with the definition developed by Codex Alimentarius in *CAC/RCP 61-2005*, Growth Promotion refers to the use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobial agents for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained. **Growth promoters** in the context of this template are antimicrobial agents used for the purpose of growth promotion.

**Therapeutic use:** Administration of an antimicrobial agent to animals to prevent, control or treat infection or disease. Acknowledging that the OIE template may be completed without consulting this guidance document, it was agreed that for reasons of clarity the OIE template would use 'Therapeutic use (including prevention of clinical signs)' in the table headings of all reporting options.

**Extrapolation:** An approach by which the total amount of antimicrobial agents used in animals was derived from a limited, but representative dataset. Details on the approach should be provided. Caution should be exercised in situations where the data sources are not representative of the whole. For example, extrapolation from a limited number of wholesalers may not adequately represent the entire antimicrobial sales market.

**Food-producing species:** The animal species that are managed by people for the purpose of producing food for humans. The relevant species may differ between countries.

**Quantitative data versus qualitative data:** The term 'quantitative' refers to a type of information based in quantities or else quantifiable data (objective properties) — as opposed to 'qualitative' information which deals with apparent qualities (subjective properties). Quantitative data may also refer to mass, time, or productivity. In the context of this template, **quantitative data** means that the amount of antimicrobial agents used in animals can be determined, for example

through information on amount of antimicrobials imported, or number of packages of specific antimicrobial products used in animals, and is reportable in the metric 'kg antimicrobial agent'. In the context of this template, **qualitative data** means that the classes of antimicrobial agents used in animals can be described, without knowing the amounts used.

**Sales of antimicrobial agent(s) used in animals versus use data:** For the purpose of data collection through the OIE template, **sales data**, also referred to as 'amount of antimicrobial agent(s) used in animals' relates to the amounts of antimicrobial agents imported, manufactured and /or sold within a country for use in animals. Sales data are used as an approximation of actual use. **Use data** refers to the amount of antimicrobial agents actually administered to animals. Such data are difficult to collect in most environments, as the data sources would be at the level of individual farmers or veterinarians.

**Veterinary medicinal product containing antimicrobial agent(s):** As defined in the glossaries of the *OIE Terrestrial Code* and the *OIE Aquatic Code*, the term *veterinary medicinal product* means any product with approved claim(s) to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal. A veterinary medicinal product containing antimicrobial agent(s) refers to veterinary medicinal products used for their antimicrobial effect due to one or more antimicrobial agents they contain.

### Baseline information

Field name	Information to be provided
<b>Contact Point for data collection</b>	Please provide the contact details of the person entering the information, also indicating the role of the person entering the data with respect to the OIE. The information is needed in case there are queries on the data provided.
<b>Name:</b> <b>Role with respect to the OIE</b> <b>Organisation:</b> <b>Address:</b> <b>Phone number:</b> <b>Email address:</b>	Please complete the fields as follows: <b>Name:</b> Salutation (e.g. Dr, Ms, Mr), first or given name, surname or family name <b>Role with respect to the OIE:</b> From the provided drop down list please choose either 'Delegate', 'National Focal Point for Veterinary Products' or 'Other' to describe your relation to the OIE. <b>Organisation:</b> Name of the organisation you work for, administrative subunit, and position – if necessary <b>Address:</b> Full mailing address of your organisation <b>Phone number:</b> Please provide your full telephone number including the international dialling code. <b>Email address:</b> Please provide the email address where you can best be reached.
<b>Year of data collection</b>	Calendar year for which you are providing data. We aim for 2013 data, but will accept more recent data or the most recent older data (but not before 2010). For each year a separate form needs to be filled in, indicating the calendar year to which the data relate.
<b>Country</b>	Please enter your country's name in full text.
<b>Are antimicrobial growth promoters authorised for use in your country?</b>	Please respond by ticking either 'Yes' or 'No'. Choose 'Yes' if your country's legislation / regulations has no provisions for antimicrobial growth promotion, but use of antimicrobial agents for growth promotion is known to occur.
<b>List of allowed antimicrobial growth promoters, if the answer to the previous question is 'yes'</b>	If antimicrobial growth promoters are used (meaning the response to the question above is 'Yes'), please list the antimicrobial agents (active ingredient name, not product name) used for growth promotion. Please report using either the simplified terminology of the tables on <b>Reporting option 1, 2 or 3</b> , or by using the terminology of the OIE List of antimicrobial agents of veterinary importance.
<b>Data source</b>	Please describe the origin of the data on antimicrobial sales for use in animals, the preferred data at this stage. The template provides options for data sources, and you are asked to report all data sources that apply. Chapter 6.8 of the <i>OIE Terrestrial Code</i> and Chapter 6.3 of the <i>OIE Aquatic Code</i> provide more detail on potential sources of such information. Possible data sources include: <ul style="list-style-type: none"> <li>• Sales data - complete data on antimicrobials sold to / bought from wholesalers.</li> <li>• Purchase data - data based on sampling of a limited number of wholesalers and requiring extrapolation to estimate the full amount of antimicrobials purchased, but should be used with care.</li> <li>• Import data - complete import data from customs.</li> </ul>



Field name	Information to be provided
	<ul style="list-style-type: none"> <li>• Manufacturing data - complete production numbers reported by manufacturers.</li> <li>• Prescription data - complete or representative sample information obtained from veterinarians; if representative sample information is obtained extrapolation to the estimated full use may be possible.</li> <li>• Antimicrobial use data - complete or representative sample information obtained from farm records; if representative sample information is obtained extrapolation to the estimated full use may be possible</li> <li>• Other data - all other ways of delivering antimicrobial agents to the animals, including distribution through state veterinary services.</li> </ul> <p>It is suggested to develop an overview to the drug distribution system in your country. Mapping out the distribution pathways in your country will help you identify the most appropriate source of information on import or sales of antimicrobial agents for use in or animals. Great care is necessary to avoid duplicate or multiple reporting of quantities; mapping out the distribution will also help you devise measures aimed at avoiding multiple reporting. Ideally, the source of information should be as close to the point of use as possible. Experience has shown that whenever possible sales data at the package level should be collected, keeping in mind that the data will be measured in kg of antimicrobial agent (please refer to the annex of this document for details on the necessary conversions). Good communication between all parties involved in the data collection is critical to obtain good data sets.</p>
<b>Data source clarification</b>	If under <b>Data source</b> the option 'Other (further specified in 'Data source clarification')' is selected, please explain here which source of information was used.
<b>Are quantitative data on sales available?</b>	<p>Please indicate whether quantitative data (i.e. data on the amount) on antimicrobial agents used in animals are available, by choosing 'Yes' or 'No'.</p> <p>If quantitative data is available for part of your country, choose 'Yes'.</p> <p>In the subsequent field '<b>Estimated coverage of accessible data on total sales</b>', indicate the extent to which the available data cover total sales of antimicrobial agents for use in animals as a percentage (in relation to the overall use). In the field '<b>Explanation of estimated coverage and extrapolations carried out</b>' please provide a description of the sales not covered by the data, if there is less than 100% coverage.</p> <p>If the data available in your country is qualitative (the types of antimicrobial agents used in animals are known but not how much is sold), choose 'No'. If you know which substances or classes of antimicrobials are used in your country, please report this in the sheet <b>Reporting option 1</b> by entering three dots, '...', in the cells that would normally hold the numbers for quantities sold.</p> <p>If you do not know which substances or classes of substances are used in animals in your country, the completion of the OIE template is terminated after completing the <b>Baseline information</b> form.</p>
<b>Estimated coverage of accessible data on total amount (in %)</b>	Please provide an estimate of the extent to which the quantitative data you report is representative of the overall antimicrobial sales for use in animals, as a percentage of the total sales in your country. If less than 100% are reported, please describe the data not covered.
<b>Is the information extrapolated from representative samples?</b>	Please indicate here, whether the data provided in your report have been extrapolated from representative samples.
<b>Explanation of estimated coverage and extrapolations carried out</b>	<p>Please explain in this field which sales are not captured by the data on antimicrobial agents used in animals reported for your country, or the nature of any extrapolations that were carried out in order to provide the data recorded in the OIE template.</p> <p>Data coverage may vary by geographical aspects; examples include but are not limited to situations that use may be well known for urban but not rural areas, or that use in certain representative regions is well known but not actually measured throughout the whole country. Incomplete data coverage may include situations where importation is not covered or statistical sampling of relevant establishments (farms, veterinary practices, etc.) is carried out. Another source of incomplete data may lie in market segment coverage, where incomplete data is available from certain market segment (e.g. some production systems are not covered such as extensive versus intensive farming systems or certain wholesalers do not report their data).</p>



Field name	Information to be provided
<b>Animal groups covered by the data</b>	Please indicate here to which broad category of animals the data provided apply, by selecting the appropriate category or categories from the list. The choices are: 'All animal species', 'All food-producing species (terrestrial and aquatic)', 'Terrestrial food-producing species', 'Aquatic food-producing species', and 'Other' ('Other' may include companion animals). Multiple selections are possible.
<b>Animals raised in your country and considered 'food producing species'</b>	Animal species considered to be food-producing animals vary between countries. The OIE needs to gain an understanding how this difference impacts the data reported to the OIE and future reporting of summary data by the OIE. Please indicate here which animals are considered as food-producing animals in your country. Multiple selections are possible.
<b>Clarification of species considered as food-producing</b>	Please provide any explanations you may feel necessary to explain which animal species are raised in your country for the purpose of providing food for humans.
<b>National report available on the web?</b>	If a national report on antimicrobial sales and/or use in animals is available in your country please insert the link to the site where the report is available on the internet.

### Classes of antimicrobial agents for reporting

All antimicrobial classes used in animals (for therapeutic use including prevention of clinical signs, as well as growth promotion, whether classified as veterinary medicines or not, with the exception of ionophores) should be included in the table by the reporting OIE Member Country.

Antimicrobial class	Guidance
<b>Aminoglycosides</b>	Includes aminocyclitols (e.g. streptomycin, dihydrostreptomycin and spectinomycin) and all other aminoglycosides (e.g. gentamicin, kanamycin, neomycin, apramycin).
<b>Amphenicols</b>	Includes florfenicol and thiamphenicol.
<b>Arsenicals</b>	Includes nitarsons, roxarsone and others.
<b>Cephalosporins</b>	May be reported as <b>Cephalosporins (all generations)</b> or in relevant category groupings ( <b>1-2 generation cephalosporins</b> as one category and <b>3-4 generation cephalosporins</b> as a second category).
<b>Fluoroquinolones</b>	Includes danofloxacin, difloxacin, enrofloxacin, marbofloxacin and other fluoroquinolones, but not other quinolones (flumequine, oxolinic acid, nalidixic acid) that are reported separately.
<b>Glycopeptides</b>	Includes avoparcin and others.
<b>Glycophospholipids</b>	Includes bambermycin (synonym flavomycin).
<b>Lincosamides</b>	Includes lincomycin, pirlimycin and others.
<b>Macrolides</b>	Includes substances with all macrolide structures, such as erythromycin, spiramycin, tylosin, tylvalosin, gamithromycin, tildipirosin, tulathromycin and others.
<b>Nitrofurans</b>	Includes furazolidone, nitrofurantoin, nitrofurazone and others.
<b>Orthosomycins</b>	Includes avilamycin and others.
<b>Other quinolones</b>	Includes flumequine, nalidixic acid, oxolinic acid and others.
<b>Penicillins</b>	Includes all penicillins (e.g. natural penicillins, aminopenicillins and others), but excludes other beta lactam antimicrobials like cephalosporins.
<b>Pleuromutilins</b>	Includes tiamulin, valnemulin and others.
<b>Polypeptides</b>	Includes bacitracin, colistin, polymyxin B and others.
<b>Quinoxalines</b>	Includes carbadox, olaquinox and others.
<b>Streptogramins</b>	Includes virginiamycin, pristnamycin, and others.
<b>Sulfonamides (including trimethoprim)</b>	Includes all sulfonamides, as well as trimethoprim and similar compounds.
<b>Tetracyclines</b>	Includes for example chlortetracycline, doxycycline, tetracycline, and oxytetracycline.
<b>Others</b>	All others not covered, including for example coumarin antimicrobials like novobiocin, fusidic acid, kirromycins, phosphonic acids like fosfo- or tobramycin, rifamycins, thioestrepton.
<b>Aggregated class data</b>	It may not be possible to individually report sales by class name for one or more antimicrobial classes for animal use, for example to protect confidential (proprietary) information or as required by legislation. Such amounts may be reported in this line.

Antimicrobial class	Guidance
	Report here the individual or cumulative amounts of antimicrobial classes used in animals that cannot be reported independently for confidentiality / proprietary reasons. If more than one data aggregation exists in your country, please sum them up for the OIE template. In cases where the amounts sold for more than one class are reported as aggregated data, please enter <AGG> in the table for those substances for which sales quantities have been included in the aggregated amount, and list the names of the classes of antimicrobial agents that cannot be reported individually in the free-text field called ' <b>If 'Aggregated class data' are reported, please list here the classes combined</b> ' located underneath the table collecting the antimicrobial quantities.

Explanatory notes on the free-text fields below the tables for reporting quantities.

Field name	Information to be provided
<b>If 'Aggregated class data' are reported, please list here the classes combined</b>	<p>If for your country, there are <b>Aggregated class data</b>, please list here the names of the classes of antimicrobial agents that cannot be reported individually.</p> <p>If sales for only one antimicrobial class that needs to remain confidential are reported as <b>Aggregated class data</b>, please enter the word 'Confidential' in this free-text field.</p> <p>Whenever possible, use the 'Antimicrobial class' terms explained above or the terminology of the <i>OIE List of antimicrobial agents of veterinary importance</i>, <a href="http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_antimicrobials.pdf">http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_antimicrobials.pdf</a>.</p> <p>Aggregated data may include substances that are not mentioned in the definition of 'Antimicrobial classes for use in animals'. In such cases, please specify here any additional classes of antimicrobials which are included in the reported amount for <b>Aggregated class data</b> that are not listed in the table.</p>
<b>If 'Others' are reported under 'Antimicrobial class', list here the classes reported</b>	Describe the class or classes reported as 'Others', using whenever possible the terminology of the <i>OIE list of antimicrobial agents of veterinary importance</i> .
<b>Please report here any additional calculations applied</b>	Please describe here calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the guidance for completing the OIE template.

### Reporting options 1, 2 and 3: Reporting quantities of antimicrobial agents

The amount of the antimicrobial agents used in animals in kilograms (kg) should be reported. Where data is available in the form of number of packages of a given pharmaceutical preparation sold or in cases or stated in international units or % weight per volume (% w/v), mathematical conversion will be necessary, which is explained in the annex to this document. In cases where the amount sold for the listed class is part of a data aggregation reported under 'Aggregated class data', please enter the three letters <AGG> in the table for all classes, for which quantities sold have been summarised.

Ideally, the OIE is interested in the amount of active entity (moiety), that is, the substance as listed in the OIE list of antimicrobial agents of veterinary importance (for example: benzylpenicillin), not the total weight of the actual chemical compound (salt, ester or other; for example: sodium or potassium benzylpenicillin) contained in a veterinary medicinal product or traded as bulk material. At this stage of the project, the precision gained by the refined reporting of amounts of active entity, achieved by mathematical conversion of amounts of chemical compound as declared on the product label, is not justified. Therefore, the OIE

template will accept the amounts of chemical compound as declared on the product label. Data on amounts of active entities will also be accepted, but the additional calculations carried out should be described in the corresponding free-text field in the OIE template (on the sheet for reporting option 1, 2 or 3, see section above for explanation).

For data sourced from customs, import or other bulk trading, information will likely come as tons of chemical compound. Please convert into kg for reporting in the OIE template; the annex provides conversion factors to kg from different weight units.

For veterinary medicinal products the content of the antimicrobial agent(s) may be stated in one of several ways, including (i) strength in milligram (mg) or gram (g) of the active ingredient per volume or weight or other unit, for example millilitre (ml), or kilogram (kg) or tablet, (ii) strength in International Units (IU) per weight, volume or other unit, or (iii) strength in per cent (%) weight per weight (w/w) or weight per volume (w/v). The annex provides details on the necessary conversions.

For veterinary products containing more than one antimicrobial agent, the amounts of each should be added to the respective class columns.

If there are no quantities to report for a class or route of administration, please enter a zero, 0, in the corresponding field of the table.

#### **Reporting option 1, 2 and 3: Differentiation by type of use**

For **Reporting option 1**, complete the columns **Therapeutic use (including prevention of clinical signs)** and **Growth promotion**. The sum of sales for **Therapeutic use** and **Growth promotion** should equal the amount entered in the column **Total amount (Growth promotion and Therapeutic indications)** for each class.

For **Reporting options 2 and 3**, **Growth promotion** can be reported jointly for terrestrial and aquatic food-producing animals.

#### **Reporting option 2 and/or 3: Differentiation by animal species group**

If sales for use in animals can be differentiated into sales for therapeutic purposes and for growth promotion and additionally by animal species category, please complete under the heading **Therapeutic use (including prevention of clinical signs)** the columns for **All animal species**, **All food-producing animals (terrestrial and aquatic)**, **Terrestrial food-producing animals**, **Aquatic food-producing animals**. These animal categories include all age groups and life stages of the relevant species. The first column of the table for both Reporting option 2 and Reporting option 3, **Total amount (Growth promotion and Therapeutic use)**, allows reporting of the total amount for all uses and animal categories per antimicrobial class. The last column labelled **Growth promotion** captures the amounts sold for growth promotion purposes in terrestrial and aquatic food-producing animals.

#### **Reporting option 3: Differentiation by routes of administration**

In the category of **Therapeutic use (including prevention of clinical signs)**, the OIE is interested in differentiating the proportion of sales by routes of administration for mass treatment (e.g. via feed) versus those more suited for treatment of individual animals (injection route, other routes). If sales for therapeutic use can be sub-divided by route of administration, please report the quantities used for the listed route of administration. If further differentiation by animal category is possible, then it should be reported if the data are available.

Column label	Guidance
<b>Oral route</b>	Includes all orally administered pharmaceutical forms, including “in water” or “in feed” administration, but also oral bolus administration.
<b>Injection route</b>	Includes all forms of parenteral administration that readily lead to elevated blood levels of the active ingredient, such as subcutaneous, intramuscular, intravenous, including intravenous infusion (intravenous drips).
<b>Other routes</b>	Summarises all other routes of administration, including intramammary preparations, and, mostly for aquatic animals, the bath route where an animal or a group of animals immersed in a solution containing the active ingredient.

### ***Calculating the quantities to report in Reporting options 1, 2 and 3***

Please refer to the annex of this document for detailed examples and the calculations necessary to report kg of antimicrobial agents intended for use in animals. As explained above, for pragmatic reasons in most cases the amount of the chemical compound as declared on the product label can be reported, though OIE Member Countries wishing to provide more refined data on amounts of active entities are welcome to do so.

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## Appendix V

This sheet of the OIE template should be completed by all OIE Member Countries		Questions/data requests in <i>italics</i> and grey font are not mandatory, if data are available they should be given.
1	<b>Contact Point for data collection</b>	
2	Name (order: salutation, first name, surname)	<free text field>
	Role with respect to the OIE	<free text field>
3	Organisation	<free text field>
4	Address	<free text field>
5	Phone number	<free text field>
6	Email address	<free text field>
6	<b>Year of data collection</b>	<free text field>
7	<b>Country</b>	<free text field>
8	<b>Are antimicrobial growth promoters authorised for use in your country?</b>	<input type="radio"/> Yes <input type="radio"/> No
9	List of allowed antimicrobial growth promoters, if the answer to the previous question is 'yes'	<free text field>
10	<b>Data source</b>	<input type="checkbox"/> Sales data – Wholesalers <input type="checkbox"/> Sales data – Retailers <input type="checkbox"/> Sales data – Marketing Authorisation Holders <input type="checkbox"/> Sales data – Registration Authorities <input type="checkbox"/> Sales data – Feed mills <input type="checkbox"/> Sales data – Pharmacies <input type="checkbox"/> Sales data – Farm shops/agricultural suppliers <input type="checkbox"/> Sales data – Industry trade associations <input type="checkbox"/> Sales data – Veterinarian <input type="checkbox"/> Purchase data – Wholesalers <input type="checkbox"/> Purchase data – Retailers <input type="checkbox"/> Purchase data – Feed mills <input type="checkbox"/> Purchase data – Pharmacies <input type="checkbox"/> Purchase data – Agricultural Cooperatives <input type="checkbox"/> Purchase data – Producer organisations <input type="checkbox"/> Import data – Customs declarations – veterinary products <input type="checkbox"/> Import data – Customs declarations – active ingredients <input type="checkbox"/> Veterinary prescription data – Sales <input type="checkbox"/> Veterinary prescription data – Prescriptions <input type="checkbox"/> Veterinary prescription data – Dispensing <input type="checkbox"/> Antimicrobial use data – Farm records <input type="checkbox"/> None <input type="checkbox"/> Other (further specified in 'Data source clarification')
11	Data source clarification	<free text field>
12	Are data on amounts of antimicrobial agents for use in animals accessible?	<input type="radio"/> Yes <input type="radio"/> No
13	Estimated coverage of accessible data on total amount (in %)	<free text field>
14	Is the information extrapolated from representative samples?	<input type="radio"/> Yes <input type="radio"/> No
15	Explanation of estimated coverage and extrapolations carried out	<free text field>
16	Animal groups covered by the data	<input type="checkbox"/> All animals <input type="checkbox"/> All food-producing animals (terrestrial and aquatic) <input type="checkbox"/> Terrestrial food-producing animals <input type="checkbox"/> Aquatic food-producing animals <input type="checkbox"/> Companion animals <input type="checkbox"/> Other
17	Food producing animal species covered by the data	<input type="checkbox"/> Cattle <input type="checkbox"/> Pigs - commercial <input type="checkbox"/> Pigs - backyard <input type="checkbox"/> Sheep <input type="checkbox"/> Goats <input type="checkbox"/> Sheep and goats (mixed flocks) <input type="checkbox"/> Layers – commercial production for eggs <input type="checkbox"/> Broilers – commercial productions for meat <input type="checkbox"/> Other commercial poultry <input type="checkbox"/> Poultry - backyard <input type="checkbox"/> Buffaloes (not <i>Syncerus caffer</i> ) <input type="checkbox"/> Cervidae (farmed) <input type="checkbox"/> Camelidae <input type="checkbox"/> Equidae <input type="checkbox"/> Rabbits/Hares <input type="checkbox"/> Bees <input type="checkbox"/> Fish – aquaculture production <input type="checkbox"/> Fish – fish farmed in fresh water <input type="checkbox"/> Crustaceans – aquaculture production <input type="checkbox"/> Molluscs – aquaculture production <input type="checkbox"/> Amphibians <input type="checkbox"/> Reptiles (e.g. Crocodiles) <input type="checkbox"/> Other <input type="checkbox"/> All
18	Clarification of species considered as food-producing	<free text field>
19	National report(s) on sales of antimicrobials for use in animals available on the web?	<free text field>
21	<b>Choosing your Reporting option, once the Baseline information is completed</b>	
22	Please choose your Reporting option in accordance with the table and complete the corresponding sheet	
24	Reporting option 1	National sales data / data on types or amounts of antimicrobial agents used in animals available Information available for food producing terrestrial or aquatic animals or both Data available per route of administration
25	Reporting option 2	Y N Y N Y or N Y
25	Reporting option 3	Y N Y N Y or N Y

## OIE template for the collection of data on antimicrobial agents used in animals

## Reporting option 1 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use

Antimicrobial class	Overall amount (Growth promotion + Therapeutic use) All animal species (kg)	Amount for Therapeutic use (including prevention of clinical signs) All animal species (kg)	Amount for Growth promotion All animal species (kg)
Aminoglycosides			
Amphenicols			
Arsenicals			
Cephalosporins (all generations)			
1-2 gen. cephalosporins			
3-4 gen cephalosporins			
Fluoroquinolones			
Glycopeptides			
Glycophospholipids			
Lincosamides			
Macrolides			
Nitrofurans			
Orthosomycins			
Other quinolones			
Penicillins			
Pleuromutilins			
Polypeptides			
Quinoxalines			
Streptogramins			
Sulfonamides (including trimethoprim)			
Tetracyclines			
Others			
Aggregated class data			
Total kg			

If 'Aggregated class data' are reported, please list here the classes combined	<free text field>	List all classes for which the amounts were combined, using whenever possible the 'Antimicrobial class' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential, please enter 'Confidential'.
If 'Others' are reported under 'Antimicrobial class', list here the classes reported	<free text field>	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.
Please report here any additional calculations applied	<free text field>	Please describe here calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the compilation of the OIE template.



OIE template for the collection of data on antimicrobial agents used in animals  
**Reporting option 2 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use and species group**

Antimicrobial class	Overall amount (Growth promotion + Therapeutic use) (kg)	Amount for Therapeutic use (including prevention of clinical signs)				Amount for Growth promotion
		All animal species (kg)	All food producing animals (terrestrial & aquatic) (kg)	Terrestrial food producing animals (kg)	Aquatic food producing animals (kg)	All food producing animals (terrestrial & aquatic) (kg)
Aminoglycosides						
Amphenicols						
Arsenicals						
Cephalosporins (all generations)						
1-2 gen. cephalosporins						
3-4 gen cephalosporins						
Fluroquinolones						
Glycopeptides						
Glycophospholipids						
Lincosamides						
Macrolides						
Nitrofurans						
Orthosomycins						
Other quinolones						
Penicillins						
Pleuromutilins						
Polypeptides						
Quinoxalines						
Streptogramins						
Sulfonamides (including trimethoprim)						
Tetracyclines						
Others						
Aggregated class data						
Total kg						
If 'Aggregated class data' are reported, please list here the classes combined	<free text field>	List all classes for which the amounts were combined, using whenever possible the 'Antimicrobial class' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential, please enter 'Confidential'.				
If 'Others' are reported under 'Antimicrobial class', list here the classes reported	<free text field>	Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.				
Please report here any additional transformations applied	<free text field>	Please describe here calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the compilation of the OIE template				

OIE template for the collection of data on antimicrobial agents used in animals  
**Reporting option 3 - Overall amount sold for/used in animals by antimicrobial class; with the possibility to separate by type of use, species group and route of administration**

Overall amount (Growth promotion + Therapeutic use)		Amount for Therapeutic use (including prevention of clinical signs)										Amount for Growth promotion		
Antimicrobial class	All animal species	All animal species			All food-producing animals (terrestrial and aquatic)			Terrestrial food-producing animals			Aquatic food-producing animals			All food producing animals (terrestrial & aquatic) (kg)
	All routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	Oral route (kg)	Injection route (kg)	Other routes (kg)	
Aminoglycosides														
Amphenicols														
Arsenicals														
Cephalosporins (all generations)														
1-2 gen. cephalosporins														
3-4 gen cephalosporins														
Fluoroquinolones														
Glycopeptides														
Glycophospholipids														
Lincosamides														
Macrolides														
Nitrofurans														
Orthosomycins														
Other quinolones														
Penicillins														
Pleuromutilins														
Polypeptides														
Quinoxalines														
Streptogramins														
Sulfonamides (including trimethoprim)														
Tetracyclines														
Others														
Aggregated class data														
Total kg														

List all classes for which the amounts were combined, using whenever possible the 'Antimicrobial class' terms or the terminology of the OIE list of antimicrobial agents of veterinary importance. Substances included in the data aggregation that are not part of the recommended terminology should also be listed. If one class was reported that needs to remain confidential, please enter 'Confidential'.

Describe the class or classes reported as 'Others', using whenever possible the terminology of the OIE list of antimicrobial agents of veterinary importance.

Please describe here calculations carried out in addition to the ones recommended by the OIE in sections 1 and 2 of the annex to the instructions for the compilation of the OIE template.



**JOINT MEETING BETWEEN THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES  
AND THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

**Paris, 8 September 2015**

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The OIE Scientific Commission for Animal Diseases (the Scientific Commission) and the OIE Terrestrial Animal Health Standards Commission (the Code Commission) held a joint meeting on Tuesday 8 September 2015 to discuss issues of mutual interest. All members of the Commissions as well as the Director General, Deputy Director General, and supporting staff of the Scientific and Technical Department and the International Trade Department of the OIE participated in the meeting.

Dr Bernard Vallat, the Director General of the OIE, emphasised the benefits of having the Scientific Commission and the Code Commission joint meetings to ensure coordination between both Commissions and welcomed the new members of both Commissions to the OIE Headquarters.

The Director General also informed the Commissions of the intention of the OIE Council to increase the transparency and efficiency of the work of all Specialist Commissions by evaluating the performance of their members based on specific criteria still and procedure still being discussed by the Council.

The main discussion points were as follows:

**1. Coordination between the two commissions**

The Director General first explained the inter-commission coordination mechanisms already established at the OIE Headquarters and reiterated its continued support to the Commissions' work, in particular by providing all the secretarial work to the Commissions.

The Director General emphasised the importance of following a two-year cycle of developing or amending OIE standards. The one-year cycle should only be used in specific circumstances such as emerging diseases or new scientific evidence with impact on disease control or on trade, which requires urgent development or amendment of OIE standards.

The Director General reminded the meeting that there was a natural link between the two Commissions as stipulated in the basic texts of the OIE related to the Terms of Reference of the Specialist Commissions including the Scientific Commission's mandate to provide up-to-date scientific information to the Code Commission.

In this regard, the Director General suggested frequent communication between the Presidents of the Commissions to facilitate the coordination and collaboration between the Commissions with the help from the Headquarters.

The Director General also highlighted the fact that depending on the availability of the budget, the Commissions could request the Director General to convene *ad hoc* Groups to seek experts' opinion in addition to the existing *ad hoc* Groups responsible for official recognition of disease status of Member Countries. When necessary and if budget permitted, a representative of each Commission could be invited to attend the *ad hoc* Group meetings as observer to guide the Group in its work without influencing the Group's position.

In regard to the availability of *ad hoc* Group reports, the Director General reiterated his view that the reports of the *ad hoc* Groups should be available to Specialist Commissions for information but they should not be part of the decision process until the report is validated by the responsible Commission.

The Director General confirmed that experts participating in *ad hoc* Groups are selected based on their scientific excellence and geographical balance, using proposals from Specialist Commissions and when possible within the network of experts from reference centres, endorsed by the World Assembly.

In response to the comments from the Director General, the Presidents of the two Commissions expressed their agreement for his suggestions and asked the Headquarters to continue to provide necessary support with regard to the exchange of working documents.

The two Commissions also agreed to schedule their meetings to enable overlap of their respective meetings, as well as those of the Biological Standards Commission, to allow them to hold joint meetings. When possible, the meeting of the Scientific Commission should coincide with the first week of the Code Commission's meeting.

The Presidents agreed with the Director General on his proposal to find suitable dates decided at least two years in advance for all the meetings of the Specialist Commissions.

## 2. Glossary

The President of the Code Commission explained that there was a need to clearly define the meaning of "OIE Standards" and "OIE Guidelines" as these could have a direct impact on the process of WTO disputes. For this reason, the Code Commission drafted definitions in consultation with the Scientific Commission and the Biological Standards Commission. He indicated that these draft definitions would be attached to the Code Commission report for Member Countries' comments.

The two Commissions also discussed the new draft definitions for *vaccination programme*, *emergency vaccination*, and *routine vaccination*, which had been developed in collaboration with the two Commissions and the Biological Standards Commission. The Presidents of the two Commissions asked the Headquarters to forward these draft definitions for consideration of the *ad hoc* Group on vaccination which would be convened in near future to draft a new horizontal chapter on vaccination for consideration by the Scientific Commission. It was agreed that the participation of representatives from the Code Commission and Biological Standards Commission would be requested.

## 3. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.)

The President of the Code Commission explained the proposed revision of several references in Chapter 1.6. to the *Terrestrial Manual*. He was informed the revision of Chapter 1.6. was included in the work plan of the Scientific Commission, and informed that the Code Commission had the intention to separate the revised Chapter 1.6. by dedicating one *Terrestrial Code* chapter to each of the disease questionnaires for ease of reference.

## 4. The model certificate for high health high performance (HHP) horses

The President of the Code Commission noted that a number of Member Countries' comments was received raising concerns on the discrepancies between some requirements of the certificate and the current *Terrestrial Code* chapters and difficulties in interpreting the content of the certificate in absence of the biosecurity guidelines included in the handbook for the management of HHP horses.

The two Commissions agreed to include the Model HHP certificate in the section of certification of the "Handbook for the management of HHP horses" since at this stage the HHP concept as such is complete but the certificate was not yet ready to be proposed for adoption as a *Terrestrial Code* chapter. Further work such as alignment with existing *Terrestrial Code* chapters and testing of the HHP concept in the field was required before a proposal for its adoption as a new *Terrestrial Code* chapter could be reconsidered.

The two Commissions also agreed on the fact that the Model HHP Certificate is an integral part of the HHP concept that would be implemented by those Member Countries wishing to apply it as an OIE guideline. Consequently, the two Commissions decided that the justification for the amendments provided by the Scientific Commission and Code Commission would be annexed to the report of the Scientific Commission.

The Director General agreed with both Commissions noting that it was important to have consistency in developing the OIE standards or guidelines to ensure transparency while enabling Member Countries to adopt and implement the HHP concept.

## **5. Bovine spongiform encephalopathy (BSE)**

The President of the Code Commission informed the Scientific Commission of Member Countries' comments on the revised chapter circulated for comments in the February 2015 Code Commission meeting report and the need for an update of the *Terrestrial Code* and *Terrestrial Manual* chapters on BSE accordingly. The Code Commission suggested to the Director General to convene an *ad hoc* Group to specifically address these Member Country comments by differentiating atypical from classical BSE in the *Terrestrial Manual* and drafting a case definition of both classical and atypical BSE for the *Terrestrial Code*.

The President of the Scientific Commission reminded the Code Commission that the last *ad hoc* Group on BSE proposed some amendments to address the issue of atypical BSE and that the proposed changes still required to be examined. In addition, it was brought to the attention of both Commissions that according to the report of the Biological Standards Commission, the modification of the *Terrestrial Manual* chapter on BSE was already tasked to experts from the OIE Reference Laboratories. The President of the Scientific Commission proposed that the *ad hoc* Group on the evaluation of BSE status dossiers would be capable of undertaking the task of reviewing the concerns from the Member Countries.

The Director General recalled however that a number of Member Countries made strong interventions on the proposed revision of the BSE chapter during the last General Session and agreed to convene a specific *ad hoc* Group with the Terms of Reference of revising the *Terrestrial Code* chapter, in light of those comments and of the revised *Terrestrial Manual* chapter.

## **6. Porcine reproductive and respiratory syndrome (PRRS)**

The President of the Scientific Commission informed the Code Commission that the task of revising Member Countries' comments on the draft chapter was accomplished with the support of the *ad hoc* Group. The amended chapter was forwarded to the Code Commission for further consideration.

The President of the Code Commission suggested that considering its agenda priorities and time constraints, the PRRS draft chapter be reviewed at the next Code Commission meeting.

## **7. Equine trypanosomiasis including Surra**

The President of the Scientific Commission informed the Code Commission that the work of the *ad hoc* Group that was convened to provide an expert opinion on the need to have a specific *Terrestrial Code* Chapter on surra and update the existing chapter on dourine was not accomplished. He suggested to the Director General to reconvene an *ad hoc* Group with additional members experienced in drafting OIE standards. The President of the Code Commission concurred with this decision.

## **8. Foot and mouth disease (FMD)**

The Scientific Commission recalled several pending issues raised by Member Countries when revising the recently adopted chapter on FMD and that were not included in the new chapter.

The President of the Code Commission explained that the Code Commission addressed Member Countries' comments made during the General Session and amended the FMD chapter accordingly, except on the pending issues mentioned, which requested more expertise. The President of the Scientific Commission indicated that the Scientific Commission was not given the opportunity to review these comments during its meeting and requested that those pending issues be forwarded to a forthcoming *ad hoc* Group meeting to seek their expert opinion.

#### **9. Dates of next meeting**

The two Commissions agreed on the dates of their next meetings to ensure an overlapping period (during the first week of the Code Commission meeting) and good coordination with other Specialist Commissions. The dates are given in their respective reports.

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