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MEETING OF THE OIE AD HOC GROUP ON ALTERNATIVES FOR SURVEILLANCE FOR DEMONSTRATION OF FREEDOM FROM FOOT AND MOUTH DISEASE (FMD) AND RECOVERY PERIODS[1]

Paris, 28-30 August 2018

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A meeting of the OIE *ad hoc* Group on alternatives for surveillance for demonstration of freedom from foot and mouth disease (FMD) and recovery periods (hereafter the Group) was held at the OIE Headquarters from 28-30 August 2018.

1. Opening

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

She thanked the experts for having signed the form for undertaking of confidentiality, as well as for having declared any potential conflict of interest. She mentioned that should any members of the Group feel a possible conflict of interest that could influence their opinion, they should state so and withdraw from discussions on that subject matter. She also encouraged the Group to capture the detailed rationale supporting its proposals and recommendations in its meeting report for the consideration of Members. She recommended that when consensus was not reached within the Group, minority opinions should be duly recorded in the meeting report.

Dr Eloit highlighted one of the core missions of the OIE as a standard-setting organisation for the safe international trade in animals and animal products, and that decisions made should be science-based. In relation to this core mission, she informed the Group that the OIE Council will meet at the end of September to initiate the preparation of the OIE 7th Strategic Plan which will address the role of the OIE in science. She indicated that OIE experts and Collaborating Centres might be consulted at a later stage in this regard.

Lastly, she informed the Group that Dr Neo Mapitse has replaced Dr Laure Weber-Vintzel as Head of the Status Department, and of the nomination of Dr Min-Kyung Park as Deputy Head of the Status Department. She also congratulated Dr Kris de Clercq on his re-election as first Vice President of the Scientific Commission for Animal Diseases (Scientific Commission).

The OIE and the Group welcomed Drs Sam Hamilton and Eoin Ryan as new members participating in an OIE *ad hoc* Group for the first time.

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

The Group was chaired by Dr David Paton. Dr Tom Smylie acted as rapporteur, with the support of the OIE Secretariat. The Group adopted the proposed agenda.

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

[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 2018 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/

3. Background

Following requests received from some Members to reduce the recovery period after FMD outbreaks, an *ad hoc* Group was convened in June 2017 to explore the alternatives for surveillance for demonstration of freedom from FMD and their possible impact on the duration of recovery periods. This Group explored and discussed the pros and cons of different options and indicated its preference: to maintain the current timing requirements of Article 8.8.7. of the *Terrestrial Animal Health Code* (*Terrestrial Code*), but to add a sentence at the end of the article, clarifying that the waiting period should be respected unless there is evidence that the appropriate level of confidence has been reached earlier by implementing additional surveillance or other measures. The Group also indicated the need to provide guidance on the qualitative methods that would be used in the evaluation of the additional surveillance and other measure of reaching the appropriate level of confidence. After consideration by the Scientific Commission of: i) the report of the *ad hoc* Group, ii) an option document linking the conclusion and its impact on the FMD Chapter of the *Terrestrial Code*, and iii) opinion of the *ad hoc* Group on the evaluation of FMD status, the Scientific Commission was informed that the two *ad hoc* Groups were in agreement with the preferred options related to the provisions on waiting time requirements, on level of confidence and the method to be used for the assessment of the level of confidence.

The two aforementioned *ad hoc* Groups (*cf.* Reports of the Scientific Commission: Annex 13 of the September 2017 meeting and Annex 11 of the February 2018 meeting) recommended that the surveillance objectives, for recovery of FMD status in a country or zone should be modified to demonstrate the absence of infection in the non-vaccinated population and the absence of transmission of FMDV in the vaccinated population. Furthermore, the current minimal waiting period (i.e. six months) set in Article 8.8.7. point 1.c). of the *Terrestrial Code* for the recovery of FMD free status (where vaccination is not practised) where emergency vaccination not followed by the slaughtering of all vaccinated animals was conducted should apply, unless evidence demonstrating freedom, with an appropriate level of confidence, could be provided earlier by implementing additional surveillance or other measures.

Elaborating on this recommendation, the main goals of the Group were to: (i) review and propose relevant amendments, clearly describing the additional surveillance or other measures required in shortening the waiting period of six months under Chapter 8.8. of the *Terrestrial Code*, (ii) develop additional questions in the recovery section of the questionnaire that Members should answer and compile appropriate information justifying and demonstrating high level of confidence to claim freedom from FMD earlier than six months. Accordingly, the Group focused on additional surveillance measures for early recovery and not on additional control measures.

The Group also considered the applicability of a similar strategy for shortening the waiting period set in Article 8.8.7. point 3.a) of the *Terrestrial Code* for the recovery of a FMD free status where vaccination *is* practised.

4. Revision of Article 8.8.7. point 1.c) - Recovery of free status without vaccination where emergency vaccination not followed by the slaughtering of all vaccinated animals is applied

The Group was in agreement with the recommendation of the previous ad hoc Groups[1] that the surveillance objectives in Article 8.8.7. point 1.c), should be to demonstrate the absence of infection in the non-vaccinated population and the absence of transmission of FMDV in the vaccinated population.

The Group emphasised that the main risk of transmission amongst vaccinated animals is associated with subclinical infection which may result from flaws in the vaccination programme (i.e. the vaccine itself was not effective or vaccination was not performed properly). Therefore, where census surveillance of vaccinated ruminants is not undertaken, to qualify for an early recovery of a free status, it would be critical for countries to demonstrate the efficacy of the emergency vaccine used and of its effective deployment when demonstrating absence of transmission in the vaccinated population, in addition to absence of infection in the non-vaccinated population.

With regard to the timing requirement, the Group also agreed that the waiting period in Article 8.8.7. point 1.c) could be shortened to less than six months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission in the vaccinated population based on proposed provisions. However, the Group suggested specifying that the period for recovery can only be reduced to a minimum of three months consistent with the minimal timeframe for the recovery of a free status where a stamping out policy is applied without emergency vaccination (Article 8.8.7. point 1.a) or where emergency vaccination and a stamping-out policy with the slaughter of all vaccinated animals is applied (Article 8.8.7. point 1.b).

The Group therefore recommended the following sentence be added at the end of Article 8.8.7. point 1.c):
"*This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission in the vaccinated population based on the provisions of Article 8.8.40. point 7.*

The Group recommended the additional requirements for shortening the waiting period for recovery of a FMD free status be listed in draft Article 8.8.40. point 7, and compliance with these requirements be documented based on draft Section 8 of Articles 1.11.1. for recovery of a free country status and 1.11.3. for recovery of a free zone status.

The Group emphasised that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the outbreak in order to plan for the applicable requirements to be met.

5. Additional requirements for shortening the waiting period for recovery of a FMD free status <u>without</u> vaccination where stamping-out policy and emergency vaccination are not followed by the slaughtering of all vaccinated animals

The Group carefully considered the additional measures listed by the previous *ad hoc* Groups[2], including their respective objective, benefits and performance.

Building on these recommendations, the Group recommended the effective implementation of the additional requirements in draft Article 8.8.40. point 7 should be well-documented and justified in order to demonstrate the absence of infection in the non-vaccinated population and the absence of transmission in the vaccinated population with a high level of confidence, and to eventually qualify for an early recovery of a free status.

Importantly, the Group stressed that these requirements for an earlier recovery of a FMD free status, were indeed additional to the other requirements applicable for the recovery of a free status as defined in Article 8.8.7. point 1.c) of the *Terrestrial Code*.

The Group proposed two options for early recovery of free status:

- "Option 1" (as detailed in draft Article 8.8.40 point 7.a) involved undertaking census surveillance of vaccinated ruminants, random sampling of pigs in all vaccinated epidemiological units, and multistage random sampling of non-vaccinated susceptible species that do not show reliable clinical signs.

- "Option 2" (as detailed in draft Article 8.8.40 points 7.b and 7.c) involved using a combination of risk-based surveillance and random serological surveillance in vaccinated herds, intensified abattoir and clinical surveillance, and multistage random sampling of non-vaccinated susceptible species that do not show reliable clinical signs, and possibly virological surveillance, as well as the demonstration of vaccine efficacy and vaccination effectiveness.

[2] *Ad hoc* Group on Alternatives for surveillance for demonstration of freedom from FMD and recovery periods – June 2017 and *Ad hoc* Group on the Evaluation of FMD Status of Members – November 2017.

With regard to option 1, the Group advised that for vaccinated ruminants, a census NSP serological survey should be conducted to identify any subclinical infection. However, this requirement for a census survey was established based on current scientific knowledge; the Group took note that if all vaccinated epidemiological units are sampled, a less stringent within herd design prevalence might be acceptable if it could be supported by further scientific evidence on the frequency of subclinical infection in herds of vaccinated ruminants. For pigs, the Group pointed out that census serological surveys may not be practical due to the potential size of the herds (i.e. potential number of animals to be sampled). Furthermore, pigs do not become carriers and the occurrence of subclinical infections in pigs, even in vaccinated individuals is rare[3]. For vaccinated pigs, the Group therefore recommended that NSP serological surveillance should be conducted in all vaccinated epidemiological units with 5% maximum design prevalence within epidemiological unit (95% confidence level).

The Group carefully considered the definition of epidemiological unit of the Glossary of the *Terrestrial Code*, as well as the definition of sampling unit and the recommendations for survey design provided in current Chapter 1.4. and draft revised Chapter 1.4. on Animal health surveillance. The Group pointed out that terms such as herd, establishment and epidemiological unit may be open to differing interpretations based on the specific context in which they are applied. The Group agreed that for the purposes of the design of the NSP serological surveys under discussion, it was important that the highest level of resolution was achieved. For example, if an intensively reared pig herd was kept in three discretely managed buildings on one establishment, each of the three buildings should be regarded as individual epidemiological units for the purposes of NSP serological sampling, and the random selection of sufficient pigs for sampling to provide 95% confidence that disease was not present at a level above 5% prevalence would need to take place independently in the populations in each of these three buildings. The term "herd" is generally understood to mean "epidemiological unit" in many contexts, but perhaps not all. The Group considered it important that Members applying for shorter recovery periods understand this point, and therefore settled on the use of the term "epidemiological unit" as being the most appropriate and least ambiguous in relation to design prevalence. The Group therefore advised that the design prevalence for NSP serological surveys should be applied in each epidemiological unit in order to achieve the highest level of resolution and allow for a high level of confidence in demonstrating the absence of transmission in vaccinated animals.

The Group noted that neither the Glossary of the *Terrestrial Code*, the current Chapter 1.4. nor the draft revised Chapter 1.4. on Animal health surveillance provided a definition of 'design prevalence'. The Group recommended such a definition could be useful to be included in the *Terrestrial Code*.

Maximum design prevalence and confidence level were set for some surveillance components as well as minimum values for vaccination coverage in the targeted and eligible population. The Group reiterated that this was more prescriptive than the usual recommendations of the *Terrestrial Code* for surveillance and vaccination. However, the Group was of the opinion that defining these parameters provided important guidance to Members to ensure that a high level of confidence can be reached.

Regarding surveillance components to be implemented in support of option 2, the Group recommended that random surveillance be performed throughout the area of emergency vaccination to provide baseline data and be strengthened by additional risk-based surveillance. The design of any risk-based surveillance, in particular the rationale for the applied stratification, should be clearly justified when answering the questionnaire.

The Group noted that ongoing virological surveillance through technologies like bulk milk testing, rope sampling and other methods may provide further information on the status of vaccinated herds; negative results would add to confidence in the free status of these herds.

[3] D.J. Paton, A.E. Füssel, W. Vosloo, A. Dekker, K. De Clercq, 2014, The use of serosurveys following emergency vaccination, to recover the status of "foot-and-mouth disease free where vaccination is not practiced", Vaccine, 32, 7050-7056

In conjunction with the NSP serological surveys for option 1 and the serological surveillance for option 2, both aiming at demonstrating the absence of transmission in the vaccinated population, the Group recommended that serological surveys be conducted in non-vaccinated susceptible species kept in the control area that do not show reliable clinical signs in order to demonstrate the absence of infection in the non-vaccinated population. In addition, the Group recommended that applicant Members for an early recovery of their free status should justify the rationale for not vaccinating certain susceptible species, and conversely, the rationale for selecting target species and herds to be vaccinated.

Vaccine efficacy and vaccination effectiveness are key to prevent infection and transmission, including subclinical infections in vaccinated animals, and should therefore be duly documented in support of any application for an early recovery of a free status. As well as evidence of high potency ($\geq$ 6 PD50 or equivalent) and a good match between the vaccine strain and the field virus, protection should also be documented for relevant target animals immunised with the specific vaccine batch and dose used in the emergency vaccination programme. Protection in these animals, against the relevant field virus, can be measured preferably by challenge, or else by serology.

6. Questionnaire for earlier recovery of FMD free status where vaccination is not practised - addendum to Section 8 of Articles 1.11.1. and 1.11.3.

The Group noted that the questionnaire for recovery of FMD free status stated, "*Member Countries applying for recognition of recovery of free status for a country/zone should […] provide detailed information as specified in Sections 1-7 (inclusive) of this questionnaire*." The Group noted that Sections 1 to 7 were primarily designed for initial applications for the recognition of a FMD free status and recommended that when filling in the questionnaire in support of the application for the recovery of a free status, applicant Members should place emphasis on the recent situation in the context of the outbreak(s) as being of most relevance. The Group noted that a questionnaire specifically targeted to applications for the recovery of free status could be developed in the future.

As Sections 1 to 7 of the questionnaire already contains baseline questions, the Group drafted questions under 'Section 8. Recovery of free status' of the relevant FMD questionnaires (i.e. Articles 1.11.1 and 1.11.3 of the *Terrestrial Code*) focusing on the additional requirements that should be documented by Members when applying for an earlier recovery according to Article 8.8.7. point 1.c) and draft Article 8.8.40. point 7. Therefore, Members seeking for an earlier recovery[4] of their free status based on the implementation of additional requirements should answer these questions, in addition to those already requested under Section 8 of the questionnaires.

7. Considerations on Article 8.8.7. point 2. - Recovery of a free status with vaccination after the suspension of a free status without vaccination

The Group explored the applicability of a similar strategy to the waiting period (i.e. 6 months after the disposal of the last animal killed) defined in Article 8.8.7 point 2: country or zone previously free from FMD without vaccination, where a stamping-out policy has been applied and a continued vaccination policy has been adopted. In other words, a country/zone previously free without vaccination seeking to recover as free country/zone status with vaccination. The Group emphasised that this represents not only a recovery of status but also a change in the initially recognised official status. Considering that a country requesting a change of status from FMD free without vaccination to FMD free with vaccination after an outbreak, usually does so due to ongoing risks, the Group considered that it would not be appropriate to shorten this waiting period.

8. Revision of Article 8.8.7. point 3.a) - Recovery of a free status <u>with</u> vaccination where a stamping-out policy and emergency vaccination are applied

The Group considered whether the additional requirements (*cf* Section 5) for shortening the waiting period would be also applicable for recovery of free status with vaccination with reference to Article 8.8.7. point 3.a) of the *Terrestrial Code*.

[4] More than three months but less than six months after the disposal of the last animal killed or the last vaccination whichever occurred last, where a stamping-out policy, emergency vaccination not followed by the slaughtering of all vaccinated animals

The Group extensively discussed this issue and concluded that, similar to the proposal made for an earlier recovery of a free status without vaccination, the waiting period for the recovery of a free status with vaccination may be reduced to a minimum of three months if the absence of infection in the non-vaccinated population and absence of transmission in the vaccinated population could be demonstrated earlier with a high level of confidence. However, since animals would already have been routinely vaccinated prior to the outbreak and emergency vaccination, the Group noted that additional factors (i.e. relationship between the routine vaccine, emergency vaccine, and the virus that caused the outbreak) would need to be taken into account in the additional requirements for shorting the waiting period for recovery. Prior vaccination might mask clinical expression of disease and the Group considered that this also gave rise to some different requirements to provide reassurance of absence of virus transmission outside of the emergency vaccination area (compared to the use of emergency vaccination within previously FMD-free country or zones).

The Group recommended the following sentence be added at the end of Article 8.8.7. point 3.a):
"*This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission in the vaccinated population based on the provisions of Articles 8.8.40. point 7. or 8.8.40. point 8. as appropriate".*

9. Additional requirements for shortening the waiting period for recovery of a free status with vaccination where a stamping-out policy and emergency vaccination is applied

The Group recommended that an early recovery of the free status with vaccination would be supported by distinct provisions for: (i) the area(s) where emergency vaccination has been applied; (ii) the area of the country/zone where emergency vaccination has not been applied.

- Area(s) of the country/zone where emergency vaccination has been applied

Regarding the early recovery of the free status of the area(s) where emergency vaccination has been applied, the Group recommended that measures similar to those described in draft Article 8.8.40. point 7 (*cf* Section 5) would provide a high level of confidence in the absence of transmission in vaccinated animals. However, the Group noted that, in practice, it might be difficult to apply census NSP serological surveillance in a population which has been routinely vaccinated due to anticipated high numbers of false positive reactors.

- Area of the country/zone where emergency vaccination has not been applied

The Group considered Article 4.3.7. on containment zones, together with the provisions for the establishment of a containment zone for FMD defined in Article 8.8.6. The Group noted that the establishment of a containment zone, based on the provisions of Article 8.8.6. that included all emergency vaccination area(s), could be one way of providing assurance that FMD has not occurred in the area outside of the emergency vaccination area(s).

An alternative option for an early recovery of the free status of the area where emergency vaccination has not been applied would be based on the demonstration of the absence of infection in non-vaccinated animals and absence of transmission in vaccinated animals with a high level of confidence. However, in that regard, the Group noted that different situations should be considered: (i) routine vaccination ensures protection against the outbreak strain; (ii) routine vaccination does not ensure protection against the outbreak strain (e.g. incursion of new serotype); (iii) routine vaccination ensures partial protection against the outbreak strain. These different situations would impact the likelihood of infection of animals routinely vaccinated and the likelihood of showing clinical signs if infected. In addition, the Group noted that other factors including vaccination coverage and timing of vaccination could also influence the rate of transmission and expression of clinical signs. The Group pointed out that information on the effectiveness of vaccination would only be relevant in support of the recovery of the free status if the routine vaccine was protective against the virus that caused the outbreak(s). Considering the above, the Group recommended that applicant Members should document the protective value of the routine vaccination but did not prescribe any minimum requirements.

Draft requirements for an early recovery of the free status of the area outside of the area(s) where emergency vaccination has been applied were listed in draft Article 8.8.40. point 8.

10. Questionnaire for earlier recovery of FMD free status where vaccination is practised - addendum to Section 8 of Articles 1.11.2. and 1.11.4.

The Group drafted questions to be included in Section 8 of Articles 1.11.2. and 1.11.4. of the *Terrestrial Code* focusing on the additional requirements to be documented by applicant Members when applying for earlier recovery of their FMD free status with vaccination in accordance with draft Article 8.8.40. points 7 and 8.

11. Further considerations

The Group suggested that after adoption in the *Terrestrial Code*, the paths for early recoveries of FMD free status with or without vaccination could be further presented to Members through the OIE workshops on official status recognition.

As indicated in Section 6 of this report, in reviewing relevant sections in Articles 1.11.1. to 1.11.4, the Group noted that the phrasing of the questionnaire was primarily designed for initial applications for the recognition of a FMD free status and may not necessarily be suitable for Members applying for the recovery of a free status. The Group mentioned that there may be benefits in further reviews of this material.

As indicated in Section 4 of this report, the Group recommended changing the requirement in Article 8.8.7. point 1.c). to require surveillance to substantiate freedom from transmission rather than freedom from infection in vaccinated animals. Indeed, the Group considered that evidence of freedom based on the demonstration of absence of infection in a non-vaccinated population and demonstration of absence of transmission of FMDV in a vaccinated population is adequate to regain a FMD free status without vaccination. However, once freedom is regained, vaccinated animals can mix with non-vaccinated animals at a national level and, if this occurs within three months, then carriers may be present if not eliminated by an appropriate surveillance approach. The Group acknowledged that with the exception of African buffalo, carriers do not play an epidemiologically significant role in FMDV transmission (as specified in Article 8.8.1. point 6 of the *Terrestrial Code*). Therefore, considering that carrier animals present negligible risk to others, even if non-vaccinated, then this could imply that the current requirements for surveillance to detect infection could be changed elsewhere in Chapter 8.8. to a requirement for detecting transmission, regardless of vaccination status.

12. Adoption of the 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. Upon circulation, the Group agreed that the report captured the discussions.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON
ALTERNATIVES FOR SURVEILLANCE FOR DEMONSTRATION OF FREEDOM
FROM FOOT AND MOUTH DISEASE (FMD) AND RECOVERY PERIODS
Paris, 28-30 August 2018

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Agenda

1) Opening

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

3) Background

4) Revision of Article 8.8.7. point 1.c) - Recovery of free status without vaccination where emergency vaccination not followed by the slaughtering of all vaccinated animals is applied

5) Additional requirements for shortening the waiting period for recovery of a FMD free status without vaccination where stamping-out policy and emergency vaccination are not followed by the slaughtering of all vaccinated animals

6) Questionnaire for earlier recovery of FMD free status where vaccination is not practised -addendum to Section 8 of Articles 1.11.1. and 1.11.3.

7) Considerations on Article 8.8.7. point 2. - Recovery of a free status with vaccination after the suspension of a free status without vaccination

8) Revision of Article 8.8.7. point 3.a) - Recovery of a free status with vaccination where a stamping-out policy and emergency vaccination are applied

9) Additional requirements for shortening the waiting period for recovery of a free status with vaccination where a stamping-out policy and emergency vaccination is applied

10) Questionnaire for earlier recovery of FMD free status where vaccination is practised - addendum to Section 8 of Articles 1.11.2. and 1.11.4.

11) Further considerations

12) Adoption of the report

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON
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FROM FOOT AND MOUTH DISEASE (FMD) AND RECOVERY PERIODS
Paris, 28-30 August 2018

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