EUROPEAN UNION

Brussels
SANTE/G2/MMK/ise (2018) 3476494

Subject: **EU comments on the OIE Terrestrial Code**

Dear Director General,

Please find enclosed the comments of the European Union on Annexes 33, 34, 35, 37, 38, 39 and 40 of the report of the February 2018 meeting of the Terrestrial Animal Health Standards Commission, for consideration at its next meeting in September 2018.

We trust you will find this useful and I thank you for your continued good cooperation.

Yours sincerely,

Dr Ulrich Herzog CVO and OIE Delegate Austria	Dr Bernard Van Goethem Director for Crisis Management in Food, Animals and Plants European Commission, DG Health and Food Safety
[redacted]	[redacted]

Dr M. Eloit
Director General
World Organisation for Animal Health (OIE)
12, rue de Prony
75017 Paris
France

Annex: 1

Copy: All Directors / Chief Veterinary Officers of the EU 28 and Iceland, Liechtenstein, Norway, Switzerland, and Albania, the former Yugoslav Republic of Macedonia, Montenegro, Serbia and Turkey; General Secretariat of the Council of the EU.

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 2 299 11 11
Office F101 3/67- Tel. direct line +32 2 295 10 16 - Fax +32 2 295 31 44

Annex 33

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter.

Comments are inserted in the text below.

Article 1.4.1.

Introduction and objectives

1) In general, *surveillance* is aimed at demonstrating the absence of *infection* or *infestation*, determining the presence or distribution of *infection* or *infestation* or detecting as early as possible exotic diseases or *emerging diseases*. Animal health *surveillance* is a tool to monitor disease trends, to facilitate the control of disease ~~*infection or infestation*~~, to provide data for use in *risk analysis*, for animal or public health purposes, to substantiate the rationale for *sanitary measures* and for providing assurances to trading partners. The type of *surveillance* applied depends on the available data sources and the outputs needed to support decision-making. The general recommendations in this chapter may be applied to all *infections* or *infestations* and all susceptible species (including *wildlife*) and may be refined. *Specific surveillance* is described in some *listed disease*-specific chapters.

EU comment

As it is possible to have infection or infestation in an animal without it developing clinical signs of disease, the EU would prefer the previous wording so the text remains as follows:

"Animal health surveillance is a tool to monitor disease trends, to facilliate the control of infection or infestation [...]"

Furthermore, the type of surveillance applied also depends on the surveillance objective or purpose, so the EU would suggest amending the text as follows:

"The type of surveillance applied depends on the objective/purpose of the surveillance, available data sources and the outputs needed to support decision-making."

Finally, it is not clear what is meant by "and may be refined" in the second to last sentence of point 1) above. The EU suggests clarifying this by adding the following at the end of the sentence:

"and may be refined by *Veterinary Services* to adapt to national or local circumstances."

2) *Wildlife* may be included in a *surveillance* system because they can serve as reservoirs of *infection* or *infestation* and as indicators of *risk* to humans and domestic *animals*. However, the presence of an *infection* or *infestation* in *wildlife* does not mean it is necessarily present in domestic *animals* in the same country or *zone,* or vice versa. *Surveillance* in *wildlife* presents challenges that may differ significantly from those in *surveillance* in domestic *animals*.

3) Prerequisites to enable a Member Country to provide information for the evaluation of its *animal health status* are:

a) that the Member Country complies with the provisions of Chapters 3.1. to 3.4. on *Veterinary Services*;

b) that, where possible, *surveillance* data be complemented by other sources of information, such as scientific publications, research data, animal production data, documented field observations and other data;

c) that transparency in the planning, execution and results of *surveillance* activities, is in accordance with Chapter 1.1.

4) The objectives of this chapter are to:

a) provide guidance on the design of a *surveillance* system and the type of output it should generate;

b) provide recommendations to assess the quality of *surveillance* systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

Bias: means a tendency of an estimate to deviate in one direction from a true *population* parameter.

Confidence: means the probability that the type of *surveillance* applied would detect the presence of *infection* or *infestation* if the *population* were infected and is equivalent to the sensitivity of the *surveillance*. Confidence depends on, among other parameters, the assumed prevalence of *infection* or *infestation*.

Probability sampling: means a sampling strategy in which every unit is chosen at random and has a known non-zero probability of inclusion in the sample.

Sample: means the group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide *surveillance* information.

Sampling unit: means the unit that is sampled~~, either in a random survey or in non random *surveillance*~~. This may be an individual *animal* or a group of *animals*, such as an *epidemiological unit*. Together, they comprise the sampling frame.

Sensitivity: means the proportion of infected sampling units that are correctly identified as positive.

Specificity: means the proportion of uninfected sampling units that are correctly identified as negative.

Study population: means the *population* from which *surveillance* data are derived. This may be the same as the target population or a subset of it.

Surveillance system: means the use of one or more *surveillance* components to generate information on the health status of animal populations.

Survey: means a component of a *surveillance* system to systematically collect information with a predefined goal on a sample of a defined population group, within a defined period.

Target population: means the population to which conclusions are to be inferred.

Test: means a procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *infestation*.

Article 1.4.3.

Surveillance systems

In designing, implementing and assessing a surveillance system, the following components should be addressed in addition to the quality of *Veterinary Services*.

1. Design of surveillance system

a) Populations

Surveillance should take into account all animal species susceptible to the *infection* or *infestation* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the *population* or only some of them. When *surveillance* is conducted only on a *subpopulation*, inferences to the target population should be justified based on the epidemiology of the disease ~~*infection or infestation*~~ and the degree to which the *subpopulation* is representative of the target *population*.

EU comment

As indicated in the EU comment above, "infection or infestation" would be more appropriate terms than disease, as an animal may have an infection with out being diseased. We would therefore prefer "infection or infestation" to remain unchanged in the text of point a) above.

Definitions of appropriate *populations* should be based on the specific recommendations of the relevant chapters of the *Terrestrial Code*.

b) Timing and Temporal validity of surveillance data

The timing and duration of *surveillance* should be determined taking into consideration factors such as:

– objectives of the *surveillance*;

– biology and epidemiology (e.g. pathogenesis, *vectors*, transmission pathways, seasonality);

– *risk* of introduction and spread;

– husbandry practices and production systems;

– accessibility of target population;

– geographical factors;

– climate conditions.

Surveillance should be carried out at a frequency that reflects the epidemiology of the *infection* or *infestation* and the *risk* of its introduction and spread.

c) Case definition

Where one exists, the *case* definition in the relevant chapter of the *Terrestrial Code* should be used. If the *Terrestrial Code* does not give a *case* definition, a *case* should be defined using clear criteria for each *infection* or *infestation* under *surveillance*. For *wildlife infection* or *infestation surveillance*, it is essential to correctly identify and report host animal taxonomy, including genus and species.

d) Epidemiological unit

The relevant *epidemiological unit* for the *surveillance* system should be defined to ensure that it is appropriate to meet the objectives of *surveillance*.

e) Clustering

Infection or *infestation* in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected *animals* within a *herd or flock*, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of *surveillance* activities and considered in the statistical analysis of *surveillance* data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection* or *infestation*.

ebis) Diagnostic tests

Surveillance involves the detection of *infection* or *infestation* according to appropriate case definitions. Tests used in *surveillance* may range from detailed laboratory examinations to clinical observations and the analysis of production records.

The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. Imperfect sensitivity or specificity, as well as prevalence, will have an impact on the conclusions drawn from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

Tests should be chosen in accordance with the relevant chapters of the *Terrestrial Manual.*

f) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies and at the appropriate organisational level to facilitate effective decision-making, whether it be for planning disease control interventions or demonstrating health status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be used to accommodate different host species, pathogenic agents, production systems and *surveillance* systems, and types and amounts of data and information available.

The methodology used should be based on the best data sources available. It should also be in accordance with this chapter, fully documented and, whenever possible, supported by reference to scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the objectives of the *surveillance* and the availability and quality of field data.

Consistency in the application of different methodologies should be encouraged. Transparency is essential in order to ensure objectivity and rationality, consistency in decision-making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

g) Scope of the surveillance system

When designing the *surveillance* system consideration should be given to the purpose of *surveillance* and how the information it generates will be used, the limitations of the information it will generate, including representativeness of the study population and potential sources of bias as well as the availability of financial, technical, and human resources.

EU comment

The EU suggests inserting the words "coverage and " before "representativeness" in the text of point g) above. Indeed, coverage (i.e. geographical areas, species, etc.), along with representativeness (of the populations being surveyed) can enable evaluation of the effectiveness and performance of the surveillance system and/or surveillance objective.

h) Follow up actions

The design of the *surveillance* system should include consideration of what actions will be taken on the basis of the information generated.

2. Implementation of the surveillance system

a) Diagnostic tests

~~*Surveillance* involves the detection of *infection* or *infestation* according to appropriate case definitions. Tests used in *surveillance* may range from detailed laboratory examinations to clinical observations and the analysis of production records.~~

~~Tests should be chosen in accordance with the relevant chapters of the *Terrestrial Manual.*~~

~~*i)* Sensitivity and specificity: The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. Imperfect sensitivity or specificity, as well as prevalence, will have an impact on the conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.~~

The sensitivity and specificity values of the tests used should be specified for each species in which they may be used and the method used to estimate these values should be documented in accordance with ~~Chapter 1.1.6. of~~ the *Terrestrial Manual*.

~~*ii)* Pooling:~~ Samples from a number of *animals* or *units* may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

b) Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper or electronic records. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis is critical. Factors influencing the quality of collected data include:

– the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as government or non-governmental organisations, and others, particularly for data involving *wildlife*;

– the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;

– maintenance of raw data rather than the compilation of summary data;

– minimisation of transcription errors during data processing and communication.

3. Quality assurance

Surveillance systems should be subjected to periodic auditing to ensure that all components function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those specified in the design, in order to implement appropriate corrective actions.

Article 1.4.4.

Surveillance methods

Surveillance systems routinely use ~~structured random and non-random~~ data collected by probability-based or nonprobability-based methods, either alone or in combination. A wide variety of *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide.

1. Disease reporting systems

Disease reporting systems are based on reporting of animal health related events to the *Veterinary Authority*. Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of *animal health status*, to generate data for *risk analysis* or for early warning and response. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspected clinical *cases* should use tests that have high specificity as described in the *Terrestrial Manual*.

Whenever the responsibility for disease reporting falls outside the scope of the *Veterinary Authority*, for example human *cases* of zoonotic diseases or *infections* or *infestations* in *wildlife*, effective communication and data sharing should be established ~~with~~ between the *Veterinary Authority* and other relevant authorities.

Participatory *surveillance* methods may be useful to collect epidemiological data that can support disease reporting systems.

~~2. Data generated by control programmes and health schemes~~

~~While focusing on the control or eradication of specific *infections* or *infestations*, control programmes or health schemes can be used to generate data that can contribute to other *surveillance* objectives.~~

2. Surveys

In addition to the principles in Article 1.4.3., the following should be considered when planning, implementing and analysing surveys.

Surveys may be conducted on the entire target *population* (i.e. a census) or on a sample.

The sources of data should be fully described and should include a detailed description of the sampling strategy used for the selection of *units* for testing. Also, consideration should be given to any biases that may be inherent in the survey design.

a) Survey design

The target and study *populations* should first be clearly defined. Depending on the design of the survey, appropriate sampling *units* should be defined for each stage.

The design of the survey will depend on the knowledge of the size, structure and distribution of the *population*, the epidemiology of the *infection* or *infestation* and the resources available.

Data on the size, structure and distribution of *wildlife populations* often do not exist. However, they should be estimated to the extent possible before the survey is designed. Expert opinion can be sought in the gathering and interpretation of such *population* data. Historical *population* data should be updated since these may not reflect current *populations*.

b) Sampling

i) Objective

The objective of probability sampling from a *population* is to select a subset of units that is representative of the *population* of interest with respect to the objective of the study, taking into account practical constraints imposed by different environments and production systems so that data from the study *population* can be extrapolated to the target *population* in a statistically-valid manner. When selecting *epidemiological units* within a *population*, probability sampling, such as a simple random selection, should be used. Where probability sampling is not feasible, non-probability-based methods may be applied and should provide the best practical chance of generating a sample that is representative of the target *population*. The objective of non-probability based sampling should be to maximise the likelihood of detection of the *infection* or *infestation*. However, this type of sampling may not be representative of the study and target *population*, unless risk factors are weighted and those weights capture the relative differences in risk and proportion between the *subpopulation* and the *population*.

The sampling method used at all stages should be fully documented.

ii) Sample size

In surveys conducted to demonstrate the presence or absence of an *infection* or *infestation* the method used to calculate sample size depends on the size of the *population*, the design of the survey, the expected *prevalence* and possible clustering, the level of confidence desired of the survey results and the performance of the tests used.

In addition, for surveys designed to estimate a parameter (e.g. *prevalence*) consideration should be given to the desired precision of the estimate.

iii) Sample selection

— probability-based sampling methods, such as:

- simple random selection;
- cluster sampling;
- stratified sampling;
- systematic sampling; or

— non-probability-based sampling methods, depending on:

- convenience;
- expert choice;
- quota;
- *risk*.

3. Risk-based methods

Surveillance activities targeting selected *subpopulations* in which an *infection* or *infestation* is more likely to be introduced or found, or more likely to spread, or cause other consequences (e.g. large economic losses or trade restrictions) are useful to increase the efficiency of detection and can contribute to early detection, freedom claims, disease control activities, and estimation of *prevalence*. Risk-based methods can be used for both probability and non-probability selection of sampling units and data collection. The effect of the selection (i.e. its impact on probability of detection) should be estimated.

Risk-based methods are useful to optimise the use of *surveillance* resources.

4. Ante-mortem and post-mortem inspection

Inspection of *animals* at *slaughterhouses/abattoirs* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse/abattoir* inspection for detecting the presence of specified diseases will be influenced by:

a) clinical and pathological signs;

b) the training, experience and number of the inspection staff;

c) the extent to which the *Competent Authority* is involved ~~involvement of the *Competent Authority*~~ in the supervision of ante-mortem and post-mortem inspection, including reporting systems;

EU comment

The EU notes that contrary to point c) above, "Veterinary Authority" is used in the rest of the text of this chapter. For reasons of consistency, we would invite the OIE to consider using "Veterinary Authority" also in point c) above.

d) the quality of construction of the *slaughterhouse/abattoir*, speed of the slaughter chain, lighting quality, etc.; and

e) independence of the inspection staff.

Slaughterhouse/abattoir inspections are likely to provide good coverage for particular age groups and geographical areas only. *Slaughterhouse/abattoir surveillance* data may only be representative of a particular *subpopulation* (e.g. only *animals* of a particular class and age are likely to be slaughtered for human consumption in significant numbers). Such limitations should be recognised when analysing *surveillance* data.

The usefulness of data generated by *slaughterhouse/abattoir* inspections is dependent on effective *animal traceability* that relates *animals* to their *herd* or *flock* or locality of origin.

5. Laboratory investigation records

Laboratory investigation records may provide useful data for *surveillance*. Multiple sources of data such as national, accredited, university and private sector *laboratories* should be integrated in order to increase the coverage of the *surveillance* system.

Valid analysis of data from different *laboratories* depends on the existence of standardised diagnostic procedures and standardised methods for data recording and interpretation as well as a mechanism to ensure the traceability of specimens to *herd or flock* or locality of origin.

6. Biological specimen banks

Specimen banks consist of stored specimens, gathered through representative sampling or opportunistic collection. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection* or *infestation*, and may allow certain studies to be conducted more quickly and at lower cost than other approaches.

57. Surveillance of Ssentinel units

Surveillance of Ssentinel *units* involve the identification and regular testing of one or more *animals* of known health or immune status in a specified geographical location to detect the occurrence of *infection* or *infestation.* Sentinel *units* provide the opportunity to target *surveillance* depending on the risk of introduction, likelihood of *infection* or *infestation,* cost and other practical constraints. Sentinel *units* may provide evidence of freedom from *infection* or *infestation*, or of their distribution.

68. Clinical ~~observations~~ surveillance

Clinical observations of *animals* in the field are an important source of *surveillance* data. The sensitivity and specificity of clinical observations are highly dependent on the criteria used to define a suspected *case*. In order to allow comparison of data, the *case* definition should be standardised. Training of potential field observers in the application of the *case* definition and reporting is important. Ideally, both the number of positive observations and the total number of observations should be recorded.

79. Syndromic ~~data~~ surveilance

EU comment

Please replace "surveilance" with "surveillance" (typographical error).

Systematic analysis of health data, including morbidity and mortality rates, production records and other parameters can be used to generate signals that may be indicative of changes in the occurrence of *infection* or *infestation*. Software may offer the prospect of extraction of syndromic data for aggregation and analysis.

810. Other data sources

a) Data generated by control programmes and health schemes

While focusing on the control or eradication of specific *infections* or *infestations*, control programmes or health schemes can be used to generate data that can contribute to other *surveillance* objectives.

b) Laboratory investigation records

Laboratory investigation records may provide useful data for *surveillance*. Multiple sources of data such as national, accredited, university and private sector *laboratories* should be integrated in order to increase the coverage of the *surveillance* system.

Valid analysis of data from different *laboratories* depends on the existence of standardised diagnostic procedures and standardised methods for data recording and interpretation as well as a mechanism to ensure the traceability of specimens to *herd or flock* or locality of origin.

EU comment

As there is additional dependence on laboratory quality control and quality assurance

systems, the EU suggests adding the following at the end of the paragraph above:

"Valid analysis of data is also dependent on laboratory quality control and quality assurance systems.".

c) Biological specimen banks

Specimen banks consist of stored specimens, gathered through representative sampling or opportunistic collection. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection* or *infestation*, and may allow certain studies to be conducted more quickly and at lower cost than other approaches.

d~~a~~) Wildlife data

Specimens for *surveillance* from *wildlife* may be available from sources such as hunters and trappers, road-kills, *wild animal meat* markets, sanitary inspection of hunted *animals*, morbidity and mortality observations by the general public, *wildlife* rehabilitation centres, *wildlife* biologists and *wildlife* agency field personnel, farmers and other landholders, naturalists and conservationists. *Wildlife* data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

Annex 33 (contd)

e~~b~~) Public health data

For zoonotic diseases public health data may be an indicator of a potential change in the *animal health status*. The *Veterinary Authority* should coordinate with human health authorities and share data for integration into *specific surveillance* systems.

f~~c~~) Environmental data

Relevant environmental data such as rainfall, temperature, extreme climatic events, presence and abundance of potential *vectors* as described in Chapter 1.5., should also be integrated into the *surveillance* system.

g~~d~~) Additional supporting data such as:

i) data on the epidemiology of the *infection* or *infestation*, including host *population* distribution;

ii) data on animal movements, including transhumance and natural *wildlife* migrations;

iii) trading patterns for *animals* and animal products;

iv) national animal health regulations, including information on compliance and effectiveness;

v) history of imports of potentially infected material;

vi) *biosecurity* in place; and

vii) the *risk* of introduction of *infection* or *infestation*.

9. Combination and interpretation of surveillance results

Depending on the objective of *surveillance*, the combination of multiple sources of data may provide an indication of the overall sensitivity of the system and may increase the confidence in the results. The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented, including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of *animal health status*. Repeated surveys may be analysed to provide a

cumulative level of confidence. However, the combination of data collected over time from multiple sources may be able to achieve an equivalent level of confidence.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity and specificity of tests used and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

In assessing the efficiency of the *surveillance* system based on multiple sources, the *Veterinary Authority* should consider the relative contribution of each component to the overall sensitivity, while considering the primary objective of each *surveillance* component.

Results from animal health *surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

~~Article 1.4.5.~~

~~**Considerations in survey design**~~

~~In addition to the principles in Article 1.4.3., the following should be considered when planning, implementing and analysing surveys.~~

~~1. Types of surveys~~

~~Surveys may be conducted on the entire target *population* (i.e. a census) or on a sample.~~

~~Surveys conducted in order to document freedom from *infection* or *infestation* should be conducted using probability-based sampling methods so that data from the study *population* can be extrapolated to the target *population* in a statistically valid manner.~~

~~The sources of data should be fully described and should include a detailed description of the sampling strategy used for the selection of *units* for testing. Also, consideration should be given to any biases that may be inherent in the survey design.~~

~~2. Survey design~~

~~The target and study *populations* should first be clearly defined. Depending on the design of the survey, appropriate sampling *units* should be defined for each stage.~~

~~The design of the survey will depend on the knowledge of the size, structure and distribution of the *population*, the epidemiology of the *infection* or *infestation* and the resources available.~~

~~Data on the size, structure and distribution of *wildlife* populations often do not exist. However, they should be estimated to the extent possible before the survey is designed. Expert opinion can be sought in the gathering and interpretation of such *population* data. Historical *population* data should be updated since these may not reflect current *populations*.~~

~~3. Sampling~~

~~a) Objective~~

~~The objective of probability sampling from a *population* is to select a subset of units that is representative of the *population* of interest with respect to the objective of the study, taking into account practical constraints imposed by different environments and production systems. When selecting *epidemiological units* within a *population*, probability sampling, such as a simple random selection, should be used. Where probability sampling is not feasible, non-probability based methods may be applied and should provide the best practical chance of generating a sample that is representative of the target *population*. The objective of non-probability based sampling is to maximise the likelihood of detection of the *infection* or *infestation*. However, this type of sampling will not be representative of the study and target *population*.~~

~~The sampling method used at all stages should be fully documented.~~

~~*b)* Sample size~~

~~In surveys conducted to demonstrate the presence or absence of an *infection* or *infestation* the method used to calculate sample size depends on the size of the *population*, the design of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.~~

~~In addition, for surveys designed to estimate a parameter (e.g. prevalence) consideration should be given to the desired precision of the estimate.~~

~~*c)* A sample may be selected by either:~~

~~*i)* probability based sampling methods, such as:~~

- ~~simple random selection;~~
- ~~cluster sampling;~~
- ~~stratified sampling;~~
- ~~systematic sampling; or~~

~~*ii)* non probability based sampling methods, depending on:~~

- ~~convenience;~~
- ~~expert choice;~~
- ~~quota;~~
- ~~*risk*.~~

Article 1.4.5.

Early warning systems

EU comment

The EU apreciates that it's suggestion to move text to be deleted from draft Article 4.Y.4. to this article was taken into account. Indeed, that information is better placed in the present article. We however note that some important information contained in the second paragraph of draft Article 4.Y.4. (see Annex 34) is missing from this article (i.e. only the first parts are included in the last indent of point 5bis) below). We invite the OIE to consider moving that information to the present article, as it consitutes important elements of early waring systems.

An early warning system is essential for the timely detection, reporting and communication of occurrence, incursion or emergence of diseases, *infections* or *infestations*, should be under the control of the *Veterinary Authority* and should include the following:

1) appropriate coverage of target *animal* populations by the *Veterinary Services*;

2) *laboratories* capable of diagnosing and differentiating relevant *infections* or *infestations*;

3) training and awareness programmes for *veterinarians*, *veterinary paraprofessionals*, livestock owners or keepers and others involved in handling *animals* from the farm to the *slaughterhouse/abattoir*, for detecting and reporting unusual animal health incidents;

4) a legal obligation by relevant stakeholders to report suspected *cases* or *cases* of *notifiable diseases* or *emerging diseases* to the *Veterinary Authority* with following information;

- the disease or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;

- the date when the signs were first noticed at the initial site and any subsequent sites;
- the names and addresses or geographical locations of suspected infected establishments or premises;
- the animal species affected, including possible human cases, and the approximate numbers of sick and dead animals;
- initial actions taken, including biosecurity and precautionary movement restrictions of animals, products, staff, vehicles and equipment;

5bis) epidemiological investigations of suspected *cases* and *cases* conducted by the *Veterinary Services*, taking into account the following:

- biosecurity to be observed when entering and leaving the establishment, premises or locality;
- clinical examinations to be undertaken (number and types of animals);
- samples to be taken from *animals* showing signs or not (number and types of *animals*), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;
- procedure for submitting samples for testing;
- size of the affected *establishment*, premises or locality and possible entry pathways;

EU comment

The indent above should also include exit pathways. We thus suggest inserting the words "and exit" before "pathways". Indeed, epidemiological investigations would normally consider both source (of incursion) and spread (to other animals/groups/holdings/areas).

- investigation of the approximate numbers of similar or possibly susceptible animals in the *establishment* and its surroundings;
- details of any recent movements of possibly susceptible animals or *vehicles* or people to or from the affected establishments, premises or locality;
- any other relevant epidemiological information, such as presence of the suspected disease in *wildlife* or abnormal *vector* activity;
- all suspected *case* investigations should provide a result, either positive or negative. Criteria should be established in advance for a *case* definition;

6) effective systems of communication between the *Veterinary Authority* and relevant stakeholders;

7) a national chain of command.

EU comment

Point 7) above is an important general component. It would be better placed further up in the list.

Early warning systems are an essential component of emergency preparedness.

EU comment

The sentence above seems out of place at the end of the article. Indeed, it would be better placed at the beginning, as it is an important general statement. Perhaps it could

be merged with the first paragraph of the article.

When a *case* of a *listed disease* is detected, *notification* shall be made to the OIE in accordance with Chapter 1.1.

EU comment

The sentence above is an unecessary duplication of the requirements included in Chapter 1.1. Furthermore, it may cause confusion as it does not address e.g. emerging diseases that also shall be notified in accordance with Chapter 1.1. Therefore, the sentence should preferably be deleted.

Article 1.4.6.

Surveillance ~~to demonstrate~~ for freedom from an infection or infestation

~~This article provides general principles for declaring freedom from an *infection* or *infestation*, including for the recognition of historical freedom.~~

1. Demonstration of freedom

A *surveillance* system to demonstrate freedom from an *infection* and *infestation* should meet the following, in addition to the general principles outlined in Article 1.4.3.

Freedom implies the absence of ~~the pathogenic agent~~ *infection* or *infestation* in an animal *population* in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of this absence. Therefore, demonstrating freedom, except for historical freedom, involves providing sufficient evidence to demonstrate to a desired level of confidence ~~(to a level of confidence acceptable to Member Countries)~~ that *infection or infestation* with a specified pathogenic agent, if present, is present in less than a specified proportion of the *population*.

However, finding evidence of *infection* or *infestation* at any prevalence in the target *population* automatically invalidates any freedom claim unless otherwise stated in the relevant chapter of the *Terrestrial Code*. The implications for the status of domestic *animals* ~~of~~ when *infection* or *infestation* is present in *wildlife* in the same country or *zone* should be assessed in each situation, as indicated in the relevant chapter of the *Terrestrial Code*.

EU comment

Since not all disease-specific chapters of the Code include indications re. disease freedom in domestic vs. wild animal pospulations, the EU suggests inserting the words "where applicable" after "as indicated" in the second sentence of the paragraph above.

Evidence from probability ~~-based~~ and non-probability risk-based data ~~sources~~ collection, ~~as stated before,~~ may increase the sensitivity of the *surveillance* ~~level of confidence or be able to detect a lower prevalence with the same level of confidence as structured surveys~~.

2. Requirements to declare a country or a zone free from an infection or infestation

a) Prerequisites, unless otherwise specified in the relevant chapter of the *Terrestrial Code*:

i) the *infection* or *infestation* has been a *notifiable disease*;

ii) an *early warning system* has been in place for all relevant species;

iii) measures to prevent the introduction of the *infection* or *infestation* have been in place;

~~*iv)* *no vaccination* against the disease has been carried out;~~

iv) the *infection* or *infestation* is not known to be established in *wildlife* within the country or *zone*.

b) Historical freedom: unless otherwise specified in the relevant chapter of the *Terrestrial Code*, a country or *zone* may be considered free without formally applying a pathogen-specific *surveillance* programme when:

i) the prerequisites listed in a) are complied with for at least the past 10 years;

ii) the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible animals;

iii) for at least 25 years there has been no occurrence of *infection* or *infestation* ~~or eradication has been achieved for the same length of time~~.

c) Where historical freedom cannot be ~~achieved~~ demonstrated:

i) the prerequisites listed in *a)* ~~are~~ have been complied with for at least as long as the *surveillance* has been in place;

ii) pathogen-specific *surveillance* has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code,* if it exists, and has not detected any occurrence of the *infection* or *infestation*.

EU comment

There are many disease-specific chapters in the Code that do not include recommendations for pathogen-specific surveillance. The EU therefore suggests replacing the words "if it exists" with "where applicable" in point ii) above.

3. Requirements to declare a compartment free from infection or infestation

a) The prerequisites listed in 2.a) i) to iii~~iv~~) are complied with for at least as long as the *surveillance* has been in place;

b) ongoing pathogen-specific *surveillance* has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code,* if ~~they~~ it exists, and has not detected any occurrence of the *infection* or *infestation*.

EU comment

There are many disease-specific chapters in the Code that do not include recommendations for pathogen-specific surveillance. The EU therefore suggests replacing the words "if it exists" with "where applicable" in point b) above.

4. Recommendations for the maintenance of freedom from infection or infestation

Unless otherwise specified in the relevant chapter of the *Terrestrial Code*, a country or *zone* that has achieved freedom in accordance with the provisions of the *Terrestrial Code* may maintain its free status provided that:

a) the *infection* or *infestation* is a *notifiable disease*;

b) an *early warning system* is in place for all relevant species;

c) measures to prevent the introduction of the *infection* or *infestation* are in place;

d) *surveillance* adapted to the likelihood of occurrence of *infection* or *infestation* is carried out. *Specific surveillance* may not need to be carried out if supported by a *risk assessment* addressing all identified pathways for introduction of the pathogenic agent and provided ~~it~~ the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible *animals*;

~~*e)* *vaccination* against the disease is not applied;~~

ef) the *infection* or *infestation* is not known to be established in *wildlife*. It can be difficult to collect sufficient epidemiological data to prove absence of *infection* or *infestation* in *wild animal* populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

Article 1.4.7.

Surveillance ~~considerations~~ in support of disease control programmes

Surveillance is an important component in disease control programmes and can be used to determine the distribution and occurrence of *infection* or *infestation* or of other relevant health-related events. It can be used to assess progress and aid in decision-making in the control or eradication of selected *infections* or *infestations*.

Surveillance used to assess progress in control or eradication of selected *infections* or *infestations* should be designed to collect data about a number of variables such as:

1) prevalence or incidence of *infection* or *infestation*;
2) morbidity and mortality;
3) frequency of *risk* factors and their quantification;
4) frequency distribution of results of the laboratory tests;
5) post-vaccination monitoring results;
6) frequency distribution of *infection* or *infestation* in *wildlife*.

The spatial and temporal distribution of these variables and other data such as *wildlife*, public health and environmental data as described in point 8~~10~~) of Article 1.4.4. can be useful in the assessment of disease control programmes.

~~Article 1.4.8.~~

~~**Early warning systems**~~

~~An *early warning system* is essential for the timely detection, identification and reporting of occurrence, incursion or emergence of *infections* or *infestations*, and should include the following:~~

~~1) appropriate coverage of target *animal* populations by the *Veterinary Services*;~~

~~2) effective disease investigation and reporting;~~

~~3) *laboratories* capable of diagnosing and differentiating relevant *infections* or *infestations;*~~

~~4) training and awareness programmes for *veterinarians*, *veterinary paraprofessionals*, livestock owners or keepers and others involved in handling *animals* from the farm to the *slaughterhouse/abattoir*, for detecting and reporting unusual animal health incidents;~~

~~5) a legal obligation by relevant stakeholders to report suspected *cases* or *cases* of *notifiable diseases* or *emerging diseases* to the *Veterinary Authority*;~~

~~6) effective systems of communication between the *Veterinary Authority* and relevant stakeholders;~~

~~7) a national chain of command.~~

~~*Early warning systems* are an essential component of emergency preparedness.~~

~~Article 1.4.9.~~

~~**Combination and interpretation of surveillance results**~~

Depending on the objective of *surveillance*, the combination of multiple sources of data may provide an indication of the overall sensitivity of the system and may increase the confidence in the results. The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented, including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of *animal health status*. Repeated surveys may be analysed to provide a cumulative level of confidence. However, the combination of data collected over time from multiple sources may be able to achieve an equivalent level of confidence.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity and specificity of tests used and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

In assessing the efficiency of the *surveillance* system based on multiple sources, the *Veterinary Authority* should consider the relative contribution of each component to the overall sensitivity, while considering the primary objective of each *surveillance* component.

Results from *animal* health *surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over estimate or an under estimate of the parameters of interest.

Annex 34

CHAPTER 4.Y.

OFFICIAL CONTROL ~~MANAGEMENT~~ OF ~~OUTBREAKS OF~~ LISTED AND EMERGING ~~AND LISTED~~ DISEASES

EU comment

The EU thanks the OIE and in general supports this new chapter.

Comments are inserted in the text below.

Concerning the invitation of the Code Commission to propose a suitable definition for "animal products" to be included in the Glossary, the EU is pleased to provide the following:

"Animal products

Means products of animal origin, animal genetic material and animal by-products."

Article 4.Y.1.

Introduction

When a *listed disease* or *emerging disease*, including a zoonosis, occurs in a Member Country, *Veterinary Services* should implement ~~a response~~ control measures proportionate to the likely impact of the disease ~~and as a result of a *risk analysis*,~~ in order to minimise its spread and consequences and, if possible, eradicate it. These measures can vary from rapid response to a new ~~*hazard*~~ disease and management of *outbreaks*, to long-term control of an endemic disease ~~*infection or infestation*~~.

The purposes of this chapter is to provide recommendations to prepare, develop and implement *official control programmes* ~~plans~~ in response to *outbreaks* ~~occurrence~~ ~~*outbreaks*~~ of *listed* and *emerging* ~~or *listed*~~ *diseases*, including zoonoses. It is not aimed at giving ready-made fit-for-all solutions, but rather at outlining principles to follow when combating animal diseases through organised control programmes ~~plans~~.

The *Veterinary Authority* should determine which diseases to establish *official control programmes* against and at which regulatory level, according to an evaluation of the actual or likely impact of the disease. Disease control programmes ~~plans~~ should be prepared in advance by the *Veterinary Authority* and *Veterinary Services* in close collaboration with the relevant stakeholders and other authorities, as appropriate ~~disposing of the necessary regulatory, technical and financial tools~~.

~~Control plans~~ They should be justified by rationales developed through *risk analysis* and ~~considering~~ taking into account animal health, public health~~,~~ and socio-economic, *animal welfare* and environmental aspects. They should be supported by relevant cost-benefit analysis when possible and include the necessary regulatory, technical and financial tools.

EU comment

The EU does not support the addition of "when possible" in the last sentence of the paragraph above, as cost-benefit analysis is essential in this context. Besides, this wording is not necessary, as OIE recommendations are always to be implemented by Member Countries "when possible". This is also expressed by the verb "should". At the most, the EU could accept the insertion of "preferably" after "They should".

Official control programmes ~~Control plans~~ should be developed with the aim of achieving defined measurable objectives, in response to a situation in which ~~purely~~ private action ~~alone~~ is not sufficient. Depending on the prevailing epidemiological, environmental and socio-economic situation, the goal may vary from the reduction of

impact to the eradication of a given ~~disease~~ *infection* or *infestation*.

~~In any case,~~ T~~t~~he components of control plans ~~for management of *outbreaks*~~ are an early ~~*detection*~~ warning system ~~(including a warning procedure),~~ ~~and~~ rapid response and ~~quick and~~ effective action, possibly followed by long-term measures. Plans should ~~always~~ include an exit strategy. Learning from past *outbreaks*, ~~and~~ reviewing the response sequence and revising the methods are critical for adaptation to evolving ~~epidemiological situations~~ circumstances and for better performance in future ~~situations~~. Experiences of the *Veterinary Services* of other Member Countries may also provide useful lessons. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well-understood and that ~~field~~ staff are trained and other stakeholders are fully aware of their respective roles and responsibilities ~~in implementing the response~~. This is especially important for diseases that are not present in the Member Country.

EU comment

In the paragraph above, the EU suggests replacing the word "rapid" with "timely", as indeed not every animal diease requires a rapid response. This would also be consistent with wording used elsewhere in the Code (e.g. proposed definition of "early warning system").

Article 4.Y.2.

Legal framework and regulatory environment

1) In order to be able to effectively control *listed diseases* and *emerging diseases* ~~and *listed diseases*~~, the *Veterinary Authority* should ensure that:

   – the *Veterinary Services* comply with the principles of Chapter 3.1., especially the services dealing with the prevention and control of ~~contagious~~ infectious animal diseases, including zoonoses;

   – the *veterinary legislation* complies with the principles of Chapter 3.4.

2) In particular, in order for the *Veterinary Services* to be the most effective when combatting animal disease *outbreaks*, the following should be addressed in the *veterinary legislation* or other relevant legal framework:

   – legal powers and structure of command and responsibilities, including responsible officials with defined powers; especially a right of entry to *establishments* or other related enterprises such as live *animal* markets, *slaughterhouses/abattoirs* and animal products processing plants, for regulated purposes of *surveillance* and disease control actions, with the possibility of obliging owners to assist;

   – sources of financing for epidemiological enquiries, laboratory diagnostic, disinfectants, insecticides, vaccines and other critical supplies;

   – sources of financing and compensation policy for livestock and property that may be destroyed as part of disease control programmes, or for losses incurred due to movement restrictions;

EU comment

The EU strongly disagrees with the addition of ", or for losses incurred due to movement restrictions" in the indent above. Indeed, whereas for the sake of clarity, compensation for products of animal origin that had to be destroyed as part of disease control programmes could explicitly be added (as suggested by the EU previously, see https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201709.pdf, p. 184), losses incurred due to movement restrictions go beyong what is practiced in the EU. While these losses can be very significant, they are difficult to assess in an objective way, and would typically be covered by private insurance schemes. The new addition cannot be supported by the EU and should therefore be deleted.

– coordination with other authorities, especially law enforcement and public health authorities.

3) Furthermore, the specific regulations, policies, or guidance on disease control activities ~~policies~~ should include the following:

– *risk analysis* to identify and prioritise ~~potential *disease*~~ *risks*, including a regularly updated list of *notifiable diseases*;

– definitions and procedures for the reporting and management of a suspected *case*~~,~~ or confirmed *case*~~,~~ of a~~n~~ *listed disease* or an *emerging disease* ~~or a *listed disease*~~;

– procedures for the management of ~~infected *establishments*~~, directly or indirectly affected by the disease ~~infected *establishment*, contact *establishment*~~;

– procedures for epidemiological investigations of *outbreaks* including tracing of *animals* and animal products;

– definitions and procedures for the declaration and management of *infected zones* and other *zones*, such as *free zones*, *protection zones*, *containment zones*, or less specific ones such as *zones* of intensified *surveillance*;

– procedures for the collection, transport and testing of animal samples;

– procedures for *animal identification* and the management of *animal identification systems* ~~the identification of *animals*~~;

– procedures for the restrictions of movements, including possible standstill or compulsory veterinary certification, of relevant *animals*, ~~and~~ animal products and fomites within, to, or from given *zones* or *establishments* or other related enterprises;

– procedures for the destruction or *slaughter* and safe disposal or processing of infected or potentially infected *animals*, including relevant *wildlife*~~,~~; ~~and~~

– procedures for the destruction and safe disposal or processing of contaminated or potentially contaminated animal products and other materials such as fodder, bedding and litter;

– procedures for cleaning, *disinfection* and disinsection of *establishments* and related premises, *vehicles/vessels* or equipment;

– procedures for compensation for the owners of *animals* or animal products, including defined standards and means of implementing such a compensation;

– ~~procedures for cleaning, *disinfection* and disinsection of *establishments* and related premises, *vehicles* or equipment;~~

– procedures for the compulsory emergency *vaccination* or treatment of *animals*, as relevant, and for any other necessary disease control actions~~,~~;

– procedures for post-control *surveillance* and recovery of status.

EU comment

The EU suggests adding the words "if applicable" at the end of the last indent above, as recovery of status will not be relevant in all cases.

Article 4.Y.3.

Preparedness

Rapid and effective response to a new occurrence or emergence of ~~contagious~~ infectious diseases is dependent on the level of preparedness. The *Veterinary Authority* should integrate preparedness planning and practice as one of its core functions. ~~Rapid, effective response to a new occurrence or emergence of contagious diseases is~~

~~dependent on the level of preparedness.~~

Preparedness should be ~~justified~~ supported by *risk analysis*, should be planned, and should include ~~training,~~ capacity building and simulation exercises.

1. Risk analysis

Risk analysis, including import *risk analysis*, in accordance with Chapter 2.1., should be used to determine ~~which~~ a list of *notifiable* *diseases* that require preparedness planning and to what extent.

A *risk analysis* identifies the pathogenic agents that present the greatest *risk* and for which preparedness is most important and therefore helps to prioritise the range of disease threats and categorise the consequent actions. It also helps to define the best strategies and control options.

The *risk analysis* should be reviewed ~~updated~~ regularly to detect changes (e.g. new pathogenic agents, or changes in distribution and virulence of pathogenic agents previously identified as presenting the major *risk* and changes in possible pathways) and be updated accordingly, taking into account the latest scientific findings.

2. Planning

Four kinds of plans, describing what governmental or local authorities and all stakeholders should do, comprise any comprehensive preparedness and response system:

a) a preparedness plan, which outlines what should be done before an *outbreak* of a *notifiable disease* or an *emerging disease* ~~or a *notifiable disease*~~ occurs;

b) a response or contingency plan, which details what should be done in the event of an occurrence of a *notifiable disease* or an *emerging disease* ~~or *notifiable disease*~~, beginning from the point when a suspected *case* is reported;

c) a comprehensive set of instructions for ~~field~~ staff and other stakeholders on how to undertake specific tasks required by the response or contingency plan;

d) a recovery plan for the safe restoration of normal activities, including food supply, possibly including procedures and practices modified in light of the experience gained during the management of the ~~*outbreak*~~ *notifiable disease* or the *emerging disease*.

3. Simulation exercises

The *Veterinary Services* and all stakeholders should be made aware of the sequence of measures to be taken in the framework of a contingency plan through the organisation of simulation exercises, mobilising a sufficient number of staff and stakeholders to evaluate the level of preparedness and fill possible gaps in the plan or in staff capacity. Simulation exercises may be organised between the *Veterinary Services* of neighbouring countries.

Article 4.Y.4.

Surveillance and early warning ~~detection~~ system

EU comment

For consistency with draft Article 1.4.5. (see Annex 33) and the text in the first paragraph below, the EU suggests slightly amending the title of this article for it to read "Surveillance and early warning systems". (Preferably, all references to "early warning system" throughout the text should be changed to the plural form, i.e. "[...] systems").

~~1)~~ Depending on the priorities identified by the *Veterinary Authority*, *Veterinary Services* should implement adequate *surveillance* for *listed diseases* in accordance with Chapter 1.4. ~~or~~ and *listed* *disease*-specific chapters, in order to detect suspected *cases* and either rule them out or confirm them. The *surveillance* should be adapted to the epidemiological and environmental situation. Early warning systems should be in place for *infections* or *infestations* for which a rapid response is desired, and should comply with the relevant

articles of Chapter 1.4. *Vector surveillance* should be conducted in accordance with Chapter 1.5.

All suspected *case* investigations should provide a result, either positive or negative. Criteria should be established in advance for a *case* definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the *Terrestrial Code* or *Terrestrial Manual*. Strong suspicion based on supportive, but not definitive, findings should lead to the implementation of local control measures as a precaution. When a *case* is confirmed, full *sanitary measures* should be implemented as planned.

EU comment

Reference is made to the EU comment on draft Article 1.4.5. (see Annex 33). Indeed, some of the information contained in the paragraph above should also / rather be included in that article.

Furthermore, the EU is of the opinion that under certain conditions, in case of strong suspicion, the Veterinary Services may decide to implement the full set of sanitary measures (e.g. stamping-out policy), pending definitive laboratory test results (e.g. in case of strong suspicion of HPAI in areas with dense poultry popultations). Some flexibility should therefore be foreseen in the wording of the two last sentences of the paragraph above (e.g. by inserting the words "at least" after "should lead to", and "At the latest" before "when a case is confirmed".

Finally, the EU suggests adding the words "if necessary and according to the assessment of the Veterinary Authority" at the end of the last sentence of the paragraph above. Indeed, there are circumstances where this would not be deemed necessary by the Veterinary Authority, upon appropriate assessment of the individual / local situation.

2) In order to implement adequate *surveillance*, the *Veterinary Authority* should have access to good diagnostic capacity. This means that the *veterinarians* and other relevant personnel of the *Veterinary Services* have adequate knowledge of the *disease*, its clinical and pathological manifestation and its epidemiology, and that laboratories approved for the testing of animal samples for the relevant *diseases* are available.

3) Suspected *cases* of *notifiable diseases* should be reported without delay to the *Veterinary Authority*, ideally with the following information:

- the *disease* or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;
- the date when the signs were first noticed at the initial site and any subsequent sites;
- the names and addresses or geographical locations of suspected infected *establishments* or premises;
- the animal species affected, including possible human cases, and the approximate numbers of sick and dead *animals*;
- initial actions taken, including *biosecurity* and precautionary movement restrictions of *animals*, products, staff, vehicles and equipment;

4) Immediately following the report of a suspected *case*, investigation should be conducted by the *Veterinary Services*, taking into account the following:

- *biosecurity* to be observed when entering and leaving the *establishment*, premises or locality;
- clinical examinations to be undertaken (number and types of *animals*);
- samples to be taken from *animals* showing signs or not (number and types of *animals*), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;

- ~~procedure for submitting samples for testing;~~
- ~~size of the affected *establishment*, premises or locality and possible entry pathways;~~
- ~~investigation of the approximate numbers of similar or possibly susceptible *animals* in the *establishment* and its surroundings;~~
- ~~details of any recent movements of possibly susceptible *animals* or *vehicles* or people to or from the affected *establishments*, premises or locality;~~
- ~~any other relevant epidemiological information, such as presence of the suspected *disease* in *wildlife* or abnormal *vector* activity;~~

~~A procedure should be in place for reporting findings to the *Veterinary Authority* and for record keeping.~~

~~5)~~ ~~All suspected *case* investigations should provide a result, either positive or negative. Criteria should be established in advance for a *case* definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the *Terrestrial Code* or *Terrestrial Manual*. Strong suspicion based on supportive, but not definitive, findings should lead to the implementation of local control measures as a precaution. When a *case* is confirmed, full *sanitary measures* should be implemented as planned.~~

~~6)~~ ~~When a *case* of a *listed disease* is detected, *notification* shall be made to the OIE in accordance with Chapter 1.1.~~

Article 4.Y.5.

General considerations when managing an outbreak

Upon confirmation of ~~Once~~ an *outbreak* of a *notifiable disease* or an *emerging disease* ~~or a *notifiable disease*~~ that is subject to an *official control programme* ~~is confirmed~~ effective *risk management* depends on the application of a combination of measures that are operating at the same time or consecutively, aimed at:

1) eliminating the source of pathogenic agent, through:
   - the *killing* or *slaughter* of *animals* infected or suspected of being infected, as appropriate, and safe disposal of dead *animals* and potentially contaminated products;
   - the cleaning, *disinfection* and, if relevant, disinsection of premises and equipment;
2) stopping the spread of *infection*, through:
   - movement restrictions on *animals*, *vehicles*, ~~and~~ equipment and people, as appropriate;
   - *biosecurity*;
   - *vaccination*, treatment or culling of *animals* at risk;
   - communication and public awareness.

Different strategies may be chosen depending on the expected outcome of the programme (i.e. eradication, containment or partial control) and the epidemiological, environmental, economic and social situation. The *Veterinary Authority* should assess the situation beforehand and at the time of the *outbreak* detection. For example, the wider the spread of the disease and the more locations affected at the beginning of the implementation of the measures, the less likely it will be that culling as a main eradication tool will be effective, and the more likely it will be that other control tools such as *vaccination* or treatment, either in conjunction with culling or alone, will be needed. The involvement of *vectors* or *wildlife* will also have a major influence on the control strategy and different options chosen. The strategies chosen will, in turn, influence the final objective of the control programme.

In any case, the management plan should consider the costs of the measures in relation to the benefits expected, and should at least integrate the compensation of owners for losses incurred by the measures, as described in regulations, policies or guidance.

In case of highly contagious or high impact disease events, the management plan should be closely coordinated through an inter-sectoral mechanism such as an incident command system.

Article 4.Y.6.

Culling of animals and disposal of dead animals and animal products

Living infected *animals* can be ~~are~~ the greatest source of pathogenic agents. These *animals* may directly transmit the pathogenic agent to other *animals*~~.~~. They may ~~and~~ also cause ~~lead to~~ indirect *infection* through the contamination of fomites, including breeding and handling equipment, bedding, feed, *vehicles*, and people's clothing and footwear, or the contamination of the environment. Although carcasses may remain contaminated for a period after death, active shedding of the pathogenic agent effectively ceases when the *animal* is killed or slaughtered. Thus, culling of *animals* is often a ~~the~~ preferred strategy for the control of contagious diseases.

EU comment

The EU suggests using the term "infectious disease(s)" consistently throughout the chapter (instead of "contagious disease(s)"), where appropriate. Indeed, in the paragraphs above and below, "infectious diseases" would be warranted, as this would be consistent with the changes made in Articles 4.Y.2. and 4.Y.3.

Veterinary Services should adapt any strategy for culling~~, *killing*~~ or disposal of dead *animals* and their products ~~strategy~~ to the transmission pathways of the pathogenic agent. A *stamping-out policy* is ~~should be~~ the preferred strategy for highly contagious diseases and for situations where the country or *zone* was ~~formerly~~ previously free or freedom was impending, while other strategies, such as test and cull, are better suited to less contagious diseases and situations where the disease is endemic.

EU comment

For clarity and consistency with the title, the words "of animals" should be inserted after "culling" in the first sentence of the paragraph above. Indeed, dead animals are not culled.

Furthermore, for the same reasons, the words "and their products" should be replaced with "and animal products", as strictly speaking these are not products of dead animals.

For control measures, including destruction of *animals* or products, to be most effective, *animal identification* and *animal traceability* should be in place, in accordance with Chapters 4.1. and 4.2.

The *slaughter* or *killing* of *animals* should be performed in accordance with Chapter 7.5. or Chapter 7.6., respectively.

The disposal of dead *animals* and their potentially contaminated products should be performed in accordance with Chapter 4.12.

1. Stamping-out policy

A *stamping-out policy* consists primarily ~~in~~ of the *killing* of all the *animals* ~~affected~~ infected or suspected of being ~~affected~~ infected, including those ~~which~~ that have been directly or indirectly exposed to the causal pathogenic agent. This strategy is used for the most contagious diseases.

A *stamping-out policy* can be limited to the affected *establishments* and, where appropriate, other *establishments* found to be epidemiologically linked with an affected *establishment*, or be broadened to include all *establishments* of a defined *zone*, when pre-emptive depopulation can be used to stop the transmission of a fast spreading pathogenic agent.

A stamping-out policy can be applied to all the animal species present on an affected *establishment*, or to all susceptible species, or only to the same species as the infected *animals*, based on the assessment of associated *risks*.

Killing should preferably be performed on site, and the carcasses either disposed of on site or transported

directly and safely to a rendering plant or other dedicated site for destruction. If to be killed outside of the *establishment* or slaughtered, the *animals* should be transported directly to a dedicated *approved* rendering plant or *slaughterhouse/abattoir* respectively, without any possible direct or indirect contacts with other *animals*. Slaughtered *animals* and their products should be processed separately from others.

~~Stamping-out can be applied to all the animal species present on affected premises, or to all susceptible species, or only to the same species as the affected *animals*.~~

Products originating from killed or slaughtered *animals*, ~~(~~ranging from carcasses, *meat*, *milk*, eggs or genetic material to hair, wool, feathers or manure, ~~slurry)~~ should be destroyed or processed in a way that inactivates the pathogenic agent. The inactivating process should be carried out in accordance with the relevant articles of the *listed disease*-specific chapters.

Stamping-out policy procedures systematically include the cleaning and *disinfection* of *establishments* and *vehicles/vessels* used for the transport of *animals*, carcasses or products, as well as of any equipment and material that has been in direct or indirect contact with the *animals*. The procedures may include disinsection or *disinfestation* in the case of *vector*-borne disease or parasitic *infestation*. These procedures should be conducted in accordance with the relevant articles of Chapter 4.13.

2. Test and cull

This strategy consists primarily of finding the ~~proven~~ infected *animals* in order to remove them from the population and either *slaughter* or kill and dispose of them. This strategy is ~~It should be~~ used for less contagious or slow-spreading diseases. *Veterinary Services* may apply different test and cull strategies based on the epidemiology of the *infection* or *infestation* or on the characteristics of available diagnostic tests. In particular, the design of test and cull strategy will depend on the sensitivity and specificity of the tests.

Apart from the selection of *animals* to be culled, the same principles apply as for *stamping-out policy* in terms of processing, treatment and disposal of dead or slaughtered *animals* and their products.

Article 4.Y.7.

Movement control

Disease spread due to the movement of live *animals*, animal products and contaminated material should be controlled by movement restrictions that are adequately enforced.

These restrictions can be applied to one or more animal species and their associated products, and to people, *vehicles/vessels* and equipment. They may vary from pre-movement certification to total standstill, and be limited to one or more *establishments*, or cover specific *zones*, or the entire country. The restrictions can include the complete isolation of individual *animals* or group of *animals*, and specific rules applied to movements, such as protection from *vectors*.

Specific rules covering movement controls should apply to each of any defined *zones*. Physical barriers ~~should~~ may be installed as needed, to ensure the effective application of movement restrictions.

Movement controls should be in place until the end of other disease control operations, ~~e.g.~~ such as a *stamping-out policy*, and after *surveillance* and a revised *risk assessment* ~~has~~ have demonstrated they are no longer needed.

Veterinary Services should coordinate their movement control actions with other relevant authorities such as local authorities~~,~~ and law enforcement agencies, and with communication media, as well as with the *Veterinary Services* of neighbouring countries in the case of transboundary animal diseases.

Article 4.Y.8.

Biosecurity

In order to avoid the spread of the pathogenic agent outside of the affected *establishments* or *infected zones*, and in addition to the management measures described in Articles 4.Y.5. to 4.Y.7., *biosecurity* should be applied, in particular measures to avoid the contamination of people's clothes and shoes, of equipment, of *vehicles/vessels*, ~~and~~ of the environment or anything capable of acting as a fomite.

When *disinfection* is applied, specific disinfectant solutions should be used for footbaths or disinfectant baths for vehicles' wheels. Single use material and clothes or material and clothes that can be effectively cleaned and disinfected should be used for the handling of *animals* and animal products~~;~~. Protection of premises from *wildlife* and other unwanted animals should be ensured~~;~~. Wastes, waste-water and other effluents should be collected and treated appropriately.

Article 4.Y.9.

Vaccination ~~and treatment~~

Vaccination in response to a contagious disease *outbreak* should be conducted in accordance with Chapter 4.X.

EU comment

With reference to the comment above, please replace the word "contagious" with "infectious" in the sentence above.

Vaccination in response to an *outbreak* requires previous planning to identify potential sources of vaccine, including vaccine banks, and to plan the possible strategies for application, such as emergency *vaccination* or ring *vaccination*.

The properties of the vaccines should be well understood, especially the level of protection against *infection* or disease and the possibility to differentiate the immune response produced by the vaccine from that produced by *infection* with the pathogenic agent.

EU comment

The EU notes that its previous suggestion to replace the word "produced" with "elicited" has not been accepted. Indeed, the term "elicited" is mostly used in relation to antibody responses. As regards immune responses, the term usually used is "induced". We would thus suggest replacing the term "produced" with "induced" in the paragraph above.

Although *vaccination* may hide ongoing *infection* or agent transmission, it can be used to decrease the shedding of the pathogenic agent, hence reduce the reproductive rate of the *infection*. In particular, when stamping-out is not feasible, *vaccination* can be used to reduce the ~~circulation~~ *prevalence* of the *infection* until its level~~s are~~ is low enough for the implementation of another strategies such as a test and cull strategy.

EU comment

In the paragraph above, please replace "strategies" with "strategy" (grammar).

Furthermore, the EU suggests adding the following sentence at the end of the paragraph above:

"Vaccination can also be used to reduce the impact of an infection by reducing clinical signs or economic losses."

Whenever *vaccination* is to be used as a tool to control *outbreaks* or spread of disease, the control plan should ~~include~~ consider an exit strategy, i.e. when and how to stop the *vaccination* or whether *vaccination* should become routine.

Article 4.Y.10.

Zoning

The *Veterinary Authority* should use the tool of zoning in accordance with Chapter 4.3.

The use of zoning for disease control and eradication is inherently linked with measures of *killing* or *slaughter*, movement control, *vaccination* and *surveillance*, which apply differently according to the *zones*. In particular,

efforts should be concentrated on those parts of a territory affected by the disease, to prevent the spread of the pathogenic agent and to preserve the status of the parts of the territory not affected by the disease.

Zones established ~~defined~~ in response to *outbreaks* of *notifiable diseases* or *emerging diseases* ~~or *listed diseases*~~ ~~may be~~ are usually *infected zones*, *containment zones* and *protection zones*~~,~~ ~~and *containment zones*~~. However, ~~or~~ other types of *zones*, ~~e.g.~~ such as *zones* of intensified *surveillance*~~,~~ or *zones* of intensified *vaccination* can also be used.

Article 4.Y.11.

Communication in outbreak management

For the best implementation of disease control measures, *Veterinary Services* should ensure good communication with all concerned stakeholders, including the general public. This should be carried out, among others, through awareness campaigns targeted at breeders, *veterinarians*, *veterinary paraprofessionals*, local authorities, the media, consumers and general public.

Veterinary Services should communicate before, during and after *outbreaks*, in accordance with Chapter 3.3.

Article 4.Y.12.

Specific post-control surveillance

Specific *surveillance* should be applied in order to monitor the effectiveness of the *official control programme* ~~plan~~, and assess the status of the remaining *animal populations* in the different *zones* established by the *Veterinary Services*.

The results of this *surveillance* should be used to reassess the measures applied, including reshaping of the *zones* and re-evaluation of the culling or *vaccination* strategies, and for the eventual recovery of free status, if possible.

This *surveillance* should be conducted in accordance with Chapter 1.4. and with the relevant articles of the *listed disease*-specific chapters.

Article 4.Y.13.

Further outbreak investigation, monitoring, evaluation and review

In order to gather information required for any management information system, *Veterinary Services* should conduct an in-depth epidemiological investigation of each *outbreak* to build up a detailed first-hand, field-based knowledge of how the disease is transmitted, and inform further disease control plans. This requires staff who have been trained in the way to conduct it and the use of the standardised data collection forms.

Information gathered and experience gained should be used to monitor, evaluate and review ~~disease~~ *official control programmes* ~~plans~~.

Annex 35

SECTION 4.

~~GENERAL RECOMMENDATIONS:~~ DISEASE PREVENTION AND CONTROL

CHAPTER 4.Z.

INTRODUCTION TO RECOMMENDATIONS FOR DISEASE PREVENTION AND CONTROL

EU comment

The EU thanks the OIE and supports this new chapter.

Article 4.Z.1.

Effective prevention and control of ~~contagious~~ infectious animal diseases, including zoonoses, is a central mandate of the *Veterinary Services* of each Member Country.

~~From the extensive experience in combatting contagious animal diseases,~~ *Veterinary Services* around the world, supported by significant progress in veterinary science, have developed and improved a number of tools to prevent, control and ~~sometimes~~ even eradicate ~~them~~ infectious animal diseases.

The following chapters of this section describe these tools and the ~~different aspects of~~ recommendations for disease prevention and control ~~to~~ that should be implemented by the *Veterinary Services*.

To effectively prevent ~~effectively~~ introduction and transmission of ~~contagious~~ infectious animal diseases while minimising potential negative impacts of *sanitary measures*, *Veterinary Services* should consider ~~devising a set of~~ developing measures ~~selected from~~ based on the recommendations ~~described~~ in this section, taking into account various factors including their impact on trade, animal welfare, public health and environment. In parallel with disease-specific *sanitary measures*, *Veterinary Services* should ~~take into account~~ consider relevant commodity-based *sanitary measures*.

Furthermore, although the general principles covering the measures described in this section are applicable to multiple diseases, *Veterinary Services* should adapt them to their circumstances, because characteristics of the pathogenic agents and the situations in which they occur differ between diseases and between countries ~~are different disease by disease and country by country~~. To this end, recommendations in this section should be read in conjunction with *listed disease*-specific recommendations in Sections 8 to 15.

Veterinary Services should ensure that any prevention and control programme be proportionate to the *risk*, practical and feasible within the national context and be based on *risk analysis*.

Prerequisites for ~~devising~~ developing such programmes ~~may~~ include:

– quality *Veterinary Services* including legislative framework, ~~and~~ *laboratory* capacity and adequate and committed funding;
– appropriate education to secure *veterinarians* and *veterinary paraprofessionals*;
– close link with research institutions;
– effective awareness of, and active cooperation with, private stakeholders;
– public-private partnerships;
– regional cooperation among *Veterinary Authorities* on transboundary animal diseases.

Annex 37

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

EU comment

The EU thanks the OIE and supports the proposed changes to this chapter.

[...]

Article 15.1.1bis.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any ASF related conditions, regardless of the ASF status of the *exporting country* or *zone*:

1) ~~canned~~ *meat* in a hermetically sealed container with a Fo value of 3.00 or more;

2) gelatine.

Other *commodities* of pigs should be traded in accordance with the relevant articles of this chapter.

Article 15.1.2.

General criteria for the determination of the ASF status of a country, zone or compartment

1) ASF is a *notifiable disease* in the entire country, and all suids showing clinical signs suggestive of ASF are subjected to appropriate field and *laboratory* investigations;

2) an ongoing awareness programme is in place to encourage reporting of all suids showing signs suggestive of ASF;

3) the *Veterinary Authority* has current knowledge of, and authority over, all domestic and *captive wild* pig *herds* in the country, *zone* or *compartment*;

4) the *Veterinary Authority* has current knowledge of the species of *wild* and *feral* pigs and African *wild* suids present, their distribution and habitat in the country or *zone*;

5) for domestic and *captive wild* pigs, an appropriate *surveillance* programme in accordance with Articles15.1.27. to 15.1.30. and 15.1.32. is in place;

6) for *wild* and *feral* pigs, and for African *wild* suids, if present in the country or *zone*, a *surveillance* programme is in place in accordance with Article 15.1.31., considering the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig and African *wild* suid populations and an assessment of the likelihood of ASF spread including taking into account the presence of *Ornithodoros* ticks where relevant;

7) the domestic and *captive wild* pig populations are separated by appropriate *biosecurity*, effectively implemented and supervised, from the *wild* and *feral* pig and African *wild* suid populations, based on the assessed likelihood of spread within the *wild* and *feral* pig and African *wild* suid populations, and *surveillance* in accordance with Article 15.1.31.; they are also protected from *Ornithodoros* ticks where relevant.

~~*Commodities* of domestic or *captive wild* pigs can be traded safely in accordance with the relevant articles of this chapter from countries complying with the provisions of this article, even if they notify *infection* with ASFV in *wild* or *feral* pigs or African *wild* suids.~~

Article 15.1.3.

Country or zone free from ASF

1. Historical freedom

A country or *zone* may be considered historically free from ASF without pathogen-specific *surveillance* if the provisions of point 1 *a)* of Article 1.4.6. are complied with~~.~~ and pig *commodities* are imported in accordance with Articles 15.1.7. to 15.1.20.

2. Freedom in all suids

A country or *zone* which does not meet the conditions of point 1) above may be considered free from ASF in all suids when it complies with all the criteria of Article 15.1.2. and when:

a) *surveillance* in accordance with Articles 15.1.27. to 15.1.32. has been in place for the past three years;

b) there has been no *case* of *infection* with ASFV during the past three years; this period can be reduced to 12 months when the *surveillance* has demonstrated no evidence of presence or involvement of *Ornithodoros* ticks;

c) pig *commodities* are imported in accordance with Articles 15.1.7. to 15.1.20.

3. Freedom in domestic and captive wild pigs

A country or *zone* which does not meet the conditions of point 1) or 2) above may be considered free from ASF in domestic and *captive wild* pigs when it complies with all the criteria of Article 15.1.2. and when:

a) *surveillance* in accordance with Articles 15.1.27. to 15.1.32. has been in place for the past three years;

b) there has been no *case* of *infection* with ASFV in domestic or *captive wild* pigs during the past three years; this period can be reduced to 12 months when the *surveillance* has demonstrated no evidence of presence or involvement of *Ornithodoros* ticks;

c) pigs and pig *commodities* are imported in accordance with Articles 15.1.7. to 15.1.20.

Commodities of domestic or *captive wild* pigs can be traded safely in accordance with the relevant articles of this chapter from countries free from ASF in domestic and *captive wild* pigs, even if they notify *infection* with ASFV in *wild* or *feral* pigs or African *wild* suids.

[...]

Article 15.1.22.

Procedures for the inactivation of ASFV in meat

For the inactivation of ASFV in *meat*, one of the following procedures should be used:

1. Heat treatment

Meat should be subjected to ~~one of the following:~~

~~*a)* heat treatment in a hermetically sealed container with a Fo value of 3.00 or more; or~~

~~*b)*~~ heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Dry cured pig meat

Meat should be cured with salt and dried for a minimum of six months.

[...]

Annex 38

GLOSSARY PART B

EU comment
The EU thanks the OIE and supports the proposed changes to the Glossary.

EARLY WARNING SYSTEM

means a system for the timely detection, ~~identification and~~ reporting and communication of an incursion or emergence of diseases, *infections* or *infestations* in a country, *zone* or *compartment*.

SANITARY MEASURE

means a measure, such as those described in various chapters of the *Terrestrial Code*, ~~destined~~ designed to protect animal or human health or life within the whole territory or a *zone* of the Member Country from *risks* arising from the entry, establishment ~~and/~~or spread of a *hazard*.

Annex 39b

CHAPTER 1.6.

PROCEDURES FOR PUBLICATION OF A SELF-DECLARATION OF DISEASE FREEDOM, RECOGNITION OF AN OFFICIAL DISEASE STATUS AND ~~FOR~~ ENDORSEMENT OF AN OFFICIAL CONTROL PROGRAMME ~~RECOGNITION~~ BY THE OIE

EU comment

The EU in general supports the proposed changes to this chapter.

Comments are inserted in the text below.

Article 1.6.1.

~~General principles~~ Publication by the OIE of a self-declaration of disease freedom by a Member Country

A Member Country~~ries~~ may ~~wish to~~ make a self-declaration ~~as to~~ of ~~the~~ freedom of a country, *zone* or *compartment* from an OIE *listed disease* or another animal disease. The Member Country may inform the OIE of the ~~its~~ claimed status ~~and the OIE may publish the claim. Publication does not imply endorsement of the claim.~~ and request that the OIE publish the self-declaration for information of OIE Member Countries.

A Member Country requesting the publication of a self-declaration should follow the Standard Operating Procedure[1] for submission of a self-declaration of disease freedom and provide documented information on its compliance with the relevant chapters of the *Terrestrial Code*, including:

EU comment

As the self-declaration can also pertain to a non-listed disease or for a listed disease for which a disease-specific Code chapter does not exist, or for a listed disease for which the disease-specific chapter does not define country or zone freedom, the EU suggests inserting the words ", where applicable," after "Terrestrial Code" in the paragraph above.

Furthermore, as the URLs of webpages change over time, we in principle suggest not including specific URLs as footnotes in the OIE Code. However, in general as regards OIE guidance documents that are published on the OIE website and that are referred to in the Code, like these SOPs on self-declaration, the EU would suggest that they be submitted for member country comment before being published on the OIE website.

- evidence that the disease is a *notifiable disease* in the entire country;
- history of absence or eradication of the disease in the country, *zone* or *compartment;*
- *surveillance* and early warning system for all relevant species in the country, *zone* or *compartment;*

[1] http://www.oie.int/en/animal-health-in-the-world/self-declared-disease-status/

– measures implemented to maintain freedom in the country, *zone* or *compartment.*

The self-declaration may be published only after all the information provided has been received and an administrative and technical screening has been performed by the OIE. Publication does not imply endorsement of the claim of freedom by the OIE and does not reflect the official opinion of the OIE. Responsibility for the accuracy of the information contained in a self-declaration lies entirely with the OIE Delegate of the Member Country concerned.

The OIE does not publish self-declarations of freedom ~~for~~ from ~~bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF)~~ diseases listed under point 1) of Article 1.6.1bis.

EU comment

In the paragraph above, it is not entirely correct to refer to "freedom from" diseases listed under point 1) of Article 1.6.1bis, as that list includes BSE for which there is official disease risk categorisation instead of official disease free status. We therefore suggest replacing the words "of freedom from" with "in relation to" or "as regards".

Article 1.6.1bis.

Official recognition by the OIE

Member Countries may request:

EU comment

In line with the amendments proposed in Article 1.6.1., the EU suggests amending the current Article accordingly, as follows:

"A member country may request: [...]".

(This change should be made throughout the Article where relevant.)

1. Official recognition of status by the OIE of ~~as to~~:

   a) freedom of a country or *zone* from African horse sickness;

   b) risk status of a country or *zone* with regard to bovine spongiform encephalopathy;

   c) freedom of a country or *zone* from classical swine fever;

   d) freedom of a country or *zone* from contagious bovine pleuropneumonia;

   e) freedom of a country or *zone* from foot and mouth disease, with or without *vaccination*;

   f) freedom of a country or *zone* from peste des petits ruminants.

EU comment

As regards possible discrepancies between the wording in points a), c), d), e) and f) above and the new Chapters 1.7., 1.9., 1.10., 1.11. and 1.12. as well as the respective disease-specific chapters (i.e. freedom from [disease] vs. freedom from [pathogenic agent]), reference is made to the EU comment included in the top box of Annex 25.

Furthermore, as regards "freedom from FMD", we note that draft Chapter 1.11. refers to "[...] where vaccination is not practised" / "[...] where vaccination is practised", as opposed to "with or without *vaccination*" as used in point e) above. Preferably, a uniform terminology (incl. use of italics) should be used.

2. Endorsement by the OIE of:

a) an *official control programme* for contagious bovine pleuropneumonia;

b) an *official control programme* for foot and mouth disease;

c) an *official control programme* for peste des petits ruminants.

~~1) the risk status of a country or *zone* with regard to BSE;~~

~~2) the freedom of a country or *zone* from FMD, with or without *vaccination*;~~

~~3) the freedom of a country or *zone* from CBPP;~~

~~4) the freedom of a country or *zone* from AHS;~~

~~5) the freedom of a country or *zone* from PPR;~~

~~6) the freedom of a country or *zone* from CSF.~~

The OIE does not grant official recognition or endorsement of an *official control programme* for ~~other~~ *diseases* other than those listed under points 1 and 2 above.

~~In these cases,~~ Member Countries should present documentation setting out the compliance of their *Veterinary Services* with ~~the applicant country or *zone* with~~ the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant *disease* chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status or endorsement by the OIE of an *official control programme*, the Member Country should submit to the OIE ~~Status Department~~ a dossier providing the information requested in the following Chapters (as appropriate): 1.7., 1.8., 1.9., 1.10., 1.11. or 1.12.~~in Articles 1.6.5. (for BSE), 1.6.6. (for FMD), 1.6.7. (for CBPP), 1.6.8. (for AHS), 1.6.9. (for PPR) or 1.6.10. (for CSF).~~

EU comment

As also proposed in Annex 24, the EU suggests inserting back the parenthesis after the chapter numbers, as this improves clarity and readability, as follows:

"[...] in the following Chapters (as appropriate): 1.7. (for AHS), 1.8. (for BSE), 1.9. (for CSF), 1.10. (for CBPP), 1.11. (for FMD) or 1.12. (for PPR).".

The OIE framework for the official recognition and maintenance of disease status is described in Resolution No. XV (administrative procedures) and Resolution No. XVI (financial obligations) adopted during the 83rd General Session in May 2015, as well as in the Standard Operating Procedures available on the OIE website[2].

The country or the *zone*, or the country having its *official control programme* endorsed will be included in the relevant list only after the evidence submitted, based on the provisions of Chapters 1.7. to 1.12., has been adopted by the World Assembly of OIE Delegates.

Retention on the list requires that the information in relevant chapters be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

EU comment

To improve readability, we suggest slightly amending the sentence above as follows:

"Retention on the list requires that the information in relevant chapters be re-submitted annually and that changes in the epidemiological situation or other significant events ~~should~~ be reported to the OIE in accordance with the requirements in Chapter 1.1."

[2] http://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/

~~Article 1.6.2.~~

~~**Endorsement by the OIE of an official control programme for FMD**~~

~~Member Countries may wish to request an endorsement by the OIE of their *official control programme* for FMD.~~

~~When requesting endorsement by the OIE of an *official control programme* for FMD, the Member Country should submit to the OIE Status Department a dossier providing the information requested in Article 1.6.11.~~

~~Article 1.6.3.~~

~~**Endorsement by the OIE of an official control programme for PPR**~~

~~Member Countries may wish to request an endorsement by the OIE of their *official control programme* for PPR.~~

~~When requesting endorsement by the OIE of an *official control programme* for PPR, the Member Country should submit to the OIE Status Department a dossier providing the information requested in Article 1.6.12.~~

~~Article 1.6.4.~~

~~**Endorsement by the OIE of an official control programme for CBPP**~~

~~Member Countries may wish to request an endorsement by the OIE of their *official control programme* for CBPP.~~

~~When requesting endorsement by the OIE of an *official control programme* for CBPP, the Member Country should submit to the OIE Status Department a dossier providing the information requested in Article 1.6.13.~~

[…]

Annex 40b

CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

EU comment

The EU in general supports the proposed changes to this chapter.

Comments are inserted in the text below.

Article 8.14.1.

General provisions

Rabies is a disease caused by neurotropic viruses of the genus *Lyssavirus* in the family *Rhabdoviridae* of the order *Mononegavirales* and is transmissible to all mammals. Members of the orders *Carnivora* and *Chiroptera* are considered to be the main reservoir hosts.

EU comment

The EU suggests replacing the second sentence of the paragraph above by the following, which is more precise and detailed, and is taken from the ICTV:

"Bats (order *Chiroptera*) are the principal reservoir hosts for most lyssaviruses, whereas carnivores (order *Carnivora*), as well as bats, maintain circulation of rabies virus."

Reference:

https://talk.ictvonline.org/ictv-reports/ictv_online_report/negative-sense-rna-viruses/mononegavirales/w/rhabdoviridae/795/genus-lyssavirus.

Rabies virus, the *Lyssavirus* formerly referred to as 'classical rabies virus, genotype-1', is found worldwide, and is responsible for the vast majority of reported animal and human rabies cases. The most common source of exposure of humans to rabies virus is the dog.

EU comment

The first part of the paragraph above as drafted could be misunderstood. For reasons of clarity, the EU suggests amending the wording as follows (reference is made to the relevant wording in Chapter 2.1.17. of the *Terrestrial Manual*, version adopted in May 2018):

"Rabies virus, the taxonomic prototype species in the *Lyssavirus* genus formerly referred to as [...]".

Other lyssavirus species have more restricted geographical and host range, with the majority having been isolated from bats, with limited public and animal health implications.

EU comment

In the beginning of the sentence above, for reasons of consistency and to avoid confusion, we suggest either referring to "Other lyssaviruses" or to "Other *Lyssavirus* species".

Furthermore, for better readability, we suggest inserting the word "a" before "more restricted".

The *incubation period* for rabies is highly variable, and the majority of *cases* will develop disease within six months of exposure.

The *infective period* for rabies virus is variable and can start before the onset of clinical signs. In dogs, cats and ferrets virus shedding can start up to 10 days before the onset of the first clinical signs and through death.

EU comment

It is not clear what is meant by "and through death" at the end of the sentence above (shedding can start through death? without onset of clinical signs?).

Official control programmes to reduce the economic and public health burden of the disease are recommended even in those countries where only haematophagous bat-mediated rabies or wild carnivore-mediated rabies are present.

The aim of this chapter is to mitigate the risk of rabies to human and animal health and to prevent the international spread of rabies virus.

For the purposes of the *Terrestrial Code*:

~~1)~~ ~~rabies is a *disease* caused by one member of the *Lyssavirus* genus: the *Rabies virus* (formerly referred to as classical rabies virus, gentype 1); all mammals are susceptible to *infection*;~~

– a *case* is any *animal* infected with the rabies virus ~~species~~;

– dog-mediated rabies is defined as any *infection* with rabies virus maintained in the dog population independently of other animal species, as determined by epidemiological studies;

EU comment

The draftting of the sentence above is a bit unclear. Indeed, "any infection [...] maintained in the dog population" could be misunderstood as referring to infection in dogs only (e.g. a case of rabies in a goat, even if transmitted by a dog, could be misunderstood as not falling under the definition of dog-mediated rabies). Furthermore, onward transmission of such viruses, even if not via a dog (e.g. from a goat infected by a dog to another goat), should still be considered as dog-mediated, as the relevant aspect here is that the dog is the reservoir species of the dog-mediated rabies virus.

The EU therefore suggests the following wording:

"- dog-mediated rabies is defined as any infection in an animal with a rabies virus strain maintained in the dog population as the reservoir species independently of, but with occasional spillovers to, other animal species, as determined by epidemiological studies, irrespective of whether the virus was transmitted by a dog;"

– the *incubation period* shall be six months.

~~Globally, the most common source of exposure of humans to rabies virus is the dog. Other mammals, particularly members of the Orders Carnivora and Chiroptera, also present a risk.~~

~~The aim of this chapter is to mitigate the risk of rabies to human and animal health and to prevent the international spread of the disease~~.

~~For the purposes of the *Terrestrial Code*, a country that does not fulfil the requirements in Article 8.14.3. is considered to be infected with Rabies virus.~~

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

~~Article 8.14.2.~~

~~**Control of rabies in dogs**~~

~~In order to minimise public health risks due to rabies, and eventually eradicate rabies in dogs, *Veterinary Authorities* should implement the following:~~

~~1) rabies should be notifiable in the whole country and any change in the epidemiological situation or relevant events should be reported in accordance with Chapter 1.1.;~~

~~2) an effective system of *disease surveillance* in accordance with Chapter 1.4. should be in operation, with a minimum requirement being an ongoing early detection programme to ensure investigation and reporting of suspected cases of rabies in animals;~~

~~3) specific regulatory measures for the prevention and control of rabies should be implemented consistent with the recommendations in the *Terrestrial Code*, including *vaccination*, identification and effective procedures for the importation of dogs, cats and ferrets;~~

~~4) a programme for the management of *stray dog* populations consistent with Chapter 7.7. should be implemented and maintained.~~

Article 8.14.2~~3~~.

~~**Rabies free** **C**~~**ountry ~~or~~ zone free from infection with rabies virus**

1) A country ~~or~~ *zone* may be considered free ~~from~~ *infection* with rabies virus when:

a~~1~~) the disease is notifiable and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;

b) all susceptible animals showing clinical signs suggestive of rabies are subjected to appropriate field and laboratory investigations;

EU comment

Point b) above is a component of the surveillance system mentioned in point c) below. The EU therefore suggests either merging both points, or moving point b) after point c).

c~~2~~*)* an ongoing system of ~~*disease*~~ *surveillance* in accordance with Chapter 1.4. and Article 8.14.9. has been in ~~operation~~ place for the past ~~two years~~ 24 months, with a minimum requirement being an ~~ongoing~~ early warning system ~~detection programme~~ to ensure investigation and reporting of animals suspected of being infected~~rabies suspect animals~~;

EU comment

For reasons of clarity, the EU suggests adding the words "in the country of zone concerned" at the end of point c) above.

d~~3~~*)* regulatory measures for the prevention of rabies are implemented ~~consistent~~ in accordance with the relevant recommendations in the *Terrestrial Code* including Articles 8.14.4. to 8.14.7.~~, including for the importation of animal~~;

e~~4~~*)* no *case* of indigenously acquired *infection* with rabies virus ~~*infection*~~ has been confirmed during the past ~~two years~~ 24 months~~;~~.

~~5) no imported *case* in the Orders Carnivora or Chiroptera has been confirmed outside a *quarantine station* for the past six months.~~

EU comment

The EU queries why the above point has been deleted. Indeed, an imported case of infection with rabies virus in a carnivore or bat that is not contained in a quarantine station should alter or at least suspend the free status of the country or zone.

Indeed, in such cases, contact to indigenous susceptible animals and thus onward spread may have occurred, therefore surveillance and epidemiological investigations should be intensified to ensure absence of secondary cases, at least during a certain period, e.g. the next 6 months.

Rather than deleting point 5) above, it could be drafted in a more flexible way with the idea that "if an imported case has been confirmed, enhanced surveillance during the next 6 months and epidemiological investigations have ruled out the possibility of secondary cases". It should then also be well related to point e) which requires no indigeneous case during the past 24 months.

2) Preventive vaccination of at-risk animals does not affect the rabies free status.

3) An imported human case of rabies does not affect the rabies free status.

Article 8.14.2bis.

Country or zone infected with rabies virus

A country or *zone* that does not fulfil the requirements of Article 8.14.2. is considered to be infected with rabies virus.

Article 8.14.2ter.

Country or zone free from dog-mediated rabies

1) A country or *zone* may be considered free from dog-mediated rabies when:

a) dog-mediated rabies is a *notifiable disease* and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;

b) an ongoing system of *surveillance* in accordance with Chapter 1.4. and Article 8.14.9. has been in place for the past 24 months, with a minimum requirement being an *early warning system* to ensure control, investigation and reporting of animals suspected of *infection* with rabies virus;

EU comment

For consistency with point 1 c) of Article 8.14.2., the term "early warning system" should not be italisised in point b) above, as that definition was not yet adopted and included in the Glossary.

c) regulatory measures for the prevention of rabies are implemented in accordance with the relevant recommendations in the *Terrestrial Code* and Article 8.14.9.;

EU comment

The EU notes that Article 8.14.9. pertains to surveillance, not prevention. Furthermore, surveillance is already referred to in point b). It would thus be more appropriate to add more specific text on what "regulatory" prevention measures are expected (e.g. with

reference to rules on the introduction of animals and, as necessary, programmes for the management of stray dog populations and the compulsory vaccination of owned dogs).

d) no *case* of indigenously acquired dog-mediated rabies has occurred during the past 24 months;

e) a programme for the management of *stray dog* populations is implemented in accordance with Chapter 7.7.

EU comment

The EU queries why no minimum time requirement is included in point e) above. Indeed, this way, a country or zone could in theory declare freedom one day after starting implementation of a stray dog populations management programme.

Furthermore, such programme should preferably be maintained after freedom declaration, for prevention purposes. Therefore, the words "and maintained" should be inserted after "is implemented" (reference is made to former point 4) of Article 8.14.2.).

Finally, with reference to the EU comment above, point e) could be merged with point c).

2) The following do not affect the status of a country or *zone* free from dog-mediated rabies:

– preventive vaccination;

– presence of rabies virus in *wildlife*;

EU comment

For reasons of clarity, the EU suggests inserting the words "except stray dogs" after "*wildlife*". Indeed, the Glossary definition of wildlife includes feral animals, i.e. stray dogs.

– imported human *cases* of rabies.

Article 8.14.34.

Recommendations for importation of domestic and captive wild mammals from countries or zones free from infection with rabies virus ~~free countries~~

~~For domestic mammals, and captive wild mammals~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) and either:

a) were kept since birth or at least six months prior to shipment in a free country or *zone*; or

b) were imported in accordance with ~~the regulations stipulated in~~ Articles 8.14.56., 8.14.67., or 8.14.78.~~ or 8.14.9.~~

Article 8.14.45.

Recommendations for importation of wild and feral mammals from ~~rabies free~~

countries or zones free from infection with rabies virus

~~For wild mammals~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) and either:

a) have been captured at a distance that precludes any contact with animals in an infected country. The distance should be defined in accordance with the biology of the species exported, including home range and long distance movements; or

b) have been kept in captivity for the six months prior to shipment in a country or *zone* free from *infection* with rabies virus ~~free country~~.

Article 8.14.5~~6~~.

Recommendations for importation of dogs, cats and ferrets from countries or zones ~~considered~~ infected with rabies virus

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11. attesting that the animals:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) were permanently identified and their identification number stated in the *certificate*;

3) and either:

a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer. The vaccine should have been produced and used in accordance with the *Terrestrial Manual* and were subjected not less than 1 ~~3~~ month~~s~~ and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5IU/ml;

EU comment

Point 3 a) above does not read very well, as it refers to "the animals:" as indicated in the chapeau sentence, but then includes three requirements, only two of which relate to "the animals", whereas one relates to the vaccine used.

In addition, vaccination in accordance with the manufacturers recommendations may not be sufficent in all circumstances. Indeed, in an eradication programme, the vaccination may be carried out more frequently than required according to the marketing authorisation of a particilar commercial vaccine, for which the instruction on frequency very often is not the same in all countries.

Furthermore, the EU does not support the change in timing in point a) above. Indeed, 3 months is the minimum time that should be kept in this context.

In fact, the timing of the antibody test (or rather the blood sampling for the antibody test) should not only be linked to the day of shipment, but also to the day of vaccination. Indeed, it is the waiting time between vaccination and shipment that is crucial, not so much the timing of sampling for the antibody test in relation to the time of shipment.

In the EU, blood sampling for the antibody test is required not earlier than 1 month

after vaccination (to allow for a sufficient titer to mount), and shipment is allowed not earlier than 3 months after the sampling, i.e. at the earliest 4 months after vaccination (this waiting time is to ensure that the antibodies were indeed elicited by the vaccination and not by a possible natural infection; 4 months will reasonably allow onset of rabies symptoms in case the animal was incubating rabies at the time of vaccination or was naturally infected shortly after vaccination i.e. prior to onset of protective immunity).

For background information and scientific rationale for these EU rules, reference is made to a pertinent opinion of the European Food Safety Authority published on 15 February 2007 and available here: https://www.efsa.europa.eu/en/efsajournal/pub/436.

Finally, in the EU, in case of travel of pet animals, the rabies antibody titration test does not have to be renewed following a satisfactory result, provided that the dog, cat or ferret is revaccinated within the period of validity of the previous vaccination and this is properly documented. Therefore, in such situations, it is not necessary to repeat the antibody test in case such an animal would be imported again after traveling back to an infected country or zone. However, as the OIE Code article above concerns the importation of dogs, cats and ferrets, i.e. the commercial movement of these animals, it is not clear whether such a derogation would be necessary in the OIE Code, as the animals concerned would be imported only once.

For the reasons stated above, the EU suggests rewording point 3 a) as follows:

"were vaccinated or revaccinated in accordance with and at least as frequently as required in the recommendations of the manufacturer~~. The~~ with a vaccine ~~should have~~ that has been produced and used in accordance with the *Terrestrial Manual*, and were subjected not less than 1 month and not more than 12 months after vaccination and not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5IU/ml;"

OR

b) were kept in a *quarantine station* for six months prior to export.

Article 8.14.6~~7~~.

Recommendations for importation of other susceptible animals ~~domestic ruminants, equids, camelids and suids~~ from countries or zones ~~considered~~ infected with rabies virus

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of rabies on the day prior to or on the day of shipment;

EU comment

For consistency with Articles 8.14.5. and 8.14.7., we suggest deleting the word "on" before "the day prior to or [...]" in point 1) above.

~~2)~~ ~~were permanently identified and the identification number stated in the *certificate*;~~

2~~3~~) either ~~EITHER~~

a) were kept for the 6 months prior to shipment in an *establishment* where there has been no *case ~~of rabies~~* for at least 12 months prior to shipment;

OR

b) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer. The vaccine was produced and used in accordance with the *Terrestrial Manual*~~.~~;

EU comment

The EU is of the opinion that for certain species (e.g. carnivores and bats), testing should also be required, (same as in point 3 a) of Article 8.14.5.). Indeed, it is not clear why the requirements for other carnivores should be more lenient than for dogs, cats and ferrets.

3) if domestic animals, were permanently identified and the identification number stated in the *certificate.*

Article 8.14.7~~8~~.

Recommendations for importation of laboratory animals from countries or zones ~~considered~~ infected with rabies virus

~~For rodents and lagomorphs born and reared in a biosecure facility~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of rabies the day prior to or on the day of shipment;

2) were born and kept since birth in a biosecure facility as described in the *Terrestrial Manual* Chapter 1.1.1 and where there has been no *case* ~~of rabies~~ for at least 12 months prior to shipment.

EU comment

The EU suggests inserting the word "susceptible" before "laboratory animals". Indeed, only certain species of laboratory animals are susceptible to rabies, while many are not (e.g. insects, reptiles, birds, etc.).

Furthermore, as the stucture of the Manual including the numbering of its chapters may change with time, the EU suggest referring to the title of specific Manual chapters, or simply to the Manual in general, rather than to a particular chapter number.

Finally, we suggest moving the article above before Article 8.14.6. Indeed, as Article 8.14.6. refers to "other susceptible animals", there may be confusion if the article pertaining to laboratory animals is placed afterwards (as certain laboratory animals would be included in "other susceptible animals").

Article 8.14.8.

OIE endorsed official control programme for dog-mediated rabies

EU comment

While in general supporting this new article, the EU queries whether, once adopted, it will necessitate to include a new chapter in Section 1 of the Code, with the relevant questionnaire. In that case, the reference to Article 1.6.Xbis in the paragraph after point 7) below would become obsolete.

The overall objective of an OIE endorsed *official control programme* for dog-mediated rabies is for Member Countries to progressively improve their dog-mediated rabies situation and eventually be able to make a self-declaration in accordance with Chapter 1.6. as a country free from dog-mediated rabies. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations* only.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for dog-mediated rabies when they have implemented measures in accordance with this article.

For its *official control programme* for dog-mediated rabies to be endorsed by the OIE, the Member Country should:

1) have a record of regular and prompt animal *disease* reporting in accordance with Chapter 1.1.;

2) submit documented evidence of the capacity of the *Veterinary Services* to control dog-mediated rabies. This evidence may be provided using data generated by the OIE PVS Pathway;

EU comment

To avoid any misunderstandings as to the nature of the OIE PVS Pathway, the EU suggests inserting the word "voluntary" before "OIE PVS Pathway".

3) submit a detailed plan of the programme to control and eventually eradicate dog-mediated rabies in the country or *zone* including:

EU comment

Point 3) above is inconsistent with the chapeau paragraph of this article, as well as with the rest of the article. Indeed, while point 3) mentions the option of eradicating dog-mediated rabies in a zone, the chapeau seems to exclude this ("[...] in accordance with Chapter 1.6. as a country free from dog-mediated rabies"). Furthermore, point c) below explicitly states that the programme is to be applicable to the entire country.

a) the timeline;

b) the performance indicators for assessing the effectiveness of the control measures to be implemented;

c) documentation indicating that the *official control programme* for dog-mediated rabies is applicable to the entire country;

4) submit a dossier on dog-mediated rabies in the country describing the following:

a) the general epidemiology in the country highlighting the current knowledge and gaps in knowledge and the progress that has been made in controlling dog-mediated rabies;

b) the measures implemented to prevent introduction of *infection*;

bbis) the rapid detection of, and response to, dog-mediated rabies *cases,* to reduce the *incidence* and to eliminate transmission in at least one *zone* in the country;

c) dog population management including *stray dog* control;

EU comment

The EU suggests including a reference to Chapter 7.7. in point c) above.

d) collaboration agreements or programmes with other *Competent Authorities* such as those responsible for public health and management of *wild* and *feral animals*;

5) submit evidence that *surveillance* of dog-mediated rabies is in place:

a) by taking into account provisions in Chapter 1.4. and Article 8.14.9.;

b) by having diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis to support epidemiological investigation;

6) where *vaccination* is practised as part of the *official control programme* for dog-mediated rabies, provide:

a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory and in accordance with the *Terrestrial Manual*;

b) detailed information on *vaccination* campaigns, in particular on:

i) target *populations*;

ii) monitoring of *vaccination* coverage;

iii) technical specifications of the vaccines used and description of the regulatory procedures in place;

7) provide preparedness and contingency plans.

The Member Country's *official control programme* for dog-mediated rabies will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.Xbis, has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the *Veterinary Services*; or

– an increase in the incidence of dog-mediated rabies that cannot be explained or addressed by the programme.

~~Article 8.14.9.~~

~~**Recommendations for importation of wildlife from countries considered infected with rabies**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals:~~

~~1) showed no clinical sign of rabies the day prior to or on the day of shipment;~~

~~2) were kept for the six months prior to shipment in an *establishment* where separation from susceptible animals was maintained and where there has been no *case* of rabies for at least 12 months prior to shipment.~~

Article 8.14.9.

General principles of surveillance

1) A Member Country should justify the *surveillance* strategy chosen in accordance with Chapter 1.4., as being adequate to detect the presence of *infection* with rabies virus, given the prevailing epidemiological situation. *Surveillance* should be under the responsibility of the *Veterinary Authority*.

For the purposes of rabies *surveillance* a suspected *case* is a susceptible animal that displays any of the following clinical signs: hypersalivation, paralysis, lethargy, abnormal aggression, abnormal vocalisation.

EU comment

The EU suggests adding "<u>any change in behaviour followed by death within 10 days</u>" at the end of the paragraph above. Indeed, rabies symptoms are not always clear, and are not limited to what is proposed in the paragraph above (which is an exhaustive list).

Furthermore, animals (especially carnivores and bats) found dead are recognised as an important source of information for rabies surveillance and should also be included.

In particular, Member Countries should have in place:

a) a formal and ongoing system for detecting and investigating suspected *cases*;

b) a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis;

c) a system for recording, managing and analysing diagnostic and *surveillance* data.

Rabies *surveillance* provides data that are indicators of the effectiveness of a rabies control programme and of the maintenance of freedom of *infection* with rabies virus in a country or *zone*.

2) In addition to principles in Chapter 1.4. the following are critical for rabies *surveillance*:

a) Public awareness

The *Veterinary Services* should implement programmes to raise awareness among the public, as well as *veterinary paraprofessionals*, *veterinarians* and diagnosticians, who should report promptly any *cases* or suspected *cases*.

b) Clinical surveillance

Clinical *surveillance* is a critical component of rabies *surveillance* and essential for detecting suspected *cases*. Therefore, a process should be in place and documented for the identification and investigation of suspected *cases* as well as for sample collection for laboratory diagnosis when rabies cannot be ruled out. Laboratory testing should use the recommended sampling techniques, types of samples and tests described in the *Terrestrial Manual*.

c) Sampling

Surveillance should target suspected *cases*. Probability sampling strategies are not always useful, as sampling of healthy animals (e.g. not involved in human exposure) rarely returns useful *surveillance* data.

d) Epidemiological investigation

In all situations, especially in countries or *zones* considering self-declaration of freedom, routine epidemiological investigation of *cases* and molecular characterisation of virus isolates from human and animal *cases* is encouraged. Such an investigation allows identification of sources of *infection*, their geographic origin and their epidemiological significance.

e) Cooperation with other Competent Authorities

The *Veterinary Authority* should coordinate in a timely manner with public health and other *Competent Authorities* and share information to support the decision-making process for the management of human and animal exposure.

In all regions, *Veterinary Authorities* of neighbouring countries should cooperate in the control of dog-mediated rabies.

EU comment
The last sentence above is not really specific to surveillance. The EU invites the OIE to consider moving it to the offical control programme, or even to the general provisions at the beginning of the chapter.