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MEETING OF THE OIE AD HOC GROUP ON CLASSICAL SWINE FEVER [1]

Paris, 5-6 July 2016

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A meeting of the OIE *ad hoc* Group on classical swine fever (CSF) (hereafter the Group) was held at the OIE Headquarters from 5 to 6 July 2016.

1. Opening

Dr Monique Eloit, Director General of the OIE, welcomed and thanked the Group for its commitment and its extensive support of the OIE in fulfilling the mandates given by Member Countries.

Dr Eloit highlighted that one of the mandates of the OIE was maintaining scientific excellence as part of the foundation of the OIE international standards setting procedure in order to preserve international credibility. She explained that the OIE remained committed to maintaining transparent and robust procedures for the selection of experts for the *ad hoc* Groups, Working Groups and Specialist Commissions, and to further expand the international scientific expertise of the OIE. She mentioned that more training tools would be made available to the OIE staff in order to further improve the implementation of the OIE 6th Strategic Plan.

Dr Gregorio Torres, Chargé de mission of the Sciences and New Technologies Department, reminded the experts that they had been selected based on their scientific expertise and that they were not representing their own countries or institutions. Prior to the meeting all experts signed a confidentiality agreement and a declaration of interests. Dr Torres emphasised that the discussions captured in the report would be attributed to the Group and not to the individual expert.

Finally, he announced that a representative of the Scientific Commission for Animal Diseases and of the Terrestrial Animal Health Standards Commission would also participate in the meeting to support the Group discussion and to guide the experts in the completion of the term of references.

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

Dr Trevor Drew acted as chair of the Group. Dr Cristobal Zepeda acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Review of Chapter 15.2. on CSF of the *Terrestrial Animal Health Code*

The Group was reminded that Chapter 15.2. had been last adopted after revision in May 2013, when the procedure for official recognition was expanded to include CSF. The Group was tasked to address the scientific comments received since the last adoption, and to update the Chapter based on the recommendations made by the prior CSF ad hoc Group, but also on the African swine fever (ASF), and FMD *ad hoc* Groups for further harmonisation.

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[1] Note: This *ad hoc* Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the September 2016 report of the Scientific Commission for Animal Diseases because this report provides its considerations and comments. It is available at: http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/scientific-commission-reports/meetings-reports/

Article 15.2.1.: General provisions

The Group noted a comment made by the *ad hoc* Group on the evaluation of CSF status of Member Countries in November 2015, with regard to the case definition. The Group clarified the text to indicate that the detection of viral antigen or nucleic acid specific to a classical swine fever virus (CSFV) in a sample with the presence of clinical signs from a suspected pig would also be included in the definition of infection with CSFV. The Group emphasised that the case definition based on demonstration of CSFV nucleic acid was not only limited to detection by reverse-transcriptase polymerase chain reaction (RT-PCR), but also included virus characterisation by sequencing and comparative analysis, which would be recommended particularly for first detection in CSF-free countries. The amended definition was more in line with the case definition in the FMD Chapter of the *Terrestrial Animal Health Code* (*Terrestrial Code*).

In response to a Member Country's comment, the Group explained that a definition of a suspected case of CSF is based on clinical signs, pathological lesions, epidemiological links or other suspects following exposure to the pathogens. The Group made note that this was a generally accepted principle that would not require specific definitions and that applied to all disease-specific chapters of the *Terrestrial Code*. Concerning the specific proposal to include virus isolation within point 2 and 3 of the case definition, the Group felt that the inclusion was not appropriate as points 2 and 3 are provided as alternatives when virus isolation is not feasible.

The Group considered the definition of the incubation period in the glossary of the OIE *Terrestrial Code* and agreed that an incubation period of 14 days would be appropriate for the purposes of the *Terrestrial Code*. (Karsten *et al.* 2005)[2]

The Group discussed the use of the term suid versus pigs. Considering the susceptible species, the Group agreed that the term pig was more appropriate for the purposes of the CSF Chapter while suid was more appropriate for the ASF Chapter.

The Group noted that not all CSFV-infected pigs show clinical signs. The Group considered it appropriate to add the possibility of finding pathological lesions suggestive of CSF in the case definition.

The Group clarified the provision that a trade ban in commodities of domestic and captive wild pigs should not be imposed when CSFV existed in wild and feral pigs provided the commodities are traded according to the recommendation of this chapter.

Article 15.2.2.: General criteria for the determination of the classical swine fever status of a country, zone or compartment

The Group highlighted that all pigs showing clinical signs or pathological lesions suggestive of CSF should be subjected to appropriate field investigation, whilst depending on the epidemiological circumstances and findings of the field investigation, laboratory investigation may not always be necessary.

Article 15.2.4.: Classical swine fever free compartment

The Group harmonised the CSF article with the updated FMD Chapter.

The Group discussed if historical freedom could be considered for CSF, noting that the current chapter does not mention the concept, while other chapters for other diseases for which the OIE recognised an official status did. The Group recommended harmonising the disease chapters for which the OIE recognises official disease status in relation to historical freedom.

[2] Karsten S., Rave G., Krieter J. (2005). Monte Carlo simulation of classical swine fever epidemics and control. II. Validation of the model. *Veterinary Microbiology*, **108**, 199-205.

The Group noted that historical freedom complying with Article 1.4.6.1. a) of the *Terrestrial Code* provided an additional level of assurance that a country was free of CSF. However, countries were expected to submit a full dossier in compliance with Article 15.2.3. when applying for official status recognition.

Article 15.2.5.: Establishment of a containment zone within a classical swine fever free country or zone

Consistent with the approach followed by the other disease chapters for official recognition of disease status, the Group added that, in the event of the recurrence of CSF in the containment zone, the approval of the containment zone would be withdrawn and the CSF-free status of the country or zone would be suspended until the relevant requirements of Article 15.2.6. were fulfilled.

The Group provided a time limit of 12 months after establishment of a containment zone for the recovery of the CSF-free status of the containment zone following the provisions of Article 15.2.6. of the *Terrestrial Code*. If freedom was not regained within 12 months, Member Countries would be required to re-apply for CSF-free status in compliance with Article 15.2.3.

The Group considered the extended concept of the containment zone that was discussed by the *ad hoc* Group for FMD in June 2016. The extended concept would cover circumstances where outbreaks continue to occur within an infected zone as long as a protection zone, in which no outbreaks have occurred, is established within and along the perimeters of a larger containment zone (please refer to the report of the *ad hoc* Group on FMD of June 2016). The Group agreed that the proposed concept would also be applicable to CSF and recommended that the Scientific Commission take a harmonised approach.

Article 15.2.6.: Recovery of free status

With regard to the surveillance provisions, the Group decided to refer only to Article 15.2.30. on surveillance, as the article is specific to additional measures associated with the recovery of free status. Nevertheless, this article does also make reference to other general surveillance provisions that need to be taken into consideration.

The Group added a point, in line with the FMD chapter, referring to the provision for recovery in case an outbreak occurs in a CSF-free compartment. The Group created point 5 to clarify when the recovery of free status should be requested. The Group added a 24-month time limit for Member Countries applying for recovery, in line with the equivalent Article in the FMD Chapter. Otherwise, Article 15.2.3. would apply.

Article 15.2.6.bis.: Direct transfer of pigs from an infected zone for slaughter in a free zone

The Group noted that, at the last meeting of the *ad hoc* Group on the evaluation of CSF status of Member Countries in November 2015, an article was drafted in response to a Member Country comment.

The Group discussed the draft article in-depth and aligned the CSF article with the FMD article requiring the pigs to have been kept in the establishment of origin for 3 months prior to movement instead of the proposed 30 days.

The Group highlighted that this article was intended for movements between zones in a country rather than movements between countries.

Article 15.2.6.ter.: Direct transfer of pigs from a containment zone for slaughter in a free zone

The Group noted that, at the last meeting of the *ad hoc* Group on the evaluation of CSF status of Member Countries in November 2015, an article was drafted in line with the FMD chapter and recommended that this draft be considered by the Specialist Commissions.

Article 15.2.8.: Recommendations for importation from countries or zones considered infected with classical swine fever virus

The Group agreed to add a provision for pigs to be quarantined for 28 days (two incubation periods) prior to shipment and subjected to a virological and serological test at least 21 days after entry into the quarantine station.

Article 15.2.9.: Recommendations for the importation of wild and feral pigs

The members of the Group discussed possible scenarios of importation of wild and feral pigs. Whilst the Group agreed that importation of wild and feral pigs was not commonly practised it was concluded that the provisions under Article 15.2.9.do provide the necessary guarantees.

The Group harmonised the isolation of 28 days in a quarantine station in line with Article 15.2.8.

Article 15.2.11.: Recommendations for importation from countries, zones or compartments infected with classical swine fever

For semen of domestic and captive wild pigs

The Group considered the draft article in the ASF chapter. Since transmission of CSFV via semen is scientifically proven, whereas transmission of ASFV via semen of domestic and captive wild pigs is much less supported by scientific evidence, the Group felt that the requirements for CSFV should be more stringent than those for ASFV.

The Group indicated that the 40-day waiting period was inpractical for importation of fresh semen and would be an unnecessary measure for risk mitigation. The provision related to a CSF-free compartment was deleted, as this scenario was covered by Article 15.2.10. Instead, a provision was made for an establishment with the addition of a surveillance requirement of at least 12 months as described in Articles 15.2.26 to 15.2.32. In addition, the Group recommended three conditions to be met: Negative results for i) virological test regardless of the vaccination status; ii) serological test at least 21 days after collection with demonstration that any antibodies are due to the vaccine, if vaccinated; and iii) serological test at least 21 days after collection, if not vaccinated.

Article 15.2.12.: Recommendations for importation from countries, zones or compartments free from classical swine fever

For in vivo *derived embryos of domestic pigs*

The Group aligned the requirement for donor females in accordance with provisions in the amended draft chapter on ASF and FMD chapter and added a requirement for fertilisation. The Group recommended that this requirement be also included in the corresponding article in the ASF chapter (article 15.1.10.).

Article 15.2.13.: Recommendations for importation from countries, zones infected with classical swine fever

The Group amended the article based on the modifications made on Article 15.2.11.

Article 15.2.14.bis: Recommendations for importation from countries or zones infected with CSFV

For fresh meat of domestic and captive wild pigs

The Group noted that the current Chapter did not have provisions for importation of fresh meat of domestic and captive wild pigs.

The members of the Group had differing opinions on whether provisions were needed for fresh meat of domestic and captive wild pigs from infected countries. The Group felt that the concept of CSF-free compartments allowed trade of fresh meat from infected countries, while compartmentalisation would not be applicable for the importation of fresh meat from wild and feral pig from infected countries. Nevertheless, the

Group drafted an article for the importation of fresh meat from domestic and captive wild pigs from infected countries based on the draft articles 8.8.22.bis. of the FMD chapter and 15.1.12.bis. of the ASF chapter, while referring the decision for inclusion to the Specialist Commissions.

Article 15.2.15.: Recommendations for the importation of fresh meat of wild and feral pigs

In response to a Member Country's comment, the Group acknowledged the difficulty in taking serological samples from carcasses of wild pigs that have been refrigerated for the purposes of trade. However, the Group felt that the serological status of wild pigs was an important part of assurance of freedom from CSF for export.

Articles 15.2.16. to 15.2.21.: Recommendations for the importation of different pig products

According to the ASF *ad hoc* Group, specifying the intended use of meat products was irrelevant since the objective was to mitigate the risk posed by the products regardless of their intended use.

The Group aligned the terminology by replacing 'establishment' with 'facility' to avoid confusion with the glossary definition of an establishment.

Article 15.2.16.: Recommendations for the importation of meat and meat products of pigs

The Group included references to the Articles 15.2.14., 15.2.14.bis. and 15.2.15. under both point 1) a) and 1) b) ii), as they refer to the importation of fresh meat.

Article 15.2.21.: Recommendations for the importation of skins and trophies

In response to a Member Country's request to incorporate recommendations on importation of skins and trophies of wild and feral pigs, the Group indicated that provision under point 2) applies.

Article 15.2.23.: Procedures for the inactivation of the classical swine fever virus in meat

Based on a scientific article by Cowan et al. (2015)[3], the Group added a requirement, under point 1. b) for 30 minutes of heat treatment at a minimum temperature of 70°C.

Article 15.2.24.: Procedures for the inactivation of the classical swine fever virus in casings of pigs

The Group considered an EFSA report[4] and concluded that there was limited information on the effect of dry salt in the inactivation of CSFV. The Group concurred with the EFSA report and other studies[5, 6] that the effectiveness of phosphate supplemented dry salt was superior to dry salt alone.

Article 15.2.25.: Procedures for the inactivation of the classical swine fever virus in skins and trophies

The Group did not find scientific evidence on the effectiveness of formalin or formaldehyde for the inactivation of CSFV in skins and trophies and decided not to include these methods in the article.

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3 Cowan L., Haines F.J., Everett H.E., Crudgington B., Johns H.L., Clifford D., Drew T.W., Crooke H.R. (2015). Factors affecting the infectivity of tissues from pigs with classical swine fever: Thermal inactivation rates and oral infectious dose. *Vet. Microbiol*., **176**, 1–9

4 EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), (2012). Scientific Opinion on animal health risk mitigation treatments as regards imports of animal casings. EFSA Journal 2012; 10(7):2820, 32 pp. doi:10.2903/j.efsa.2012.2820

5 Wijnker J.J., Depner K.R., Berends B.R. (2008). Inactivation of classical swine fever virus in porcine casing preserved in salt. *International journal of food microbiology*, **128**, 411-413

6 Wieringa-Jelsma T., Wijnker J.J., Zijlstra-Willems E.M., Dekker A., Stockhofe-Zurwieden N., Maas R., Wisselink H.J., (2011). Virus inactivation by salt (NaCl) and phosphate supplemented salt in a 3D collagen matrix model for natural sausage casings. *International journal of food microbiology*, **148**, 128-134.

Article 15.2.25.bis.: Procedures for the inactivation of CSFV in bristles

The Group agreed that boiling bristles in water for at least 30 minutes would inactivate CSFV. The Group did not find the scientific evidence related to other effective inactivation treatments such as the use of 0.5% formalin as suggested by some Member Countries.

Article 15.2.25.ter.: Procedures for the inactivation of CSFV in litter and manure from pigs

With reference to Bøtner & Belsham (2012)[7] and Weesndorp et al. (2008)[8], the Group considered and agreed that the provisions in the amended draft ASF chapter was sufficient for CSFV inactivation in litter and manure from pigs.

Article 15.2.28.: Surveillance strategies

In response to a Member Country's comment, the Group added a reference to contingency planning while acknowledging that contingency planning should be part of an emergency response rather that part of a surveillance programme. The Group acknowledged the general need for guidance on contingency planning and understood that this was in the agenda of the OIE.

The Group partially agreed with the second comment of the Member Country and amended the text to further clarify that a surveillance strategy should estimate (not establish) the prevalence or demonstrate the absence of CSFV infection based on clinical investigation or on randomised and targeted sampling methods.

The Group emphasized that clinical investigation was a key element of CSF surveillance and should be retained.

In response to the comments of a Member Country, the Group proposed that the Spanish translation for 'targeted' should be 'dirigido' instead of 'especifico'.

The Group proposed to clarify the article by adding type of production systems as a risk factor of CSF transmission among the risk factors already mentioned i.e. temporal and spatial distribution of past outbreaks, pig movements and demographics.

The Group agreed with a Member Country's comment that, when designing a surveillance system, due to the recognised cross-reactivity with ruminant pestiviruses in the serological diagnosis of CSF, the factors mentioned in point 4 should be taken into account.

The Group agreed that the survey design should not be compromised when using sera collected for other purposes. The Group amended the paragraph for clarity and considered that survey populations and statistical design were implicit within the existing text.

The Group agreed that it was sensible to move the last paragraph and the four points (a, b, c and d) of the Article to the end of Article 15.2.27. for general conditions and methods for surveillance.

Article 15.2.31. Surveillance for classical swine fever virus in wild and feral pigs

The Group considered the definition of 'monitoring' and 'surveillance' provided in the glossary of the *Terrestrial Code* and did not agree with a Member Country's comment to use the term 'monitoring' instead of 'surveillance' in this article. The Group acknowledged that surveys to estimate the prevalence or to demonstrate absence of the disease in wild pig populations may be difficult to design, however, actions could still be taken based on the results of the surveillance. Therefore, the Group considered the term 'surveillance' as more appropriate term to be used throughout the article.

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7 Bøtner A. Belsham G.J. (2012). Virus survival in slurry: Analysis of the stability of foot-and-mouth disease, classical swine fever, bovine viral diarrhoea and swine influenza viruses. Volume 157, Issues 1–2, 25, 41–49.

8 Weesendorp E., Stegeman A., Loeffen W.L.A. (2008). Survival of classical swine fever virus at various temperatures in faeces and urine derived from experimentally infected pigs. Volume 132, Issues 3–4, 10 December 2008, 249–259.

The Group disagreed with a Member Country's proposal to include domestic pigs in the text, as this article was dedicated to wild and feral pigs. The Group clarified that the provisions on the interpretation of diagnostic results should correspond with the recommendations in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*).

Article 15.2.32.: The use and interpretation of diagnostic tests in surveillance

In response to a Member Country's comment, the Group concurred that any positive ELISA test result should be further investigated. The Group explained that differential neutralisation tests should indicate whether the virus involved was a ruminant pestivirus or CSFV and clinical signs may not always be present even if CSFV was involved, which would particularly be true in infected mature pigs or in pigs infected with moderate strains of CSFV.

The Group acknowledged that a direct fluorescent antibody test (FAT) may have some value as a preliminary screening test. However, as mentioned in the *Terrestrial Manual*, FAT does not completely rule out CSFV infection, and could generate large numbers of inconclusive results. Furthermore, FAT requires a high level of skill and training to perform and maintain and to the Group's knowledge there is not international ring trial for the FAT. The Group therefore concluded that PCR was the test of choice for virological screening of tissues, with sequencing and isolation used to confirm the identity of any positive results.

As requested by a Member Country, the Group proposed a text to explain the first flowchart.

However, the Group expressed concerns regarding translation of the definitions of a case into flowcharts. The Group discussed extensively how to capture the diagnostic algorithms in a single flowchart without causing confusion or misunderstanding, and concluded that schematic representations should be included in the *Terrestrial Manual* rather than in the *Terrestrial Code*. Furthermore, with new emerging diagnostics and science, only the *Terrestrial Manual* and not the *Terrestrial Code* would need to be updated. The Group suggested removing both flowcharts from the amended chapter.

4. The implication of the description of differentiate infected from vaccinated animals (DIVA) vaccines in the *Terrestrial Manual* Chapter 2.8.3. on CSF

The Group discussed the current situation of the DIVA vaccines, and agreed that there were no sufficiently validated vaccines or diagnostic methods to give confidence on DIVA vaccines. As a consequence, the Group proposed either to: i) delete the option of allowing for CSF freedom when vaccination is practised in point 4 of Article 15.2.3, or ii) keep the option as it is but indicate that this provision was under study. The Group decided not to modify the text while leaving the decision to the Scientific Commission.

The Group agreed that there was a need for review and updating the *Terrestrial Manual*, particularly to include the latest development in DIVA vaccines, and suggested that the Biological Standards Commission update the chapter accordingly.

5. Adoption of report

The Group reviewed the draft report provided by the rapporteur and agreed to circulate the draft report electronically for comments before the final adoption.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 5-6 July 2016

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Agenda

1. Opening
2. Adoption of agenda, and appointment of chairperson and rapporteur
3. Review of Chapter 15.2. on CSF of the *Terrestrial Animal Health Code*
4. Implication of the description of differentiate infected from vaccinated animals (DIVA) vaccines in the *Terrestrial Manual* Chapter 2.8.3. on CSF
5. Adoption of the report

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MEETING OF THE OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 5-6 July 2016

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