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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, 14-16 June 2017

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 14 to 16 June 2017.

1. Opening

On behalf of Dr Monique Eloit, Director General of the OIE, Dr Matthew Stone, the OIE Deputy Director General for International Standards and Science, welcomed and thanked the Group for its commitment and its extensive support towards the OIE in fulfilling the mandates given by Member Countries. He extended his appreciation to the institutions that kindly allowed the experts to participate in the meeting.

Dr Stone highlighted that the OIE 6th Strategic Plan underpinned the importance of maintaining scientific excellence as the foundation of the OIE international standards setting procedure to preserve international credibility. Furthermore, he mentioned the OIE's work strategy to attract and engage the relevant expertise from Member Countries and to increase the pool of renowned experts to be part of this important process.

Dr Stone reminded the experts that they had been selected based on their scientific expertise and thanked them for having signed the form for undertaking of confidentiality, as well as for having declared any potential conflict of interest. He 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.

Dr Stone mentioned that Chapter 8.8. of the *Terrestrial Animal Health Code* (*Terrestrial Code*) on FMD is a complex chapter that has been subject to recent revisions and noted the challenges in establishing a simple methodology to demonstrate freedom from FMD through identifying and combining applicable alternative tools that would fit to all scenarios and that could allow flexibility in the post-outbreak recovery periods. He encouraged the experts to first focus on drafting surveillance requirements for the recovery of a previously recognised FMD free status and to explore the possibilities of a shorter waiting period for future incorporation in Chapter 8.8. as well as consider the implementation for other diseases and the relevance of inclusion of this approach in the horizontal chapter on Animal health surveillance (Chapter 1.4.).

Dr Laure Weber-Vintzel, Head of the Status Department, informed the Group that the OIE Status Department has started a project on the identification of associated factors related to the suspensions and recoveries of FMD- free status during the last 20 years since its first official recognition in 1996.This project would include an analysis of measures linked to the recovery periods in order to reveal any possible trends as well as to identify possible factors that could reduce the waiting periods. The analysis would be based on the information collected by the OIE World Animal Health Information System (WAHIS) through the immediate notifications of important epidemiological events submitted by Member Countries and on the information provided in Member Countries' dossiers when applying for the recovery of their suspended status.

[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 2017 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/

The OIE and the Group welcomed Drs Katharina Stärk, Sarah Welby and Abdulnaci Bulut 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 Cristóbal Zepeda Sein. Dr Tom Smylie acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Introduction, assumptions and general considerations

The Group first reviewed the terms of reference provided to the Group in order to establish its work programme and direction for this meeting. The Group agreed that:

- its discussion would focus on situations in which emergency vaccination is applied and the vaccinated animals are not removed from the population;
- its discussion would be based on the assumption that stamping out in accordance with Article 8.8.7. Point 1.c) of the *Terrestrial Code* and emergency vaccination using high potency vaccination in compliance with Chapter 2.1.8. Section C of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* are performed;
- even with the current recovery period (6 months), demonstrating the absence of infection in vaccinated populations as described in Article 8.8.7. Point 1.c) through census or sample surveys cannot be done with absolute certainty, due to the limitations of the available diagnostic tests;
- the objective of surveillance in vaccinated populations should be to demonstrate the absence of transmission of FMDV;
- evidence of freedom based on the demonstration of absence of infection in an unvaccinated population and demonstration of absence of transmission of FMDV in a vaccinated population is adequate to regain a FMD free status without vaccination;
- with the exception of African buffalo, carriers do not play an epidemiologically significant role in FMDV transmission (cf Article 8.8.1. Point 6 of the *Terrestrial Code*);
- in a well-managed emergency vaccination programme, the expected prevalence of vaccinated herds with carriers and the number of carriers within those herds is likely to be very low[2].

4. Review of the different surveillance system components

To explore alternatives for surveillance for demonstration of freedom from FMD after emergency vaccination, the Group discussed the definition and aim of different surveillance system components and considered the factors contributing to their sensitivity and specificity.

While the Group focused mostly on sensitivity as this is most pertinent to the demonstration of freedom, it was noted that specificity should also be considered, to estimate the occurrence of false-positive results for which appropriate follow-up should be performed. The review of each surveillance system component is summarised in **Table 1**.

[2] Arnold ME, Paton DJ, Ryan E, Cox SJ, Wilesmith JW. Modelling studies to estimate the prevalence of foot-and-mouth disease carriers after reactive vaccination. Proc. R. Soc. B, 2008; 275, 107–115. doi:10.1098/rspb.2007.1154

Table 1. Aim of the different surveillance system components:

Type of surveillance	**Definition**	**Objective**	**Contributing factors to sensitivity**	**Contributing factors to specificity**
Passive clinical	Reporting of clinical signs to the veterinary authority	Detection of clinical disease	Species, production systems, vaccination status of animals, awareness/compliance of producers, reporting system	Occurrence of other conditions with similar clinical signs
Enhanced passive clinical	Encouraging reporting of clinical signs to the veterinary authority through methods to enhance awareness and reporting	Same as above	Improve the frequency and timeliness of detection and reporting of clinical disease	Same as above
Active clinical	Active search for clinical cases under the supervision of the veterinary authority following the requirements of Article 1.4.4. of the *Terrestrial Code*	Same as above	Systematic clinical inspections, targeted approach if applicable	Same as above
Serological	Detection of antibodies resulting from infection or vaccination at animal or herd level	Detection of structural protein (SP) or non-structural protein (NSP) antibodies at animal or herd level	Sensitivity of diagnostic test; survey design (prevalence; sample size), time since infection, quality of samples	Specificity of diagnostic test, follow up procedures to confirm positive results, vaccine purity
Virological	Detection of virus, viral antigen or viral ribonucleic acid specific to FMDV (virus isolation, PCR, antigen detection ELISA)	Demonstrate the presence of FMDV or evidence of current or past FMDV infection	Quality of samples, test method, time from infection, intermittent shedding in case of oesophagopharyngeal fluids	Quality of samples
Abattoir	Detection of signs or lesions compatible with FMD either at ante- or post-mortem inspection	Detection of suspect FMD cases either at ante- or post-mortem inspection	Speed of slaughter chain, type and intensity of inspection, species and virus type, competency of inspector	Frequency of lesions due to other reasons
Enhanced abattoir	Intensified detection of signs or lesions compatible with FMD either at ante- or post-mortem inspection	Intensified detection of suspect FMD cases either at ante- or post-mortem inspection	Intensified ante- or post-mortem inspections specifically targeted to FMD	Same as above
Syndromic	Detection of indirect indicators leading to suspicion of FMD	Monitoring of production, performance data and other indicators to trigger disease investigation	Availability and quality of data, establishment of baselines for triggering investigation	Availability and quality of data, establishment of baselines for triggering investigation, other conditions with similar syndromes

The Group noted that **syndromic surveillance**[3] typically consists of a combination of statistical methods applied to data routinely collected for other purposes with the intention to detect unspecific signals indicative of an unusual event such as a disease outbreak. Detection of a signal requires follow-up investigations to verify whether a signal is associated with a relevant disease event. The Group concluded that this surveillance approach would offer little benefits in the context of regaining FMD free status because of the indirect nature of evidence, the technological requirements (i.e. ongoing electronic data collection), the complexity of the analytical approach as well as the substantial time delay between signal detection and confirmation of an outbreak. Furthermore, it is likely to be substantially outperformed by clinical surveillance. If already in place, syndromic surveillance could contribute to the confidence of demonstrating freedom.

The Group also discussed the role of **participatory surveillance** in demonstrating freedom from FMD. The Group considered that participatory surveillance is not a surveillance system component *per se* but rather a way of increasing stakeholder engagement in surveillance activities and therefore concluded that its contribution in the recovery of a previously recognised free status is limited.

5. Application of different surveillance system components and additional tools in vaccinated and unvaccinated populations

The Group considered the application of the different surveillance system components identified in Table 1 in vaccinated (cf **Table 2**) and unvaccinated (cf **Table 3**) populations and estimated their performance at herd level and their contribution to the overall confidence of freedom from FMD. The assessment of performance of the difference surveillance system components was conducted under the assumption that serological surveillance activities begin 30 days after the last vaccination or last case, whichever occurs later, in accordance with Article 8.8.42.of the *Terrestrial Code*.

Table 2. Performance of the different surveillance system components in a vaccinated population

Type of surveillance	**Sensitivity of surveillance at herd level**	**Specificity of surveillance at herd level**	**Contribution to demonstrating freedom**
Passive clinical	**Low** because clinical signs are less likely in vaccinated animals	**Low** because other diseases can show similar clinical signs	**Low** (both the negative and positive predictive values would be low)
Enhanced passive clinical	**Same as above**	**Same as above**	**Higher than above**
Active clinical	**Same as above**	**Same as above**	**Higher than above**
Serological	**High**	**High** (given that the false positive reactors are followed up in accordance with Article 8.8.40.)	**High** but not sufficient on its own
Virological	**Depends on the test method, sample size**: PCR=High (serum) Virus isolation=Low Antigen detection ELISA=Low	**High**	**High** as part of follow-up of serological results

[3] Dórea FC, Sanchez J, Revie CW. Veterinary syndromic surveillance: Current initiatives and potential for development. *Preventive Veterinary Medicine*, Volume 101, Issues 1–2, 1 August 2011, Pages 1-17. doi.org/10.1016/j.prevetmed.2011.05.004

Type of surveillance	Sensitivity of surveillance at herd level	Specificity of surveillance at herd level	Contribution to demonstrating freedom
Abattoir	**Low** i) Most likely animals with clinical signs will not be sent for slaughter ii) Subclinically infected animals will not show pathological lesions iii) Ability to trace back the origin of the animals iv) Number of animals coming from each herd to be slaughtered	**High** depending on the frequency of lesions due to other causes	**Low**
Enhanced abattoir	**Higher than above**	**Same as above**	**Higher than above**

Table 3. Performance of the different surveillance system components in an unvaccinated population

Type of surveillance	Sensitivity of surveillance at herd level	Specificity of surveillance at herd level	Contribution to demonstrating freedom
Passive clinical	**High** Clinical signs will be readily apparent with the exception of sheep and goats	**Low** because other diseases can show similar clinical signs	**High** except in sheep and goats; dependent on number of suspect cases reported and overall effectiveness of the suspect reporting system
Enhanced passive clinical	**Same as above**	**Same as above**	**Higher than above**
Active clinical	**Same as above**	**Same as above**	**Higher than above**
Serological	**High**	**High** (very low proportion of reactors would be expected)	**High**
Virological	**High** Not likely to be used as a front-line test; May not be practical/cost-effective	**High**	**Moderate** (as serology is considered more efficient) High for bulk milk tank testing and air filtration system sampling[4] (area of on-going research)
Abattoir	**Low** i) Most likely animals with clinical signs will not be sent for slaughter ii) Subclinically infected animals will not show pathological lesions iii) Ability to trace back the origin of the animals iv) Number of animals from each herd Better for sheep and goats as clinically infected animals may be difficult to detect at the herd of origin	**High** depending on the frequency of lesions due to other causes	**Moderate**
Enhanced abattoir	**Higher than above**	**Same as above**	**Higher than above**

[4] Nelson N, Paton DJ, Gubbins S, Colenutt C, Brown E, Hodgson S, Gonzales JL. Predicting the Ability of Preclinical Diagnosis To Improve Control of Farm-to-Farm Foot-and-Mouth Disease Transmission in Cattle. *J. Clin. Microbiol*.2017; doi:10.1128/JCM.00179-17

To recover a previously FMD free status, the Group emphasised that the surveillance system should achieve a high level of confidence in the absence of infection in unvaccinated populations and the absence of transmission of FMDV in vaccinated populations, taking into account the information provided through the combination of different surveillance system components as listed in Table 1. Member Countries should assess the overall performance of the combined system by considering the contribution of the different surveillance system components, individually and over time, to the demonstration of freedom.

The Group considered that quantitative methods such as scenario trees[5] may be useful to estimate the overall confidence in disease freedom, if carried out properly. However, the availability of data and expertise may be a limiting factor in some situations. For this purpose, qualitative or semi-quantitative methods could also be considered.

In addition to the combination of these surveillance system components, the Group considered **post-vaccination monitoring**[6] as an important tool contributing to the demonstration of freedom from FMD. Taking into account that virus transmission is unlikely to occur in effectively immunised populations, estimating the proportion of immune animals in a vaccinated population would increase the confidence in substantiating absence of FMDV transmission.

6. Considerations regarding the concept of risk-based surveillance

A short presentation on the experience gained from the implementation of a risk-based surveillance programme in Thrace region was shared with the Group. The project started in 2013 and was led and coordinated by the European Commission for the control of FMD (EuFMD), to provide confidence in FMD freedom and to improve capacity for early detection in the high risk areas in the common borders of Bulgaria, Greece and Turkey. The statistical target of the project was to achieve a 95% level of confidence in disease freedom for all countries but with different design prevalence for each of them. The surveillance activities consisted of serological and clinical surveillance in targeted species at farm and abattoir level on a 3-month surveillance cycle. The confidence of freedom from FMD in the region was estimated by analysing the collected data by output-based methods[7]. It was highlighted that the model is based on the approach that multiple activities of different sensitivity can be combined and that it could build confidence in disease freedom over time, which means the more evidence is available, the more confidence in the probability of disease freedom is gained.

The Group considered the potential to use risk-based approaches for demonstrating freedom in vaccinated populations. It concluded that in order to make surveillance more efficient, stratification of the population based on risk factors relevant to FMD exposure can be considered. These factors could include, but not limited to: i) proximity to known infected herds, ii) region/establishment with numerous movement of animals, iii) known epidemiological links to infected herds and iv) species, production systems and herd size.

7. Surveillance requirements and other measures for the recovery of a previously recognised FMD free status and the possibility of a shorter waiting period

The Group discussed approaches to increase the level of confidence in demonstrating freedom from FMD and identified additional surveillance system components and measures to be applied. These are summarised in Table 4.

Member Countries would have flexibility in the application of different surveillance system components provided that a high level of confidence can be achieved. The period of recovery of status would be dependent on the time required to achieve the stated level of confidence.

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5 Martin PAJ, Cameron AR, Greiner M. Demonstrating freedom from disease using multiple complex data sources 1: A new methodology based on scenario trees. *Preventive Veterinary Medicine* 79.2007; 71–97

6 Ferrari G, Paton DJ, Duffy SJ, Bartels CJ, Knight-Jones TJD, Metwally S, Münstermann S. OIE-FAO Foot and mouth disease post-vaccination monitoring guidelines.2016

7 Cameron AR. The consequences of risk-based surveillance: Developing output-based standards for surveillance to demonstrate freedom from disease. *Prev Vet Med.* 2012 Aug 1;105(4):280-6. doi: 10.1016/j.prevetmed.2012.01.009.

Table 4. Requirements for a possible shorter recovery period

Status of animal population	**Current *Terrestrial Code* requirements Article 8.8.7. Point 1.c)**	**Objective**	**Additional measures**	**Benefit**
Vaccinated population in the control area*	Demonstration of absence of infection through serological surveillance in vaccinated population in accordance with Articles 8.8.40. to 8.8.42.	Demonstration of absence of virus transmission through serological surveillance in vaccinated population in accordance with Articles 8.8.40. to 8.8.42.	- Assessment of immunity of the vaccinated population in accordance with Article 8.8.40. Point 6 - Active clinical surveillance	- Population immunity above a defined threshold will increase the confidence of the absence of virus transmission - Increase detection of clinical cases
Unvaccinated population in control area*	Demonstration of absence of infection in the sub-population through serological surveillance in accordance with Articles 8.8.40. to 8.8.42.		- Enhanced abattoir surveillance - Active clinical surveillance	Increase detection of clinical cases
Remaining area where vaccination is not applied	Demonstration of absence of infection in the area through serological surveillance in accordance with Articles 8.8.40. to 8.8.42.		- Enhanced passive surveillance - If already in place, syndromic surveillance could contribute to the confidence of demonstrating freedom	Increase detection of clinical cases

*control area: area designated by the Veterinary Authority in response to the occurrence of FMD outbreaks, in order to control and prevent its spread to uninfected areas. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of surveillance. The control area could be comprised of two separate areas where movement control is in place and in which measures of different intensity are conducted.

The Group made note that surveillance in vaccinated populations would involve the detection and identification of herds with reactors that could be indicative of exposure to FMDV, keeping in mind that reactors to NSP can also include previously infected and recovered, false-positives and potential carriers and the follow-up of reactors should be consistent with Article 8.8.42. of the *Terrestrial Code.*

The Group suggested that, should there be a need for an objective method of assessment of the surveillance information in Member Countries' dossiers for FMD free status, the use of a quantitative approach, such as a scenario tree model, for the analysis and evaluation of surveillance system components could be considered.

8. Conclusions and consideration for other diseases and relevance of inclusion in Chapter 1.4.

Recovery of status, where emergency vaccination not followed by the slaughtering of all vaccinated animals is used, should depend on demonstrating the absence of infection in the unvaccinated population and the absence of transmission of FMDV in the vaccinated population.

Article 8.8.7. Point 1.c) of the *Terrestrial Code* does not currently include the concept of demonstration of absence of FMDV transmission. The Group recommended modifying the surveillance objective, for recovery of FMD free status in country or zone where vaccination is not practised, to reflect the surveillance objectives above.

In order to reduce the time of recovery, the Group concluded that the implementation of additional surveillance and other measures as described in Section 7 of this report should be applied and suggested that this be added as appropriate in the *Terrestrial Code*.

The Group briefly discussed the applicability of the above-mentioned conclusions regarding countries having a FMD free status where vaccination is practised facing an outbreak and had applied emergency vaccination. However, the Group considered that there are additional factors that should be discussed prior to further application.

Although the Group did not discuss the implementation of this approach for other diseases, it agreed that in principle, the assessment of the contribution of different surveillance system components to estimate the overall confidence in claiming freedom could be applied to other diseases; several examples already exist in published scientific literature[8].

9. 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

[8] Welby S, Van Schaik G, Veldhuis A, Brouwer-Middelesch H, Peroz C, Santman-Berends IM, Fourichon C, Wever P, Van der Stede Y. Effectiveness and Cost Efficiency of Different Surveillance Components for Proving Freedom and Early Detection of Disease: Bluetongue Serotype 8 in Cattle as Case Study for Belgium, France and the Netherlands. *Transboundary and Emerging Diseases*. 2016; doi:10.1111/tbed.12564

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, 14-16 June 2017

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Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Introduction, assumptions and general considerations
4. Review of the different surveillance system components:
    - passive clinical surveillance
    - enhanced passive clinical surveillance
    - active clinical surveillance
    - serological surveillance
    - virological surveillance
    - abattoir surveillance
    - enhanced abattoir surveillance
    - syndromic surveillance
    - participatory surveillance
5. Application of different surveillance system components and additional tools in vaccinated and unvaccinated populations
6. Considerations regarding the concept of risk-based surveillance
7. Surveillance requirements and other measures for the recovery of a previously recognised FMD free status and the possibility of a shorter waiting period
8. Conclusions and consideration for other diseases and relevance of inclusion in Chapter 1.4.
9. Adoption of report

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON
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Paris, 14-16 June 2017

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