

MEETING OF THE OIE AD HOC GROUP ON SURVEILLANCE¹

Paris, 19 – 21 June 2017

A meeting of the OIE *ad hoc* Group on surveillance (hereafter the Group) was held at the OIE Headquarters from 19 to 21 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 to revise a cornerstone chapter of the *Terrestrial Animal Health Code (Terrestrial Code)*. Chapter 1.4. on Animal health surveillance. The chapter is critical for Member Countries to assess the animal disease situation, to monitor the progress of disease control programmes and subsequently to substantiate self-declarations of disease freedom or meet the requirements for the official recognition of disease freedom by the OIE. Revising this chapter and providing more structured, detailed and consistent guidance for animal health surveillance would therefore be greatly beneficial to the OIE and its Member Countries.

In 2016, the Terrestrial Animal Health Standards Commission (Code Commission) undertook the review of Chapter 1.4. and a revised chapter was circulated to Member Countries for comments. Member Countries made significant comments and indicated the need to further revise the chapter. The OIE Director General decided to convene the *ad hoc* Group to further review the chapter and to address these comments.

Dr Stone extended his thanks to Dr Bonbon, President of the Terrestrial Animal Health Standards Commission and Dr Brückner, President of the Scientific Commission for Animal Diseases, for participating in the Group. He acknowledged that their guidance was especially valuable considering that revisions made in Chapter 1.4. might also have an impact on the disease-specific chapters of the *Terrestrial Code*.

Dr Stone reminded the experts that they were not representing their own countries or institutions in the Group and that they are required to declare any actual or potential conflict of interest and respect the confidentiality of the process.

Dr Brückner and Dr Bonbon both mentioned that the Group should not only address Member Countries' comments but also review the entire Chapter 1.4. based on most recent developments in surveillance methodologies. In addition, they informed the Group that an OIE Guide to Terrestrial Animal Health Surveillance was published in 2014², therefore there would be no need for providing detailed technical guidance in Chapter 1.4.

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

The Group was chaired by Dr Zepeda Sein, and Dr Galon acted as rapporteur, with the support of the OIE Secretariat. The Group adopted the proposed agenda.

The terms of reference, agenda and list of participants are presented as Appendices I, II and III, 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 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/>

² <http://www.oie.int/for-the-media/press-releases/detail/article/a-new-oie-guide-to-better-surveillance-and-detection-of-health-risks-related-to-animals/>

3. Revision of the Terrestrial Code Chapter 1.4. Animal Health Surveillance

The Group considered the Member Countries' comments and addressed them when reviewing Chapter 1.4. The proposed revisions are presented below:

3.1. Article 1.4.1. Introduction and objectives

a) Article 1.4.1. point 1

Current Article 1.4.1. covers surveillance of both diseases and infections. The Group agreed it was also relevant for infestation, as expressed by a number of Member Countries in their comments.

The Group considered the current definitions of infection and infestation provided in the Glossary of the *Terrestrial Code*, as well as the definitions provided in the dictionary of epidemiology of the International Epidemiological Association³.

According to the definition provided in the Glossary, one characteristic of an infestation compared to an infection is that an infestation is external. The Group proposed to revise the definition of infection in the Glossary to encompass both infection and infestation for the purpose of the *Terrestrial Code*. The Group proposed the following definition of infection: “means the entry or colonisation, and development or multiplication, of a pathogenic agent in or on the body of humans or animals”.

If this revised definition was to be adopted by Member Countries, the definition of infestation would be removed from the Glossary and any specific references to infestations would subsequently need to be removed from the relevant *Terrestrial Code* chapters.

This revised definition of infection was used by the Group when further revising Chapter 1.4.

b) Articles 1.4.1. point 1 and 2

The Group improved the structure of the first two points of current Article 1.4.1. by regrouping all general aspects on surveillance in point 1 and focusing point 2 on wildlife.

c) Article 1.4.1. point 3

The Group reviewed the prerequisites to enable a Member Country to provide information for the evaluation of its animal health status. The Group expanded the list of sources of information that may complement surveillance data provided in Article 1.4.1. point 3.b. In addition, the Group stressed that transparency should apply to all activities included in the definition of *surveillance* provided in the Glossary, and therefore simplified Article 1.4.1. point 3.b. by removing the surveillance activities which were listed.

d) Article 1.4.1. point 4

The Group pointed out that the objective of chapter 1.4. was not only to “provide guidance to the type of outputs that a surveillance system should generate” as mentioned in current Article 1.4.1. point 4.a. but also, and importantly, to provide guidance on the design of a surveillance system.

3.2. Article 1.4.2. Definitions

The Group reviewed the definitions provided in Article 1.4.2. and proposed minor changes to improve clarity. In particular, the Group clarified that in the context of “probability sampling”, units are chosen at random. In addition, the Group amended the definition of “survey” to better reflect its interconnections with surveillance. Furthermore, the Group pointed out that the terminology “test system” was not used elsewhere in Chapter 1.4. and agreed to remove it.

³ <http://irea.ir/files/site1/pages/dictionary.pdf>

3.3. Article 1.4.3. Surveillance systems

The current Article 1.4.3. “Principles of surveillance” lists various types of surveillance (Article 1.4.3. point 1) and defines critical elements (Article 1.4.3. point 2). The Group considered that these critical elements were applicable to all types of surveillance and suggested that it would be best to revise the order and to start by describing the components of a surveillance system. The Group revised and renamed Article 1.4.3. accordingly.

The proposed components were listed into three categories:

- Design of surveillance system, which includes the components: populations, temporal validity of surveillance data, case definition, epidemiological unit, clustering, analytical methodologies, and scope of the surveillance system;
- Implementation of surveillance system, which includes the components: testing, and data collection and management;
- Quality assurance.

Within each category, the components were ordered to best reflect the sequence of actions when designing and implementing surveillance.

In addition, the Group suggested amending the definition of some components for clarity. The proposed revisions are listed hereafter following the order of components proposed in the revised Article 1.4.3:

- “populations”: the Group provided more precise guidance on the approach to make inferences from the target population when surveillance is conducted only on a sub-populations and specified that such inference should be based on the epidemiology of the disease.
- “time frame”: the Group observed that “temporal validity of surveillance data” would capture more accurately the scope of this component and further clarified that temporal validity depends on the epidemiology of the infection as well as on the risks of its introduction and spread.
- “epidemiological unit”: the Group considered the definition provided in the Glossary of the *Terrestrial Code* which only refers to a group of animals as epidemiological units. Whilst the Group agreed that, most often, an epidemiological unit consists of a group of animals, it pointed out that, in some circumstances, an epidemiological unit may consist of an individual animal. The Group suggested amending the Glossary’s definition of an epidemiological unit to capture this point.
- “clustering”: the Group stressed that the correct translation of “cluster” into Spanish should be “conglomerados” and not “concentracion de infeccion” as it appears in the Spanish version of Chapter 1.4.
- “analytical methodologies”: the Group emphasised that the use of sophisticated mathematical or statistical analyses should be considered when justified by the objectives of the surveillance.
- “validation”: the Group recommended that it should encompass various limitations and suggested to rename it “scope of the surveillance system”. The Group emphasised that the potential limitations should first be taken into consideration when designing a surveillance system and, at a later stage, when analysing the information generated by the system.
- “testing”: in order to improve the structure of the description, the Group split the content into two sections, namely sensitivity and specificity, and pooling. The Group also included a reference to Chapter 1.1.6. “*Principles and methods of validation of diagnostic assays for infectious diseases*” of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*, as a recommendation for estimating the sensitivity and specificity of diagnostic assays when this information was not available in the *Terrestrial Manual*’s diseases-specific chapter.
- “quality assurance”: in order to better reflect the full cycle of quality assurance, the Group added a recommendation for corrective actions to be taken whenever deviations of procedures from those documented were observed during auditing.

3.4. Article 1.4.4. Surveillance methods

The Group noted that types of surveillance were described in the current Article 1.4.4. “*Structured population-based surveys*” and in the current Article 1.4.5. “*Structured non-random surveillance*”. The Group questioned the relevance of this distinction and decided to draft new articles on surveillance methods and data sources (draft article 1.4.4.) and on considerations in survey design (draft article 1.4.5.).

The Group developed draft Article 1.4.4. based on information provided in the current Article 1.4.5.

With regard to disease reporting systems, the Group emphasised the need for sharing the information generated by disease reporting systems with all relevant authorities, including the human health sector, when appropriate. In addition, the Group noted that participatory surveillance methods might support disease reporting systems.

The Group agreed that the current Article 1.4.5. point 1.c. “targeted testing and screening” actually addressed risk-based surveillance methods. The Group complemented the provisions on these methods by adding considerations on their purposes and benefits. In addition, the Group pointed out that risk-based methods could be used for either probability or non-probability selection of sampling units and data collection.

With respect to *ante-mortem* and *post-mortem* inspection, the Group noted that the current article stated that their sensitivity and specificity should be predetermined. Since these characteristics might be difficult to determine, the Group considered this point irrelevant and removed it from the revised article. The Group expanded the list of factors which influence the accuracy of *ante-mortem* and *post-mortem* inspections by adding the clinical and pathological signs of the disease as well as the professional independence of the inspection staff. The Group also mentioned that the usefulness of the data generated by *ante-mortem* and *post-mortem* inspections was dependent on effective traceability systems.

Regarding sentinel units, the Group agreed to remove the particular emphasis that was placed on vector-borne diseases, as sentinel units may as well be relevant for other types of diseases or infections.

With respect to clinical observations, the Group stressed that the specificity and sensitivity of clinical observations are highly dependent on the criteria used to define clinical suspects.

The Group described syndromic surveillance and participatory surveillance.

The Group agreed to include a section on “Other data sources” expanding the scope of the existing section on wildlife data and making reference to public health data and environmental data as other additional supporting data that might be relevant for animal health surveillance.

3.5. Article 1.4.5. Considerations in survey design

The Group developed the draft Article 1.4.5. based on the provisions provided in the current Article 1.4.4.

The Group discussed the following terminology: “random sampling” versus “probability sampling” and “non-random sampling” versus “non-probability sampling”. The Group concluded that they were synonyms and for the sake of consistency with the definitions provided in Article 1.4.2., as well as for consistency throughout the chapter, the Group agreed to adopt the terminology “probability sampling” and “non-probability sampling”.

In the section pertaining to the objective of sampling, the Group specified that the objective of probability sampling is to select a subset of units that is representative of the population of interest whilst the objective of non-probability sampling is to maximise the likelihood of detection of the disease or infection.

With regard to the section on sample size, the Group pointed out that the parameters to be taken into account to define a sample size depended on the purpose of the study and listed the parameters to be taken in account for each purpose.

3.6. Article 1.4.6. Surveillance to demonstrate freedom from disease or infection

The Group acknowledged that provisions of Article 1.4.6. were critical for the OIE mandate since they apply to the official recognition of disease free status and self-declaration of disease freedom.

a) Article 1.4.6. point 1. Demonstration of freedom

This point was based on the requirements of the current Article 1.4.6. point 5 without any substantial changes.

b) Article 1.4.6. point 2. Requirements to declare a country or a zone free from a disease or infection

This point was revised based on the current Article 1.4.6. point 1.

For the sake of clarity, the Group agreed to remove most of the general preconditions listed under “premises” at the beginning of the current Article 1.4.6. point 1 as they were considered either generalities or already addressed. However, the Group stressed that the precondition “*the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible animals*” was critical for the demonstration of a free status on historical grounds, considering the absence of specific surveillance.

The Group agreed with the path to demonstrate freedom based on historical grounds defined in the current Article 1.4.6. point 1.a. If a disease or infection has never occurred or has been eradicated for at least 25 years and the disease agent is likely to produce identifiable signs, historical freedom can be demonstrated in the absence of pathogen-specific surveillance, provided a range of requirements (pertaining to disease notification, early detection, prevention of disease introduction, etc.) are fulfilled for at least 10 years.

The Group discussed the path to demonstrate freedom if historical freedom cannot be achieved, with respect to the recommendations defined in the current Article 1.4.6. point 1.b. stating that in the absence of pathogen-specific surveillance requirements in the *Terrestrial Code*, the same range of requirements as for historical freedom should be fulfilled for at least 10 years. The Group agreed that these requirements were indeed critical to substantiate freedom from disease. However the Group observed that some flexibility should be allowed to determine the most appropriate period during which these requirements should have been fulfilled before freedom can be declared.

Importantly, the Group emphasised that all provisions described in revised Article 1.4.6.point 2. were applicable unless otherwise specified in the disease-specific chapters of the *Terrestrial Code*. In addition, the Group stressed that the provisions for the demonstration of freedom were applicable to all relevant susceptible species as defined in the disease-specific chapter of the *Terrestrial Code*.

The Group emphasised that for the establishment of free compartments, specific surveillance should be carried out as recommended in Chapters 4.3. and 4.4. of the *Terrestrial Code*.

c) Article 1.4.6. point 3. Recommendations for the maintenance of freedom from disease or infection

This article was based on a revision of the requirements of the current Article 1.4.6. point 2. recommending the discontinuation of pathogen-specific surveillance while maintaining a disease or infection free status. The Group recommended broadening the scope of this article to define the provisions for the maintenance of a disease free status over time.

The Group specified that in order to substantiate the maintenance of a disease free status over time, risk-based surveillance should be implemented. If an appropriate risk assessment demonstrated that the risks of introduction along all of the identified pathways for introduction were negligible, pathogen-specific surveillance may not be necessary.

In addition, the Group clarified that an early detection system as well as measures to prevent the introduction of the pathogen should be maintained in all relevant susceptible species.

The Group suggested removing point 3 on self-declaration of freedom from disease or infection and point 4 of the current Article 1.4.6. on international recognition of disease or infection free status as they were not directly related to surveillance but to the procedure. The Group recommended including these points in Chapter 1.6. of the *Terrestrial Code* on procedures for self-declaration and for official recognition by the OIE.

3.7. Article 1.4.7. Surveillance considerations in support of disease control programmes

This current Article 1.4.7. on surveillance for distribution and occurrence of infection was revised and renamed. The Group stressed that surveillance was an important component of all disease control programmes.

The Group pointed out that the list of variables that may be collected in the context of surveillance conducted in support of disease control programmes listed in draft Article 1.4.7. was not intended to be exhaustive.

The Group noted that measurable variables should primarily be considered to assess the progress in disease control or eradication and pointed out that the temporal and spatial distribution of these variables should be considered when assessing the surveillance results.

Amongst the list of variables, the Group replaced “frequency distribution of antibody titres” by the “frequency distribution of results of the laboratory tests”, since not only antibody titres but other laboratory techniques might be relevant for some disease or infections. In addition, the Group modified “proportion of immunised animals after a vaccination campaign” by including a reference to post-vaccination monitoring, since OIE/FAO guidelines for performing post-vaccination monitoring were recently developed for the use of Member Countries⁴.

3.8. Draft Article 1.4.8. Early warning systems

To support Member Countries willing to develop early warning systems, the Group drafted a new article, based on the definition of an early detection system provided in the Glossary of the *Terrestrial Code*.

The Group recommended the use of the term “early warning system” over “early detection system” for consistency with the terminology used by other international organisations.

The Group emphasised that an early warning system was an essential component of surveillance and emergency preparedness.

The Group reviewed the list of characteristics of an early warning system, clarified the description of some characteristics, and expanded the list of characteristics by adding awareness programmes and effective systems of communication.

The Group recommended revising the definition of an early detection system in the Glossary and removing the list of characteristics from the definition whilst retaining the list in the revised chapter. The Group proposed a definition for early warning system. The proposed definition is as follows:

- ‘Early warning system’: “means a system for the timely detection, identification of and reporting of an incursion or emergence of diseases/infections in a country, zone or compartment.”

3.9. Draft Article 1.4.9. Combination and interpretation of surveillance results

The Group drafted this article based on the current Articles 1.4.5. point 4. and 1.4.3. point 2.i. The Group emphasised that a combined interpretation of surveillance results may provide an indication of the overall sensitivity and confidence of the surveillance system. In addition, the Group stressed that potential biases should be taken into consideration when assessing the results of a surveillance system.

⁴ OIE/FAO Foot and Mouth Disease Vaccination and Post-Vaccination Monitoring Guidelines.

4. Adoption of the report

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

.../Appendices

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Terms of reference

The OIE *Terrestrial Animal Health Code (Terrestrial Code)* Chapter 1.4. Animal Health Surveillance was last updated in 2012. The purpose of this chapter is to provide guidance to the type of outputs that a surveillance system should generate and to provide recommendations to assess the quality of a given surveillance system.

In February 2016, the Terrestrial Animal Health Standards Commission reviewed Chapter 1.4. for consistency both within the chapter and with the remainder of the *Terrestrial Code*. The Chapter was circulated for Member Countries comment after the Specialist Commission meetings of February 2016.

A significant number of Member Countries indicated the need to further review some of the concepts currently included in the chapter. Considering the impact of the chapter on all disease-specific chapters, in particular on those diseases for which the OIE officially recognises disease free status, the Specialist Commissions suggested to the OIE Director General to convey a dedicated *ad hoc* Group to review the chapter and to address Member Countries' comments.

1. Address Member Countries' comments received after the February 2016 Specialist Commission meetings.
 2. Review the current chapter and amend it according to the latest scientific knowledge taking into consideration the impact on the disease-specific *Terrestrial Code* chapters.
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Agenda

1. Opening
 2. Adoption of the agenda and appointment of chairperson and rapporteur
 3. Revision of the Terrestrial Code Chapter 1.4. Animal Health Surveillance
 4. Adoption of the report
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Appendix III

MEETING OF THE OIE AD HOC GROUP ON SURVEILLANCE Paris, 19-21 June 2017

List of participants

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