EUROPEAN UNION

Brussels
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Subject: **EU comments on the OIE Terrestrial Code and the OIE Aquatic Code and Manual**

Dear Director General,

Please find enclosed the comments of the European Union on Annexes 14 to 24 to the report of the February 2019 meeting of the Terrestrial Animal Health Standards Commission (Annex 1), as well as on Annexes 17 to 22 to the report of the February 2019 meeting of the Aquatic Animal Health Standards Commission (Annex 2), for consideration at their next meeting in September 2019.

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

Yours sincerely,

Dr Geronimo Brănescu CVO and OIE Delegate Romania	Dr Bernard Van Goethem Director for Crisis Management in Food, Animals and Plants European Commission, DG Health and Food Safety

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

Annexes: 2

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.

Annex 1

Annex 14

GLOSSARY

EU comment

The EU in general supports the proposed changes to the Glossary.

A comment is inserted in the text below.

EPIDEMIOLOGICAL UNIT

means a group of *animals* with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogenic agent~~.~~, ~~This may be~~ because they share a common environment ~~(e.g. *animals* in a pen)~~, or because of common management practices. Usually, ~~this~~ an *epidemiological unit* is a *herd* or a *flock*. However, ~~an *epidemiological unit*~~ it may also ~~refer to~~ be ~~groups such as~~ a group of *animals* in a pen or a group of *animals* belonging to residents of a village, or a group of *animals* sharing a communal animal handling facility or, in some circumstances, ~~to~~ a single *animal*. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogenic agent.

EU comment

The EU suggests indicating that this definition applies to domestic animals. Indeed, the examples given are not adapted to wild animals, for which defining that term would be rather challenging.

Annex 15

CHAPTER 1.1.

NOTIFICATION OF DISEASES, INFECTIONS AND INFESTATIONS, AND PROVISION OF EPIDEMIOLOGICAL INFORMATION

EU comment

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

We note however that the Code Commission seems to keep changing its mind as to the use of "disease" on the one hand, "infection and infestation" on the other, or rather "disease, infection and infestation" altogether. We would appreciate if a common line could finally be agreed and applied consistently throughout the Code.

A further comment is inserted in the text below.

Article 1.1.1.

For the purposes of the *Terrestrial Code* and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, Member Countries shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its territory or territories.

All *notifications* and all information sent by the OIE to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Authority* shall be regarded as having been sent by the country concerned.

Article 1.1.2.

1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their pathogenic agents, and to assist in achieving better worldwide control of these diseases.

2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.

3) For the purposes of this chapter, an 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given ~~disease,~~ disease, *infection* or *infestation* that is the subject of a *notification*. An event is specific to a pathogenic agent and strain, when appropriate, and includes all related *outbreaks* reported from the time of the ~~immediate~~ *notification* within 24 hours through to the final report. Reports of an event include susceptible species, number and geographical distribution of affected animals and *epidemiological units*.

EU comment

While in principle agreeing with changing "immediate notification" for "notification within 24 hours" for reasons of consistency with Article 1.1.3. and also reasons of logic, the EU suggests instead referring to both Articles 1.1.3. and 1.1.4., as follows:

"[…] from the time of the ~~immediate~~ notification ~~within 24 hours~~ as referred to in Articles 1.1.3. and 1.1.4. through to a final report. […]".

Indeed, both of these articles are pertinent in this context, however only Article 1.1.3. includes the requirement to send the notification within 24 hours.

Furthermore, the EU would encourage the OIE to consequently make that same change also in the Aquatic Code as well as in the context of WAHIS and the future OIE-WAHIS. Indeed, it would be desirable to use such terminology in a consistent way throughout all OIE texts and publications to avoid any possible confusion.

4) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the OIE disease reporting format.

5) The detection of the pathogenic agent of a *listed disease* in an *animal* should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between diseases and their pathogenic agents is constantly developing and that the presence of a pathogenic agent does not necessarily imply the presence of a disease, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1) above.

6) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of diseases~~, *infections* and *infestations*~~. Information shall include *biosecurity* and ~~quarantine~~ *sanitary measures* ~~and~~ including restrictions applied to the movement of *animals*, animal products, biological products and other miscellaneous objects which could by their nature be responsible for the transmission of diseases~~, *infections* or *infestations*~~. In the case of diseases transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the *Headquarters*:

1) in accordance with relevant provisions in the disease-specific chapters, *notification*, through the World Animal Health Information System (WAHIS) or by fax or email within 24 hours, of any of the following events:

   a) first occurrence of a *listed disease*~~, *infection* or *infestation*~~ in a country, a *zone* or a *compartment*;

   b) recurrence of an eradicated *listed disease*~~, *infection* or *infestation*~~ in a country, a *zone* or a *compartment* following the final report that declared the ~~*outbreak*~~ event ended;

   c) first occurrence of a new strain of a pathogenic agent of a *listed disease*~~, *infection* or *infestation*~~ in a country, a *zone* or a *compartment*;

   d) recurrence of an eradicated strain of a pathogenic agent of a *listed disease* in a country, a *zone* or a *compartment* following the final report that declared the event ended;

   ~~*d*~~*e)* a sudden and unexpected change in the distribution or increase in incidence or virulence of, or morbidity or mortality caused by, the pathogenic agent of a *listed disease*~~, *infection* or *infestation*~~ present within a country, a *zone* or a *compartment*;

   ~~*e*~~*f)* occurrence of a *listed disease*~~, *infection* or *infestation*~~ in an unusual host species;

2) weekly reports subsequent to a *notification* under point 1) above, to provide further information on the evolution of the event which justified the *notification*. These reports should continue until the *listed disease*~~, *infection* or *infestation*~~ has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3) will satisfy the obligation of the Member Country; for each event notified, a final report should be submitted;

3) six-monthly reports on the absence or presence and evolution of *listed diseases*~~, *infections* or *infestations*~~ and information of epidemiological significance to other Member Countries;

4) annual reports concerning any other information of significance to other Member Countries.

Article 1.1.4.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the *Headquarters*:

1) a *notification* through WAHIS or by fax or email, when an *emerging disease* has been detected in a country, a *zone* or a *compartment*;

2) periodic reports subsequent to a *notification* of an *emerging disease*:

   a) for the time necessary to have reasonable certainty that:

   – the ~~disease,~~ *infection* or *infestation* has been eradicated; or

   – the situation has become stable;

   OR

   b) until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE list as described in Chapter 1.2.;

3) a final report once point 2 *a)* or *b)* above is complied with.

~~Article 1.1.5.~~

~~1) The *Veterinary Authority* of a country in which an *infected zone* is located shall inform the *Headquarters* when this zone or the entire country becomes free from the disease, *infection* or *infestation*.~~

~~2) A country or *zone* may be considered to have regained freedom from a specific disease, *infection* or *infestation* when all relevant conditions given in the *Terrestrial Code* have been fulfilled.~~

~~3) The *Veterinary Authority* of a Member Country which establishes one or several *free zones* shall inform the *Headquarters* giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the *zones* on a map of the territory of the Member Country.~~

Article 1.1.6~~5~~.

1) Although Member Countries are only required to notify *listed diseases*~~, *infections* and *infestations*~~ and *emerging diseases*, they are encouraged to provide the OIE with other important animal health information.

2) The *Headquarters* shall communicate by email or through the interface of WAHIS to *Veterinary Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.~~5~~4. and other relevant information.

Annex 16

CHAPTER 1.6.

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

EU comment

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

In general, we would suggest the title and structure of the chapter reflect the level of importance of the three different types of status; 1) recognition of official animal health status, 2) endorsement of official control programme and 3) publication of self-declaration of disease freedom.

Therefore, the title should be reworded as follows:

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

Furthermore, the order of the articles should be:

1) Article 1.6.1. Application for official recognition of animal health status and endorsement of official control programme by the OIE;

2) Article 1.6.2. Maintenance of official recognition of animal health status and endorsement of official control programme by the OIE;

3) Article 1.6.3. Publication by the OIE of a self-declaration of disease freedom by a Member Country.

Further 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 (available on the OIE website)[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:

- 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*;
- 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.

EU comment

The EU suggests clarifying the objective of the "administrative and technical screening" performed by the OIE. This would be important to avoid any confusions, since the self-declaration is not endorsed by the OIE, even if published.

An *outbreak* in a Member Country, a *zone* or a *compartment* having a self-declared free status results in the loss of the self-declared free status. Member Countries wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this article.

EU comment

The EU suggests including a statement such as "except when otherwise provided for in the listed disease specific chapter" in the paragraph above. Indeed, not in all diseases does a single outbreak automatically change the status of the country or zone (e.g. Chapter 8.11. on tuberculosis). Furthermore, depending on the disease, there may be cases in wildlife or outbreaks in other species not considered epidemiologically significant in the disease specific chapter, which would also not necessarily lead to a change of status.

Alternatively, instead of explicitly linking loss of status with an outbreak, reference could be made to "non-compliance" with the pertinent requirements, similar to how it is drafted in Article 1.6.3. for maintenance of status. This would also take account of the fact that other types of "non-compliances" than outbreaks may lead to loss of status, e.g. requirements linked to vaccination, introduction of animals or surveillance.

Finally, the paragraph could distinguish between diseases for which there are no disease specific provisions in the Code as regards the disease free status of the country, zone or compartment and those for which there are such provisions. For the latter, it should furthermore not be possible to declare a free compartment if this is not provided for in the disease specific chapter.

The OIE does not publish self-declarations for ~~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)~~ *listed diseases* ~~listed~~ under point 1) of Article 1.6.2~~1bis~~.

EU comment

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

For reasons of clarity, the EU suggests inserting the words "referred to" before "under point 1) of Article 1.6.2".

Article 1.6.2~~1bis~~.

Application for ~~O~~official recognition of animal health status and endorsement of official control programme by the OIE

EU comment

For reasons of consistency with the title of the chapter, the EU suggests amending the title of Article 1.6.2. as follows:

"Application for ~~official~~ recognition of official animal health status and [...]".

The same change would also be warranted in point 1) below (and throughout the chapter).

As an alternative, the terminology could be aligned to "official recognition of animal health status" throughout the chapter (vs. "recognition of official animal health status").

Obiter dictum: we note that the OIE website uses "official disease status" instead of "official animal health status" (http://www.oie.int/en/animal-health-in-the-world/official-disease-status/); the terminology should preferably be consistent across all OIE texts and publications.

A Member Country~~ies~~ may request:

1) official recognition of *animal health status* by the OIE of ~~as to~~:

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

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

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

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

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

EU comment

For reasons of consistency with the terminology used in Chapter 8.8., the EU suggests replacing the words "with or without vaccination" in point e) above with "where vaccination is either practiced or not practiced".

f) freedom of a country or *zone* from peste des petits ruminants (PPR);

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~~.~~;

d) an *official control programme* for dog-mediated rabies.

~~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 of *animal health status* 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., 1.4., 3.1., ~~and~~ 3.2. and 4.3. of the *Terrestrial Code*, when relevant, and with the provisions of the relevant disease-specific chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of ~~disease~~ *animal health status* or endorsement by the OIE of an *official control programme*, the Member Country should follow the Standard Operating Procedures (available on the OIE website) and submit to the OIE ~~Status Department~~ a dossier providing the information requested 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).

EU comment

Since a new Chapter 1.13. will need to be drafted with the questionnaire for the application for endorsement by the OIE of an official control programme for dog mediated rabies, we suggest inserting a reference to that new chapter in the paragraph above.

The OIE framework for the official recognition ~~and maintenance~~ of ~~disease~~ *animal health status*, the endorsement of *official control programmes*, and their maintenance is described in relevant Resolutions ~~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] adopted by the World Assembly of OIE Delegates.

The country or the *zone*~~, or the country having its *official control programme* endorsed~~ will be included in the relevant lists of official *animal health status* or endorsed *official control programmes* 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.

EU comment

With reference to the EU comment above, we suggest replacing "1.12." with "1.13." in the paragraph above.

When a Member Country requests official recognition of *animal health status* for a *zone*, the boundaries of the proposed *zone* should be clearly defined describing the geographical boundaries of the *zone*. When applying for a free *zone* being adjacent to another *zone* of the same status, it should be stated if the new *zone* is being merged or kept separate. If the proposed *zone* remains separate, details should be provided on the control of the movement of susceptible animals and their products between the *zones* in accordance with Chapter 4.3.

EU comment

The wording of the second part of the first sentence of the paragraph above is redundant ("boundaries of the zone" used twice). This should preferably be reworded as follows:

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

"[...], the boundaries of the proposed zone should be clearly defined by describing its ~~the~~ geographical limits~~boundaries of the zone~~".

Furthermore, the EU invites the OIE to consider including a similar paragraph as the one above also in Article 1.6.1.

The overall objective of the OIE endorsed *official control programmes* is for Member Countries to progressively improve their animal health situation and eventually attain official recognition of *animal health status*. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *zones*.

EU comment

The last part of the first sentence of the paragraph above is confusing, as there is no recognition of official animal health status [*or:* official recognition of animal health status] for dog-mediated rabies.

This leads to the question of what the purpose is of having an official control programme for dog-mediated rabies endorsed by the OIE (as part of the global strategic plan "Zero by 30" of FAO, OIE, WHO and GARC) when there is no official animal health status recognised by the OIE that can eventually be attained by the country or zone.

Article 1.6.3.

Maintenance of official recognition of animal health status and endorsement of official control programme by the OIE

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.

EU comment

For reasons of clarity and consistency, the EU suggests inserting the words "of official animal health status or endorsed official control programmes" after "lists", as well as "of the Terrestrial Code" after "relevant chapters". Furthermore, we suggest replacing the word "reported" with "notified" (for consistency with the terminology of Chapter 1.1.).

Non-compliance with the requirements for the maintenance of an *animal health status* results in the suspension of that status. Member Countries may apply for the recovery of a previously recognised status, following the provisions of the relevant disease-specific chapter, within 24 months after suspension. When the status has not been recovered within 24 months of its suspension, it is withdrawn and Member Countries should reapply following the procedure for the application for official recognition of *animal health status*.

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

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

– significant problems with the quality of the *Veterinary Services* as described in Section 3 of the *Terrestrial Code;* or

– an increase in the incidence of the disease that cannot be addressed by the programme.

Annex 17

CHAPTER 3.4.

VETERINARY LEGISLATION

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 3.4.1.

Introduction and objective

Good governance is a recognised global public good and is of critical importance to Member Countries. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for *Competent Authorities* to meet their obligations as defined in the *Terrestrial Code* and the relevant recommendations of the Codex Alimentarius Commission. It should also comply with the relevant requirements of international instruments ~~dedicated~~ related to the mitigation of biological threats. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in *sanitary measures*, including changes in legislation that affect trade, and provide relevant information.

For the purposes of the *Terrestrial Code*, *veterinary legislation* comprises all legal instruments necessary for the governance of the veterinary domain.

The objective of this chapter is to provide advice and assistance to Member Countries when formulating or modernising *veterinary legislation* so as to comply with OIE standards and other relevant international standards and instruments, thus ensuring good governance of the entire veterinary domain.

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

Hierarchy of legislation: means the ranking of the legal instruments as prescribed under the fundamental law (e.g. the constitution) of a country. Respect for the hierarchy means that each legal instrument must comply with higher order legal instruments.

Legal instrument: means the legally binding rule that is issued by a body with the required legal authority to issue the instrument.

Primary legislation: means the legal instruments issued by the legislative body of a Member Country.

Secondary legislation: means the legal instruments issued by the executive body of a Member Country under the authority of primary legislation.

Stakeholder: means a person, group, or organisation that can affect or be affected by the impacts of *veterinary legislation*.

Veterinary domain: means all the activities that are directly or indirectly related to *animals*, their products and by-products, which help to protect, maintain and improve ~~the~~ animal health, ~~and~~ *animal welfare* and veterinary public health ~~of humans, including by means of the protection of animal health and *animal welfare*, and food safety~~ consistent with a One Health approach.

Annex 17 (contd)

Article 3.4.3.

General principles

1. Respect for the hierarchy of legislation

Veterinary legislation should ~~scrupulously~~ respect the hierarchy between primary legislation and secondary legislation, to ensure that the primary legislation provides the legal basis for the application and enforcement of the secondary legislation.

2. Legal basis

Competent Authorities should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative ~~and geographic~~ levels within the whole territory.

When primary legislation requires that secondary legislation be made to implement the legislative scheme, or to provide details to the legislative scheme, the relevant secondary legislation should be developed and enacted as soon as possible.

Veterinary legislation should be consistent with national, regional and international law, as appropriate, including civil, penal and administrative laws.

3. Transparency

Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.

Competent Authorities should ensure communication of *veterinary legislation* and related documentation to stakeholders.

4. Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities* and legal experts to ensure that the resulting legislation has been evaluated through an impact analysis, as appropriate, and is scientifically, technically and legally sound.

To facilitate implementation of the *veterinary legislation*, *Competent Authorities* should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

5. Quality of legislation and legal certainty

Veterinary legislation should be clear~~,~~ and coherent~~, and stable and transparent~~ provide legal certainty and protect citizens against unintended adverse side effects of legal instruments. ~~It~~The legislation should be stable but regularly evaluated and updated as appropriate to be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

1) be drafted in a manner that establishes clear authorities, rights, responsibilities and obligations (i.e. 'normative');

~~2) be unambiguous, with clear and consistent syntax and vocabulary;~~

~~3~~2) ~~be precise, accurate and consistent in the repeated use of the terminology;~~ be accurate, clear, precise and unambiguous, and use consistent terminology;

3) include only definitions that are ~~sufficient,~~ necessary and relevant to the country;

4) contain no definitions or provisions that create ~~any~~ ~~duplication or~~ contradiction or unnecessary duplication ~~or ambiguity~~;

5) include a clear statement of scope and objectives;

6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; ~~and~~

7) make provision for the financing needed for the execution of all activities of *Competent Authorities*~~;~~ or these activities ~~the financing should be ensured~~ should be supported by appropriate financing in accordance with the national funding system~~.~~; and

8) indicate when the legislation comes into effect and its impact on similar pre-existing legislation, in particular regulations.

EU comment

The EU suggests using a different term than "regulations" in point 8 above. Indeed, depending on the legal system, the terms for legal instruments and their meaning will vary significantly. For example, in the EU, "Regulation" is a specific legal term that can be used both for basic acts as well as for implementing acts. Therefore, to accommodate all countries, a more neutral wording should be used (such as "implementing acts" or simply "secondary legislation" as defined for the purposes of this chapter).

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, ~~capacitated~~ have the necessary technical, administrative and infrastructure capacity and be organised to ensure that all necessary actions are taken ~~quickly~~ timely and coherently to effectively address animal health, *animal welfare* and veterinary public health ~~and *animal welfare*~~ matters of concern ~~emergencies effectively~~.

Veterinary legislation should provide for a chain of command that is ~~as~~ effective~~.~~ ~~as possible (i.e.~~ as short as possible, and with all responsibilities clearly defined~~)~~. For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved such as in relation to environmental, food safety or other public health matters, including biological threats and natural disasters, a reliable system of coordination and cooperation should be in place.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.1.2.

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

a) ~~officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force;~~ the *Competent Authority* has all the necessary legal authorities to achieve the purposes of the legislation, including the powers to enforce the legislation;

b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith and in accordance with professional standards;

c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality and transparency, as appropriate; and

d) at least the following powers are available through the primary legislation:

i) access to premises and vehicles for carrying out inspections;

ii) access to documents;

iii) ~~taking samples;~~ application of specific *sanitary measures* such as:

- taking samples;

~~*iv)*~~ - retention (setting aside) of ~~*animals* and goods~~ *commodities*, pending a decision on final disposition;

~~*v)*~~ - seizure and destruction of ~~*animals*, products and food of animal origin~~ *commodities* and fomites;

~~*vi)*~~ - suspension of one or more activities of an inspected ~~establishment~~ facility;

~~*vii)*~~ - temporary, partial or complete closure of inspected ~~establishments~~ facilities; ~~and~~

~~*viii)*~~ - suspension or withdrawal of authorisations or approvals~~.~~; ~~and~~

- restrictions on the movement of *commodities*, *vehicles/vessels* and, if required, other fomites and people~~.~~;

- establishment of compensation mechanisms;

- listing disease for mandatory reporting; and

- ordering of *disinfection*.

EU comment

In general, it is difficult to list sanitary measures for which veterinary legislation should ensure that the Competent Authority has the necessary powers to establish. The list cannot be complete, and which sanitary measures are most important might differ from country to country. The best solution might be to delete the "such as"-list.

Alternatively, the following changes are suggested:

The EU recommends that "establishment of compensation mechanisms" is moved from a point under point d)iii) to a new point e). It is questionable whether "establishment of compensation mechanisms" is a sanitary measure according to the relevant definition in the Glossary. Indeed, the sanitary measure would be the culling / killing of suspected / infected / at risk animals. Having a compensation mechanism is of major importance for diseases being reported to the authorities, and veterinary legislation should ensure that the Competent Authority has the necessary powers to establish compensation mechanisms.

Furthermore, the EU recommends that "inspected" is deleted from the sentences "suspension of one or more activities of an inspected facility" and "temporary, partial or complete closure of inspected facilities" as it may be necessary to suspend activities / temporarily closure of facilities before they are inspected, e.g. in connection with a suspicion a farm should be closed (i.e. not allowed to move animals) immediately upon the time the suspicion is reported to the authorities and thereby before the farm is inspected.

Finally, the EU suggests adding ", disinfestation or pest control" to the last indent above.

These essential powers ~~must~~ should be clearly identified as they can result in actions that may conflict with individual rights ascribed in fundamental laws.

2. Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific tasks related to official activities. The specific tasks delegated, the competencies required, the bodies to which the tasks are delegated, ~~and~~ the conditions of supervision by the *Competent Authority* and the conditions of

withdrawals of delegations should be defined.

~~For this purpose, the *veterinary legislation* should:~~

~~*a)* define the field of activities and the specific tasks covered by the delegation;~~

~~*b)* provide for the control, supervision and, when appropriate, financing of the delegation;~~

~~*c)* define the procedures for making delegation;~~

~~*d)* define the competencies to be held by persons receiving delegation; and~~

~~*e)* define the conditions of withdrawals of delegations.~~

Article 3.4.6.

Veterinarians and veterinary paraprofessionals

~~1.~~ ~~Veterinary medicine/science~~

~~In order to ensure quality in the conduct of veterinary medicine/science, the *veterinary legislation* should:~~

~~*a)* define the prerogatives of *veterinarians* and of the various categories of *veterinary paraprofessionals* that are recognised by the Member Country;~~

~~*b)* define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary paraprofessionals*;~~

~~*c)* prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary paraprofessionals*;~~

~~*d)* define the conditions to perform the activities of veterinary medicine/science; and~~

~~*e)* identify the exceptional situations, such as epizootics, under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.~~

~~2.~~ ~~The control of veterinarians and veterinary paraprofessionals~~

~~*Veterinary legislation* should provide a basis for regulation of *veterinarians* and *veterinary paraprofessionals* in the public interest. To that end, the legislation should:~~

~~*a)* describe the general system of control in terms of the political, administrative and geographic configuration of the country;~~

~~*b)* describe the various categories of *veterinary paraprofessionals* recognised by the Member Country in accordance with its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;~~

~~*c)* prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to *veterinarians* and *veterinary paraprofessionals*;~~

~~*d)* provide for the possibility of delegation of powers to a professional organisation such as a *veterinary statutory body*; and~~

~~*e)* where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation.~~

1. The regulation of veterinarians and veterinary paraprofessionals

Veterinary legislation should provide a basis for the regulation of *veterinarians* and *veterinary paraprofessionals* in the interests of the public. To this end, the legislation should:

a) provide for the creation of a *veterinary statutory body*;

b) describe the prerogatives, the functioning and responsibilities of the *veterinary statutory body*;

c) describe the general structure and system of regulation of *veterinarians* and *veterinary paraprofessionals* by the *veterinary statutory body*; and

d) give authority to the *veterinary statutory body* to ~~make secondary legislation or otherwise deal with~~ provide basic principles for or regulate the following matters:

i) describe the various ~~categories~~ specialisations of *veterinarians* and categories of *veterinary paraprofessionals* recognised in the country in accordance with its needs, notably in animal health, animal welfare and food safety;

ii) define the prerogatives of the various ~~categories~~ specialisations of *veterinarians* and categories of *veterinary paraprofessionals* that are recognised in the country;

iii) define the minimum initial and continuous educational requirements and competencies for the various ~~categories~~ specialisations of *veterinarians* and categories of *veterinary paraprofessionals*;

iv) prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary paraprofessionals*;

EU comment

As already indicated in our comments provided in December 2018 (available here https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201809.pdf), the point above should be limited to the recognition of specialisations of veterinarians and paraprofessionals, as the veterinary legislation should give the authority to the VSB to provide basic principles for or regulate the recognition of the qualifications. The VSB does not always have the legally based authority to prescribe the conditions for recognition. The EU therefore suggests deleting the words "prescribe the conditions for".

v) define the conditions to perform the activities of veterinary medicine/science, including the extent of supervision for each category of *veterinary paraprofessionals*;

vi) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to *veterinarians* and *veterinary paraprofessionals*;

vii) ~~identify the exceptional situations, such as epizootics,~~ define the conditions (except those that are under the responsibilities of the *Competent Authority*) under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

EU comment

The EU suggests deleting the point above, because in the EU it is not up to the VSB to regulate this type of issue which is completely within the competence of the Competent Authority.

2. If the *veterinary legislation* does not create a *veterinary statutory body* for the regulation of *veterinarians* and *veterinary paraprofessionals*, the legislation should at least address all the elements listed in paragraphs 1. d) (i) to (vii) to ensure quality in the conduct of veterinary medicine/science.

Article 3.4.7.

Laboratories in the veterinary domain

1. Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;

b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and

c) *laboratories* recognised by the *Competent Authority* to conduct ~~analyses~~ ~~in-house~~ testing required under the legislation ~~e.g.~~ for the purposes of safety and quality control~~.~~, e.g. bacteriological testing for pathogenic agents in milk at a dairy processing plant.

Veterinary legislation should define the conditions for the classification, approval, operations and supervision of each of these types of *laboratories*, including conditions for laboratory biosafety and biosecurity.

2. Reagents, diagnostic kits and biological agents and products

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) procedures for authorising the use and transfer of reagents, diagnostic kits and biological agents and products that are used to perform official analyses and other purposes approved by the *Competent Authority*;

b) quality assurance by manufacturers and providers of reagents used in official analyses and other purposes approved by the *Competent Authority*; and

c) ~~surveillance~~ oversight of marketing of reagents, diagnostic kits and biological agents and products where these can affect the quality of analyses required by the *veterinary legislation*.

3. Laboratory containment and control of biological agents and products

Veterinary legislation should make provisions for the effective containment and control of biological agents and products into, within and out of the laboratory, including their disposal when applicable, as described in Chapter 5.8. of the *Terrestrial Code* and Chapter 1.1.4. of the *Terrestrial Manual*.

Article 3.4.8.

Health provisions relating to animal production

1. Identification and traceability

Veterinary legislation should provide a basis for actions to address all the elements in point 6) of Article 4.2.3.

2. Animal markets and other gatherings

Veterinary legislation should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

a) registration of animal markets and other animal gatherings;

b) health measures to prevent *disease* transmission, including procedures for ~~cleaning and~~ *disinfection*, and *animal welfare* measures; and

c) provision for veterinary ~~checks~~ inspections.

3. Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction ~~as appropriate~~ in relation to the *risk* of disease transmission. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4. Animal feed

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) standards for the production, composition and quality control of animal feed in relation to the *risk* of disease transmission;

b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

c) recall from the market of any product likely to present a hazard to human health or animal health.

5. Animal by-products

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) definition of the animal by-products subject to the legislation;

b) rules for collection, transport, processing, use and disposal of animal by-products;

c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

d) rules to be followed by animal owners.

6. Disinfection

Veterinary legislation should provide a basis for actions to address the regulation and use of products and methods of *disinfection* relating to the prevention and control of animal *diseases*.

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the *Competent Authorities* to manage diseases of importance to the country, present or not, ~~and to list those diseases, guided by the recommendations in Chapters 1.1 and 1.2,~~ as well as *emerging diseases*, using a risk-based approach. The legislation should also provide for the listing and mandatory reporting of diseases of importance to the country.

1. Surveillance

Veterinary legislation should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to *diseases* listed by the *Competent Authority*.

Annex 17 (contd)

2. Disease prevention and control

a) *Veterinary legislation* should include general animal health measures applicable to all *diseases* and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular *diseases* listed in the country.

b) The legislation should also provide a basis for contingency plans to include the following for use in disease responses:

i) administrative and logistic organisation to activate, implement and coordinate activities;

ii) exceptional powers of the *Competent Authority*; and

iii) ~~special and temporary~~ measures to address all identified *risks* to human or animal health including accidental or deliberate introduction of biological agents or products.

c) *Veterinary legislation* should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of *killing* or *slaughtering* of *animals* and seizure or destruction of carcasses, *meat*, animal feed or other things or the financing of these measures should be ensured in accordance with the national funding system.

3. Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to *emerging diseases* including those due to natural, accidental or deliberate introduction of biological agents, using a risk-based approach.

Article 3.4.10.

Animal welfare

1. General provisions

Veterinary legislation should provide a basis for actions to address the *animal welfare* related requirements in Section 7.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

2. Stray dogs and other free-roaming animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

Veterinary ~~medicines and biologicals~~ medicinal products

Veterinary legislation should provide a basis for assuring the quality of *veterinary* ~~medicines and biologicals~~ *medicinal products* and minimising the *risk* to human, animal and environmental health associated with their use, including the development of antimicrobial resistance.

1. General measures

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) definition of *veterinary* ~~medicines and biologicals~~ *medicinal products*, including any specific exclusions; and

b) regulation of the importation, manufacture, safety, efficacy, distribution and usage of, and commerce in, *veterinary* ~~medicines and biologicals~~ *medicinal products*~~, including laboratory biosafety and biosecurity measures~~.

EU comment

While the additions in point b) are pertinent, we would suggest separating these elements into 2 points for reasons of clarity, as follows:

b) regulation of the authorisation to ensure availability of veterinary medicinal products are sure, safe and efficient; and

c) regulation of the importation, manufacture, ~~safety, efficacy,~~ distribution and usage of, and commerce in, veterinary medicinal products.

Furthermore, while agreeing with the Code Commission that laboratory biosafety and biosecurity measures do not fit well under this section, we would prefer keeping these important elements by moving them to an appropriate section.

2. Raw materials for use in veterinary ~~medicines and biologicals~~ medicinal products

Veterinary legislation should provide a basis for actions to address the elements listed below:

a) quality standards for raw materials used in the manufacture or composition of *veterinary* ~~medicines and biologicals~~ *medicinal products* and arrangements for checking quality;

~~*b)* establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and~~

~~*c*~~*b)* ~~requirements for~~ restrictions on substances in *veterinary* ~~medicines and biologicals~~ *medicinal products* that may, through their effects, interfere with the interpretation of veterinary diagnostic test results or the conduct of other veterinary checks.

3. Authorisation of veterinary medicinal products ~~medicines and biologicals~~

a) *Veterinary legislation* should ensure that only authorised *veterinary* ~~medicines and biologicals~~ *medicinal products* may be placed on the market.

b) Special provisions should be made for:

i) *veterinary medicinal products* incorporated into medicated feed;

ii) products prepared by authorised *veterinarians* or authorised pharmacists; ~~and~~

iii) emergencies and temporary situations; and

iv) establishment of withdrawal periods for relevant *veterinary medicinal products* and maximum residue limits for the active substance contained in each such product.

EU comment

For reasons of logic, the EU suggests mentioning MRLs first, as these are the basis for determining the withdrawal periods, as foolows:

"establishment of maximum residue limits for the active substance and withdrawal periods for relevant veterinary medicinal products ~~and maximum residue limits for the active substance contained in each such product~~ containing these substances."

c) *Veterinary legislation* should address the technical, administrative and financial conditions associated

with the granting, renewal, refusal and withdrawal of authorisations.

EU comment

For completeness, the EU suggests inserting the word "<u>suspension</u>" after "granting" in point c) above.

d) In defining the procedures for seeking and granting authorisations, the legislation should:

i) describe the ~~role~~ <u>responsibilities</u> of the relevant *Competent Authorities*; and

ii) establish rules providing for the transparency in decision making.

e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

~~4. Quality of veterinary medicines and biologicals~~

~~*Veterinary legislation* should address the following elements:~~

~~*a)* the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;~~

~~*b)* conditions for the conduct of trials;~~

~~*c)* qualifications of experts involved in trials; and~~

~~*d)* surveillance for adverse effects arising from the use of veterinary medicines and biologicals.~~

EU comment

The EU would prefer keeping point 4) above, however orienting it towards the control of the quality of Veterinary medicinal products, as follows:

"4. Quality of veterinary medicines and biologicals

Veterinary legislation should provide a basis for:

- A system of surveillance of the quality of veterinary medicinal products marketed in the country;

- A system of surveillance of falsification."

~~5~~4. <u>Establishments producing, storing and wholesaling veterinary ~~medicines and biologicals~~ medicinal products</u>

Veterinary legislation should provide a basis for actions to address the following elements:

a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling or otherwise distributing *veterinary* ~~medicines and biologicals~~ <u>*medicinal products*</u> or raw materials for use in making *veterinary* ~~medicines and biologicals~~ <u>*medicinal products*</u>;

EU comment

For completeness, the EU suggests inserting the word "<u>exporting</u>" after "importing" in point a) above.

b) definition of the responsibilities of operators;

c) good manufacturing practices appropriate;

EU comment

For completeness, the EU suggests inserting the word "<u>and distribution</u>" after

"manufacturing" in point c) above.

d) reporting on adverse effects to the *Competent Authority*; and

e) mechanisms for traceability and recall.

~~6~~5. Retailing, use and traceability of veterinary ~~medicines and biologicals~~ medicinal products

Veterinary legislation should provide a basis for actions to address the following elements:

a) control over the distribution of *veterinary* ~~medicines and biologicals~~ *medicinal products* and arrangements for traceability, recall and conditions of use;

b) establishment of rules for the prescription and provision of *veterinary* ~~medicines and biologicals~~ *medicinal products* to end users;

c) restriction to *veterinarians* or other authorised professionals and, as appropriate, authorised *veterinary paraprofessionals*, of commerce in *veterinary* ~~medicines and biologicals~~ *medicinal products* that are subject to prescription;

d) obligation of *veterinarians*, other authorised professionals or authorised *veterinary paraprofessionals* to inform end users of the withdrawal periods of relevant *veterinary medicinal products* and the obligation of end users to observe those withdrawal periods when using those products;

~~*d*~~*e)* the supervision by an authorised professional of organisations approved for holding and use of *veterinary* ~~medicines and biologicals~~ *medicinal products*;

~~*e*~~*f)* the regulation of advertising claims and other marketing and promotional activities; and

~~*f*~~*g)* reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards and taking into account the *risk* of accidental and deliberate contamination. The role of the *Veterinary Services* in food safety is described in Chapter 6.2.

1. General provisions

Veterinary legislation should provide a basis for actions to address the following elements:

a) the conduct of ~~veterinary~~ ante- and post-mortem inspections at *slaughterhouses/abattoirs* in accordance with Chapter 6.3.;

~~*a*~~*b)* controls over all stages of the production, processing and distribution of food of animal origin;

~~*b*~~*c)* recording all significant animal and public health events that occur during primary production including *slaughter*;

~~*c*~~*d)* giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;

~~*d*~~*e)* inspection for compliance with food standards, where this is relevant to health or safety;

~~*e*~~*f)* inspection and audit of premises;

~~*f*~~*g)* prohibition of the marketing of products not fit for human consumption; and

~~*g*~~*h)* provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

Veterinary legislation should provide a basis for actions to address the following elements:

~~*a)* arrangements for inspection and audit;~~

~~*b)* the conduct of inspection and audit;~~

~~*c*~~*a)* health standards including measures to control diseases, and monitoring and enforcement of maximum residue levels (MRL); ~~and~~

~~*d*~~*b)* the ~~application~~ use of ~~health identification marks that are visible to the intermediary or and final user~~ visible marks that indicate the product has been inspected.

The *Competent Authority* should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

3. Operators responsible for premises and establishments pertaining to the food chain

Veterinary legislation should provide a basis for actions to address the following elements as appropriate:

a) registration of premises and establishments by the *Competent Authority*;

b) the use of *risk*-based management procedures; and

c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import and export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements ~~relating to import and export procedures and veterinary certification~~ referred to in Section~~s~~ 2 Risk Analysis and Section 5 Trade measures, import/export procedures and veterinary certification.

Annex 18

CHAPTER 4.Y.

OFFICIAL CONTROL PROGRAMMES ~~MANAGEMENT OF OUTBREAKS OF~~ FOR 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.

Article 4.Y.1.

Introduction

When a *listed disease* or *emerging disease*~~, including a zoonosis,~~ occurs in a Member Country, the *Veterinary* ~~*Services*~~ *Authority* 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 (e.g. the first occurrence ~~to~~ of a ~~new~~ ~~*hazard*~~ disease) ~~and management of *outbreaks*~~, to long-term control (e.g. of an endemic disease) ~~*infection or infestation*~~.

The purpose~~s~~ of this chapter is to provide recommendations to prepare, develop and implement *official control programmes* for ~~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 transmissible animal diseases ~~through organised control programmes plans~~. Although this chapter focuses primarily on *listed* and *emerging diseases*, the recommendations may also be used by the *Veterinary Authorities* for any *notifiable diseases* or diseases against which they have established *official control programmes*.

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

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*.

The general components of an *official control programme* should include:

1) a plan of the programme to control or eradicate the relevant disease in the country or *zone;*

2) ~~regular and prompt animal disease reporting~~ appropriate *veterinary legislation*;

3) emergency preparedness plans and emergency response plans;

EU comment

The EU suggests adding the words "as appropriate" at the end of point 3 above. Indeed

control measures do not necessarily require emergency plans as this would depend on the evaluation of the impact of the disease.

4) *surveillance* of the relevant disease in accordance with Chapter 1.4.;

~~4~~5) regular and prompt animal disease reporting;

6) ~~rapid~~ detection and management of~~, and response to,~~ *cases* of the relevant disease, to reduce the *incidence* and the prevalence ~~to~~ by eliminat~~e~~ing transmission;

EU comment

The EU suggests replacing the word "eliminating" with "minimising" in point 6 above. Indeed, it may not be possible to entirely eliminate transmission. This is already indicated by use of the term "reduce" in connection with incidence and prevalence. Therefore "minimising transmission" seems more appropriate.

~~5~~7) measures implemented to prevent introduction or spread of the relevant disease, including *biosecurity* and *sanitary measures* including movement control;

~~6~~8) a *vaccination* programme, as ~~relevant~~ appropriate;

~~7~~9) ~~preparedness and contingency plans~~ measures to protect public health, as appropriate;

~~8~~10) communication and collaboration ~~with other~~ among all relevant *Competent Authorities*.

~~In any case,~~ T~~t~~he critical components of *official control programmes* ~~plans for management of *outbreaks*~~ for diseases that are not present in the ~~Member Country~~ country or *zone* are measures to prevent the introduction of the disease, ~~an~~ an early ~~*detection*~~ warning system ~~(including a warning procedure),~~ ~~and~~ and a plan for rapid response and ~~quick and~~ effective action, possibly followed by long-term measures. Such ~~Plans~~ programmes should ~~always~~ include ~~an~~ exit strategy options.

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 future 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

It is not clear what is meant by "Plans" in the last sentence of the paragraph above. Indeed, as the article mainly deals with "official control programmes" but also mentions "contingency plans", this needs to be clarified. Preferably, the word "Plans" should be replaced by "Programmes".

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~~ transmissible 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~~ authority; 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 dedicated staff and additional supporting staff when needed;

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

– sources of financing for communication and awareness campaigns;

– sources of financing and compensation policy for ~~livestock~~ *commodities* and property that may be lost or destroyed ~~as part of disease control programmes, or for direct losses incurred due to movement restrictions imposed by the control programme~~;

– 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~~ assess 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 forward and backward tracing of ~~*animals* and animal products~~ *commodities* and fomites;

– 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~~ *commodities* 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~~ collection, treatment or safe disposal ~~or processing~~ of contaminated or potentially contaminated ~~animal~~ products of animal origin ~~and other materials~~;

– procedures for collection, treatment or safe disposal of contaminated or potentially contaminated fodder and effluents such as ~~fodder,~~ bedding~~, and~~ litter, manure and waste water;

– 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~~ *commodities*, 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~~ implementation of *vaccination* programmes or treatment of *animals*, as relevant, and for any other necessary disease control actions~~.~~;

– procedures for post-control *surveillance* and possible gaining or recovery of status, as relevant.

Article 4.Y.3.

Emergency ~~P~~preparedness

In case of occurrence of an *emerging disease* or a *listed disease* that was not present in the country or *zone*, or of sudden increase of *incidence* of a *listed disease* that is present, ~~R~~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 define emergencies and integrate emergency preparedness planning, ~~and practice~~ equipping, training and exercising within the *official control programmes* against these diseases 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.~~

EU comment

As indicated in the EU comment above, control measures do not necessarily require emergency plans since this would depend on the evaluation of the impact of the disease. The EU therefore suggests inserting the notion of "according to an evaluation of the actual or likely impact of the disease or risk analysis" in the first sentence of the paragraph above.

Emergency ~~P~~preparedness should be ~~justified~~ supported by *risk analysis*, should be planned in advance, 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,~~ Emergency planning consists of describing the following in advance:

- what ~~governmental or~~ national and local authorities and ~~all~~ relevant stakeholders should do~~.~~; ~~comprise any comprehensive preparedness and response system~~
- how they should be trained, equipped and exercised to be ready to do it;
- how their actions should be activated and coordinated.

This implies the development of:

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

EU comment

The EU suggests reverting back to "notifiable disease" in points 2 a), b) and d) above. Indeed, as indicted in the first sentence of point 1 above, each country should determine a list of diseases that are notifiable at national level based on risk analysis, for which preparedness planning is required. That list may well differ from the OIE list of diseases in Chapter 1.3., which is why reference to "*listed disease*" (as defined in the Glossary) would not be appropriate.

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 and other relevant agencies.

Article 4.Y.4.

Surveillance and early warning ~~detection~~ 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 are an integral component of emergency ~~preparedness~~ management. They should be in place for diseases ~~*infections* or *infestations*~~ for which a rapid response is desired, and should comply with the relevant articles of Chapter 1.4. When used, ~~*V*~~*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 of a *listed disease* or an *emerging disease* based on supportive, but not definitive, findings should lead to at least the implementation of ~~local~~ pre-emptive control measures ~~as a precaution~~. ~~When~~ Once a *case* is confirmed, full *sanitary measures* should be implemented ~~as planned~~.

~~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~~ for outbreak management

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

1) ~~epidemiological investigation to~~ tracing ~~back and~~ forward and backward animals in contact and potentially infected or contaminated ~~products~~ *commodities* or fomites through epidemiological investigation;

~~1~~2) 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 other potentially contaminated ~~products~~ *commodities*;
- the cleaning, *disinfection* and, if relevant, disinsection of premises and equipment;

~~2~~3) stopping the spread of *infection*, through:

- movement restrictions on ~~*animals*~~ *commodities* and fomites, ~~*vehicles*, and equipment and people,~~ as appropriate;
- *biosecurity*;

EU comment

The EU suggests inserting a new indent here as follows:

"- zoning as described in Article 4.Y.8.;".

Indeed, zoning is a crucial tool for stopping the spread of an infection that is mentioned below (Article 4.Y.8.) so should be added here for consistency.

- *vaccination*, treatment or culling of *animals* at risk;

– control of *vectors*;

– communication and public awareness.

Different strategies may be chosen depending on the expected outcome of the *official control 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~~ response measures 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~~ transmissible or high impact disease events, the ~~management plan~~ response measures 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~~ other potentially contaminated commodities

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*~~ transmission of pathogenic agents through live organisms (*vectors*, people) or 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~~ transmissible diseases.

Veterinary Services should adapt any strategy for culling of *animals*~~, *killing*~~ or disposal of dead *animals* and ~~their products~~ other potentially contaminated *commodities* ~~strategy~~ to the transmission pathways of the pathogenic agent. A *stamping-out policy* is ~~should be~~ the preferred strategy for highly ~~contagious~~ transmissible 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~~ transmissible diseases and situations where the disease is endemic.

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~~ other ~~related~~ potentially contaminated ~~products~~ *commodities* 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~~ transmissible 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*.

Depopulation and carcass disposal can be applied to *wildlife* within a defined *zone*, 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~~ more suitable for less ~~contagious~~ transmissible 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. *Veterinary Services* may adjust test and cull strategies to the changes of the *prevalence*.

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~~ *commodities* and fomites 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~~ *commodities*, and to different types of fomites (e.g. people, clothing, *vehicles/vessels* and equipment). They may vary from pre-movement certification to total standstill, and be limited to one ~~or more~~ *establishment* only or multiple *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.

Zoning

The *Veterinary Authority* should use the tool of zoning in *official control programmes*, 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.

EU comment

The EU suggests adding the words "biosecurity and communication" after "surveillance" in the first sentence of the article above, as these are also important elements described in this chapter.

Zones established in response to *outbreaks* of *listed diseases* or *emerging diseases* are usually *infected zones*, *containment zones* and *protection zones*. However, other types of *zones*, such as *zones* where *specific surveillance, vaccination* or other activities are conducted, can also be used.

Article 4.Y.~~8~~9.

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.

Disinfection and disinsection should be applied in accordance with Chapter 4.13. 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~~10.

Vaccination ~~and treatment~~ and treatment

Vaccination as part of an *official control programme* ~~in response to a contagious disease *outbreak*~~ should be conducted in accordance with Chapter 4.17.

Vaccination programmes, especially in response to an *outbreak*, require ~~previous~~ planning to identify potential sources of vaccine, including vaccine or antigen banks, and to plan the possible strategies for application, such as ~~emergency~~ barrier, blanket, ~~*vaccination* or~~ ring or targeted *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~~ induced by *infection* with the pathogenic agent or to differentiate live vaccine strains from field strains.

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 strategy~~ies~~ such as a test and cull strategy.

Vaccination can also be used to minimise 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 *official control programme* ~~plan~~ should ~~include~~ consider a cost/benefit analysis with regard to trade and public health and an exit strategy, i.e. when and how to stop the *vaccination* or whether *vaccination* should become systematic ~~routine~~.

Treatment can also be used as part of an *official control programme*. It would require planning to identify potential sources of *veterinary medicinal products*, and to plan the possible strategies for application and an exit strategy.

~~Article 4.Y.10.~~

~~**Zoning**~~

~~The *Veterinary Authority* should use the tool of zoning in *official control programmes*, 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 part of the *official control programme* and 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~~.

EU comment

The EU suggests adding the word "feedback" after "monitoring" in the title of Article 4.Y.13., and inserting the sentence below after the first sentence of the first paragraph of this article:

"Feedback from Veterinary Services staff about the organisation and procedures of official control programmes should be performed."

Indeed, feedback is also an important element that is currently not well reflected in the

text.

Annex 19

USER'S GUIDE

EU comment

The EU in general supports the proposed changes to the User's Guide.

A comment is inserted in the text below.

[...]

B. *Terrestrial Code* content

[...]

3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of ~~pathogenic agents~~ diseases, infections and infestations. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, zone or compartment.

[...]

C. Specific issues

[...]

5. Trade requirements

Animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from those recommended by the *Terrestrial Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with OIE standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the obligations and ethical responsibilities of importing and exporting countries in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters. Chapter 5.3. also describes the OIE informal procedure for dispute mediation.

The OIE aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to 15. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question. Chapter 2.2. describes the criteria used to assess the safety of commodities.

EU comment

The EU suggests italicising the term "listed disease" when used in the paragraph above, as that term is defined in the Glossary.

In general, the EU notes that none of the terms defined in the Glossary are italicised in the User's Guide and queries why that is so.

[...]

Annex 20

CHAPTER 8.11.

INFECTION WITH *MYCOBACTERIUM ~~TUBERCULOSIS~~ BOVIS* AND *M. CAPRAE*

EU comment
The EU takes note of the proposal to delist *M. tuberculosis* in Chapter 1.3. and of related changes in Chapter 8.11. These are based on the opinion provided by an expert panel that assessed *M. tuberculosis* against the listing criteria of chapter 1.2., that was endorsed by the OIE Scientific Commission (SCAD September 2018 meeting report).
The EU firmly believes that it is important to apply the criteria of Chapter 1.2. rigorously and consistently, and to base any decision on listing or delisting of pathogenic agents on available science (i.e. peer-reviewed publications). However, this particular case raises the question of whether the listing criteria should be applied to the individual species of pathogens or to the Mycobacterium tuberculosis complex as such. Indeed, these pathogens are related disease agents that infect a similar range of species, provide positive results in the same diagnostic assays and may present different patterns of infection. We suggest that this question be addressed in the guidance document and Standard Operating Procedures for the application of the listing criteria by experts convened by the OIE currently being developed within the OIE.
The EU acknowledges that within the Mycobacterium tuberculosis complex (MTBC), *M. tuberculosis* may not exactly meet some of the listing criteria, more specifically criteria 1 and 4a/4b/4c, in terms of published evidence. This was the conclusion of the panel of experts and the OIE Scientific Commission in September 2018. We however note that the February 2017 report of the OIE Scientific Commission provides a list of scientific publications demonstrating the impact of *M. tuberculosis* in livestock and wildlife (criteria 4b and 4c) which was the scientific rationale for listing *M. tuberculosis* in May 2017.
Nevertheless, the EU would prefer keeping *M. tuberculosis* listed in Chapter 1.3. and included in Chapter 8.11. This is due to the major public health significance of *M. tuberculosis*, not least its potential antimicrobial resistance risks, but also to its animal health impact. In essence, *M. tuberculosis* infected livestock should not be traded internationally.
Indeed, EU experts indicate that *M. tuberculosis* does occurs in cattle, sometimes in a significant proportion of MTBC infections (Bhembe *et al*., 2018. BioMed Research International 2018(12):1-12). What's more, *M. tuberculosis* can be transmitted from cattle to humans and between cattle, as secreted *M. tuberculosis* has been detected in milk of experimentally infected cattle (Villarreal- Ramos *et al*. 2018. Sci Rep. 8 (1): 894).
Finally, EU experts advise that the possible lack of published evidence for livestock to human and livestock to livestock transmission is likely because of scarce research and low priority on *M. tuberculosis* in cattle due to scantiness of resources in the regions where it occurs more frequently, i.e. developing countries with high endemicity for human tuberculosis. In addition, conducting such transmission studies would be very

complex in countries with high human tuberculosis prevalence, as discernibility of zoonotic transmission would likely be low.

The EU will provide OIE with more scientific data as and when it becomes available.

Finally, we would like to point out that should the proposed deletion of the second paragraph of Article 8.11.1. be maintained (i.e. the definition of MTBC for the purposes of the Code), it may be necessary to define MTBC in Chapter 6.12. for the purposes of that chapter (zoonoses transmissible from non-human primates).

Article 8.11.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *infection* of animals with ~~a member of the~~ *Mycobacterium bovis and M. caprae* ~~*tuberculosis(M. tuberculosis)* complex~~.

~~For the purposes of the *Terrestrial Code*, *M. tuberculosis* complex comprises *M. bovis*, *M. caprae* and *M. tuberculosis*, but excludes vaccine strains.~~

Many different domestic and *wild animal* species belonging to diverse mammalian taxa are known to be susceptible to *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*. Their epidemiological significance depends on the degree of susceptibility, the husbandry system, the density, spatial distribution and ecology of populations as well as the pathogenesis and transmission pathways. In some geographical regions, certain *wild animal* species can act as reservoirs.

For the purposes of this chapter, 'animals' means domestic and *captive wild animal* populations of the following categories:

1) bovids: this term means bovines (*Bos taurus*, *B. indicus*, *B. frontalis*, *B. javanicus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, and bison (*Bison bison* and *B. bonasus*);

2) cervids: this term means red deer *(Cervus elaphus elaphus)*, wapiti/elk *(C. elaphus canadensis)*, sika *(C. nippon)*, samba *(C. unicolorunicolor)*, rusa *(C. timorensis)*, roe deer *(Capreolus capreolus)*, fallow deer *(Dama dama)*, white-tailed, black-tailed and mule deer (*Odocoileus* spp.) and reindeer/caribou *(Rangifer tarandus)*;

3) goats *(Capra hircus)*;

4) New World camelids: this term means alpacas *(Lama guanicoe pacos)* and llamas *(Lama guanicoe glama)*.

The chapter deals not only with the occurrence of clinical signs caused by *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*, but also with the presence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in the absence of clinical signs.

For the purposes of the *Terrestrial Code*, the following defines the occurrence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*:

– ~~a member of *M. tuberculosis* complex~~ *M. bovis* or *M. caprae*, excluding vaccine strains, has been identified in a sample from an animal or a product derived from that animal;

OR

– positive results to a diagnostic test have been obtained and there is an epidemiological link to a *case* of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*, excluding vaccine strains, or there is other reason to suspect *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*.

When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.11.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *M. bovis* and *M. caprae* ~~*M. tuberculosis* complex~~ *infection* status of the animal population of the country, *zone* or *herd* of origin.

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

Article 8.11.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any ~~*M. tuberculosis* complex-related~~ conditions related with *M. bovis* and *M. caprae*, regardless of the ~~*M. tuberculosis* complex *infection*~~ *M. bovis* and *M. caprae* status of the animal populations of the country, *zone* or *herd* of origin:

1) *fresh meat* and *meat products* originating from animals that have been subjected to ante- and post-mortem inspections as described in Chapter 6.2.;

2) cured hides, skins and trophies;

3) gelatine, collagen, tallow and *meat-and-bone meal*.

Article 8.11.3.

Country or zone historically free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in specified animal categories

A country or *zone* may be considered historically free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in specified animal categories when the requirements of point 1 *a)* of Article 1.4.6. have been met for the relevant animal categories.

Article 8.11.4.

Country or zone free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids

1) To qualify as free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids, a country or *zone* should satisfy the following requirements:

   a) *infection* in animals is a *notifiable disease* in the entire country;

   b) a *surveillance* programme based on regular testing of all *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* was not present in at least 99.8% of the *herds* representing at least 99.9% of the bovids in the country or *zone*;

   c) a *surveillance* programme in accordance with Chapter 1.4. is in place to detect *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in the country or *zone* through ante- and post-mortem inspections of bovids as described in Chapter 6.3.;

   d) regulatory measures have been implemented for the early detection of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids;

   e) bovids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.11.7., 8.11.10. and 8.11.12.

2) To maintain the status as free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids, a country or *zone* should satisfy the following requirements:

   a) the requirements in points 1 *a)*, 1 *c)*, 1 *d)* and 1 *e)* above are met;

   b) a *surveillance* programme based on regular testing of bovids is in place in the country or *zone* to detect *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in accordance with Article 1.4.4.;

   c) once the *surveillance* programme described in point *b)* has demonstrated that *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* has not been present in at least 99.8% of the *herds* representing 99.9% of the bovids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.3.

3) The country or *zone* status of free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids is not affected by the occurrence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in other animal categories or *feral* or *wild animals* provided that measures intended to prevent transmission of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* to bovids have been implemented and are periodically reassessed.

Article 8.11.5.

Country or zone free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in cervids

1) To qualify as free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in cervids, a country or *zone* should satisfy the following requirements:

   a) *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in animals is a *notifiable disease* in the entire country;

   b) regular testing of all cervid *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* was not present in at least 99.8% of the *herds* representing at least 99.9% of the cervids in the country or *zone*;

   c) a *surveillance* programme is in place to detect *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in the country or *zone* through ante- and post-mortem inspections as described in Chapter 6.3.;

   d) regulatory measures have been implemented for the early detection of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in cervids;

   e) cervids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.11.7., 8.11.11. and 8.11.12.

2) To maintain the status as free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in cervids, a country or *zone* should satisfy the following requirements:

   a) the requirements in points 1 *a)*, 1 *c)*, 1 *d)* and 1 *e)* above are met;

   b) a *surveillance* programme based on regular testing of cervids is in place in the country or *zone* to detect *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in accordance with Article 1.4.4.;

   c) once the *surveillance* programme described in point *b)* has demonstrated that *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* has not been present in at least 99.8% of the *herds* representing 99.9% of the cervids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.3.

3) The country or *zone* status free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in cervids is not affected by the occurrence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in other animal categories or *feral* or *wild animals* provided that measures intended to prevent transmission of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* to cervids have been implemented and are periodically reassessed.

Article 8.11.6.

Herd free from infection with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids or cervids

1) To qualify as free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*, a *herd* of bovids or cervids should satisfy the following requirements:

   a) the *herd* is in a country or *zone* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in bovids or in cervids and is certified free by the *Veterinary Authority*;

   OR

   b) the *herd* satisfies the following requirements:

      i) *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in animals is a *notifiable disease* in the entire country;

      ii) no occurrence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* has been detected in the *herd* for at least the past 12 months;

      iii) bovids or cervids in the *herd* have shown no clinical signs of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* or lesions at ante- or post-mortem inspections for at least the past 12 months;

iv) two tests have been performed with negative results at a minimum interval of six months on all bovids or cervids over six weeks of age present in the *herd* at the time of testing. The first test was performed at least six months after the removal of the last *case*;

v) bovids or cervids and their germplasm introduced into the *herd* comply with Articles 8.11.7., 8.11.10., 8.11.11. and 8.11.12.;

vi) for at least the past 12 months, there has been no occurrence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in other *herds* of the same *establishments* or measures have been implemented to prevent any transmission of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* from these other *herds*.

2) To maintain the free status, either:

a) the requirements in point 1 *a)* are met;

OR

b) the requirements in points 1 *b) i)* to *iii)*, *v)* and *vi)* are met and bovids or cervids in the *herd*:

i) showed a negative result to an annual test to ensure the continuing absence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; OR

ii) showed a negative result to a test every two years to ensure the continuing absence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* if it has been confirmed that the annual percentage of *herds* infected with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* is not more than 1% of all *herds* in the country or *zone* during the past two years; OR

iii) showed a negative result to a test every three years to ensure the continuing absence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* if it has been confirmed that the annual percentage of *herds* infected with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* is not more than 0.2% of all *herds* in the country or *zone* during the past four years; OR

iv) showed a negative result to a test every four years to ensure the continuing absence of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* if it has been confirmed that the annual percentage of *herds* infected with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* is not more than 0.1% of all *herds* in the country or *zone* during the past six years;

OR

c) the requirements in points 1 *b) i)* to *iii)*, *v)* and *vi)* are met; and

i) the risk of transmission of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* from known *wildlife* reservoirs has been assessed through active *surveillance*;

ii) all *herds* identified as being at risk are subjected to a testing programme commensurate with the assessed epidemiological risk of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*. In identifying *herds* at risk, the following should be considered:

– a location associated with suspected or confirmed *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in *wildlife*; or

– a history of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* within last five years; or

– an epidemiological link with *herds* in either of the two points above.

Article 8.11.7.

Recommendations for the importation of bovids or cervids for breeding or rearing

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bovids or cervids:

1) showed no clinical signs of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of shipment;

2)

a) originate from a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* that is in a country or *zone* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or

b) originate from a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and have been tested for *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* with negative results within 30 days prior to shipment; or

c) have been isolated for at least six months prior to shipment including protection from contact with any reservoir of ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.11.8.

Recommendations for the importation of goats for breeding or rearing

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

1) *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in animals is a *notifiable disease* in the entire country;

2) the goats showed no clinical signs of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of shipment;

3) either:

a) the goats have been kept since birth in *herds* in which no *case* of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* has been detected for the past three years; or

b) have been isolated for at least six months prior to shipment including protection from contact with any reservoir of ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.11.9.

Recommendations for the importation of bovids or cervids for slaughter

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bovids or cervids:

1) showed no clinical signs of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of shipment;

2) either:

a) originate from a country, *zone* or *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or

b) are not being culled as part of an eradication programme against *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and were tested for *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* with negative results within 30 days prior to shipment.

Article 8.11.10.

Recommendations for the importation of semen of bovids

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

1) the donor males showed no clinical signs of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of collection of the semen;

2) the donor males:

   a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5. and complied with Article 4.6.2.; or

   b) were kept in a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* that is in a country or *zone* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or

   c) were kept in a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and showed negative results to a test performed within 30 days prior to collection of the semen, which was collected, processed and stored in accordance with Articles 4.5.4., 4.5.5., and 4.6.5. to 4.6.7.

Article 8.11.11.

Recommendations for the importation of semen of cervids

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

1) the donor males showed no clinical signs of *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* on the day of collection of the semen;

2) the donor males either:

   a) were kept in a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in a country or *zone* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or

   b) were kept in a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* and showed negative results to a test performed within 30 days prior to collection of the semen, which was collected, processed and stored in accordance with Articles 4.5.4., 4.5.5., and 4.6.5. to 4.6.7.

Article 8.11.12.

Recommendations for the importation of embryos of bovids or cervids

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

1) the donor females either:

   a) originated from a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* in a country or *zone* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or

   b) were kept in a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*, and were subjected to a test for *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae* with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;

2) the semen used for embryo production complied with Article 8.11.10. or Article 8.11.11.;

3) the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. to 4.9.

Article 8.11.13.

Recommendations for the importation of milk and milk products of bovids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *milk* or *milk products*:

1) have been derived from bovids in a *herd* free from *infection* with ~~*M. tuberculosis* complex~~ *M. bovis* and *M. caprae*; or

2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

_____

Annex 21

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU comment

Reference is made to the EU comment inserted in Annex 20.

[...]

Article 1.3.1.

The following are included within the category of multiple species diseases, *infections* and *infestations*:

– Anthrax
– Crimean Congo hemorrhagic fever
– Equine encephalomyelitis (Eastern)
– Heartwater
– Infection with Aujeszky's disease virus
– Infection with bluetongue virus
– Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*
– Infection with *Echinococcus granulosus*
– Infection with *Echinococcus multilocularis*
– Infection with epizootic hemorrhagic disease virus
– Infection with foot and mouth disease virus
– Infection with *Mycobacterium ~~tuberculosis~~* complex ~~*bovis* and *Mycobacterium caprae*~~
– Infection with rabies virus
– Infection with Rift Valley fever virus
– Infection with rinderpest virus
– Infection with *Trichinella* spp.
– Japanese encephalitis
– New World screwworm *(Cochliomyia hominivorax)*
– Old World screwworm *(Chrysomya bezziana)*
– Paratuberculosis
– Q fever
– Surra *(Trypanosoma evansi)*
– Tularemia
– West Nile fever.

[...]

Annex 22

CHAPTER 8.15.

INFECTION WITH RIFT VALLEY FEVER VIRUS

EU comment

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

Comments are inserted in the text below.

Article 8.15.1.

General provisions

1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.

2) Humans and many animal species are susceptible to *infection*. For the purposes of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants with Rift Valley fever virus (RVFV).

EU comment

The EU suggests changing the system used in this chapter in relation to susceptible species. Indeed, from a zoological point of view, it seems odd referring to ruminants throughout the chapter and defining ruminants for the purposes of this chapter as including dromedary camels. A simple and much clearer alternative would be to insert "and dromedary camels" after "ruminants" in point 2) above, and to refer to "animals" instead of "ruminants" in the rest of the chapter. Furthermore, point 6 d) below should be amended as follows:

"d) 'animals' means ruminants and dromedary camels ~~ruminants include dromedary camels~~".

Finally, the EU queries why other species of camels, such as New World Camelids, are excluded from the scope of the chapter.

3) The following defines the occurrence of *infection* with RVFV:

a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant; or

b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from a ruminant epidemiologically linked to a confirmed or suspected *case* of RVF, or giving cause for suspicion of association or contact with RVFV; or

c) antibodies to RVFV antigens which are not the consequence of *vaccination*, have been identified in a sample from a ruminant with either epidemiological links to a confirmed or suspected *case* of RVF, or giving cause for suspicion of association or contact with RVFV.

4) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days.

5) In areas where RVFV is present, epizootics of RVF may occur following favourable climatic, environmental conditions and availability of susceptible host and competent *vector* populations. Epizootics are separated

by inter-epizootic periods. The transition from an inter-epizootic period to an epizootic complies with point 1 *d)* of Article 1.1.3. in terms of notification.

6) For the purposes of this chapter:

a) 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of *zone*;

b) 'epizootic of RVF' means the occurrence of *outbreaks* at an incidence ~~substantially~~ exceeding that during an inter-epizootic period or the occurrence of indigenous human cases;

EU comment

The EU is of the opinion that the occurrence of indigenous human cases alone i.e. without detection of cases in animals (as also stipulated in Article 8.15.5.) should not qualify as an "epizootic of RVF". Indeed, while we acknowledge that human cases are usually preceded or at least accompanied by cases in animals and humans thus sadly play the role of sentinel, in the absence of detection of cases in animals an epizootic cannot be declared. Furthermore, in such a situation it is not clear what the OIE would expect to be notified by member countries in accordance with point 1 d) of Article 1.1.3., since human cases do not warrant an immediate notification under that article. Finally, human cases are not part of the case definition of infection with RVFV detailed in point 3) of this article that explicitly makes reference to ruminants only.

c) 'inter-epizootic period' means the period of variable duration, often long, with intermittent low level of *vector* activity and low rate of virus transmission, which is often not detected;

d) ruminants include dromedary camels.

7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south western Arabian Peninsula. However, *vectors*, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the *infection*.

8) When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.15.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the *exporting country*.

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

Article 8.15.2.

Safe commodities

When authorising import or transit of the following *commodities* and any products made from them, *Veterinary Authorities* should not require any RVF-related conditions, regardless of the RVF status of the ruminant population of the *exporting country*:

1) hides and skins;

2) wool and fibre.

Article 8.15.3.

Country or zone free from RVF

A country or a *zone* may be considered free from RVF when *infection* with RVFV is notifiable in the entire country and either:

1) it meets the requirements for historical freedom in point 1 *a)* of Article 1.4.6.; or

2) met the following conditions:

a) an on-going pathogen-specific *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with RVFV in ruminants in the country or *zone* for a minimum of ten years; and

EU comment

A minimum period of 10 years seems excessive, at least in certain situations. Indeed, as there are no specific provisions in this chapter for regaining freedom in a previously free country or zone, this provision i.e. 10 years of freedom from infection would apply in all cases. This appears especially restrictive for example in situations of limited introduction of the disease in an area located outside the known zone of RVF distribution and it is eradicated through stamping out and/or vaccination coupled with specific surveillance (incl. for competent vectors that may not be endemically established in that area). In such cases, a shorter period would seem more adequate.

b) during that period no indigenous human cases have occurred in the country or *zone*.

EU comment

With reference to the EU comment above, we query why the animal health status of a country or zone should directly depend on the absence of indigenous human cases. While it is true that the occurrence of human cases without detection of animal cases should trigger doubts on the quality of the veterinary surveillance, such a link should be indicative and indirect only in terms of the animal health status.

In this context, it is worth noting that such a dependence of the animal health status on the absence of human cases is only foreseen in the RVF chapter, and not in any other Code chapter were it could also be relevant (zoonoses such as rabies, West Nile Fever, etc.).

A country or *zone* free from RVF will not lose its free status through the importation of ruminants that are seropositive, so long as they are either permanently identified as such or destined for immediate *slaughter*.

Article 8.15.4.

Country or zone infected with RVFV during the inter-epizootic period

A country or *zone* infected with RVFV, during the inter-epizootic period, is one in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.

Article 8.15.5.

Country or zone infected with RVFV during an epizootic

A country or *zone* infected with RVFV, during an epizootic, is one in which *outbreaks* of RVF are occurring at an incidence ~~substantially~~ exceeding that of the inter-epizootic period; or one in which indigenous human cases of RVF are occurring even in the absence of detection of animal *cases*.

EU comment

The EU does not support the newly added clause in the paragraph above. Reference is made to the EU comment on Article 8.15.1.

Article 8.15.6.

Strategies to protect from vector attacks during transport

Strategies to protect animals from *vector* attacks during transport should take into account the local ecology of the *vectors* and potential *risk management* measures include:

EU comment

As bionomics and insecticide resistance are important aspects to take into consideration in this context, the EU would suggest inserting the words "<u>, bionomics and potential insecticide resistance</u>" after the word "ecology" in the sentence above. Indeed, it does not make sense to spray insecticides if the mosquitoes to be killed are resistant to the molecule that is sprayed. In addition, the word "<u>and</u>" should be inserted before "include" at the end of the sentence, for better readability.

Furthermore, it is also important to treat the vehicles transporting the animals, and to consider insecticides in addition to insect repellents. The EU therefore suggests inserting "<u>and vehicles</u>" after "animals" and "<u>and insecticides</u>" after "repellents" in point 1 below.

1) treating animals with insect repellents prior to and during transportation;

2) *loading*, transporting and *unloading* animals at times of low *vector* activity;

3) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect-proof netting;

EU comment

We suggest replacing "en route" with "<u>on their way</u>" for clarity reasons.

4) using historical and current information to identify low risk ports and transport routes.

Article 8.15.7.

Recommendations for importation from countries or zones free from RVF

<u>For ruminants</u>

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

1) were kept in a country or *zone* free from RVF since birth or for at least 14 days prior to shipment;

AND

2) either:

a) were vaccinated at least 14 days prior to leaving the free country or *zone*; or

b) did not transit through an area experiencing an epizootic during transportation to the *place of shipment*; or

c) were protected from *vector* attacks when transiting through an area experiencing an epizootic.

Article 8.15.8.

Recommendations for importation from countries or zones infected with RVFV during the inter-epizootic period

<u>For ruminants</u>

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

1) showed no sign of RVF on the day of shipment;

2) met one of the following conditions:

a) were vaccinated against RVF at least 14 days prior to shipment with a modified live virus vaccine; or

EU comment

The EU queries why in point 2a) above modified live vaccines are recommended, whereas in other articles there are no such specifications for the type of vaccine (i.e. Articles 8.15.7., 8.15.9. and 8.15.10.). Indeed, use of inactivated vaccines in general would seem more reasonable from a safety point of view, especially as regards importation of vaccinated animals into free countries. However in that respect, we query whether 1 dose and 14 days would be sufficient to guarantee safe trade.

b) were held for at least 14 days prior to shipment in a *vector*-protected *quarantine station*, which is located in an area of demonstrated low *vector* activity. During this period the animals showed no clinical sign of RVF;

AND

3) either:

a) did not transit through an area experiencing an epizootic during transportation to the *place of shipment*; or

b) were protected from *vector* attacks when transiting through an area experiencing an epizootic.

Article 8.15.9.

Recommendations for importation from countries or zones infected with RVFV during an epizootic

For ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the 1

EU comment

In the sentence above, "1" should be replaced with "animals:" (editorial).

1) showed no sign of RVF on the day of shipment;

EU comment

In point 1) above, "sign" should be replaced with "clinical signs" for reasons of clarity and consistency with other articles.

2) did not originate in the area of the epizootic;

EU comment

The EU suggests substantiating point 2) above as follows:

"2) did not originate in the area of the epizootic based on the surveillance network;".

3) were vaccinated against RVF at least 14 days prior to shipment;

4) were held for at least 14 days prior to shipment in a *vector*-protected *quarantine station*, which is located in an area of demonstrated low *vector* activity outside the area of the epizootic. During this period the animals showed no sign of RVF;

5) either:

a) did not transit through an area experiencing an epizootic during transportation to the *place of shipment*; or

b) were protected from *vector* attacks when transiting through an area experiencing an epizootic.

Article 8.15.10.

Recommendations for importation from countries or zones not free from RVF

For semen and *in vivo* derived embryos of ruminants

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

1) showed no sign of RVF within the period from 14 days prior to and 14 days following collection of the semen or embryos;

AND

2) either:

a) were vaccinated against RVF at least 14 days prior to collection; or

b) were demonstrated to be seropositive on the day of collection; or

c) testing of paired samples has demonstrated that seroconversion did not occur between semen or embryo collection and 14 days after.

Article 8.15.11.

Recommendations for importation of fresh meat and meat products from ruminants from countries or zones not free from RVF

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from:

1) ruminants which showed no clinical sign of RVF within 24 hours before *slaughter*;

2) ruminants which were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;

3) carcasses which were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*.

Article 8.15.12.

Recommendations for importation from countries or zones not free from RVF

For milk and milk products

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the consignment:

1) was subjected to pasteurisation; or

2) was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.15.13.

Surveillance

Surveillance should be carried out in accordance with Chapter 1.4.

1) During an epizootic, *surveillance* should be conducted to define the extent of the affected area.

2) During the inter-epizootic period, *surveillance* and monitoring of climatic factors predisposing an epizootic should be carried out in countries or *zones* infected with RVFV.

3) Countries or *zones* adjacent to a country or *zone* in which epizootics have been reported should determine their RVF status through an on-going *surveillance* programme.

To determine areas of low *vector* activity (see Articles 8.15.8. and 8.15.9.) *surveillance* for arthropod *vectors* should be carried out in accordance with Chapter 1.5.

Examination of *vectors* for the presence of RVFV is an insensitive *surveillance* method and is therefore not recommended.

Annex 23

CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS

EU comment

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

Comments are inserted in the text below.

[...]

Article 12.6.6.

Recommendations for the importation of domestic equids for unrestricted movement

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

2) came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

3) were ~~immunised~~ vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual*, ~~between 21 and 90 days before shipment either with a primary course or a booster; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.~~ in accordance with one of the following procedures:

EU comment

The EU suggests inserting the words "and considered effective against the virus lineages as recommended by OIE" after "in the Terrestrial Manual" in point 3) above.

Indeed, the current situation has shown that in some cases horses were vaccinated but got diseased. There may be many reasons for this, but some of the currently marketed vaccines do not include the lineages recommended by OIE. This means even if applied according to manufacturer's instructions, if the wrong vaccine was used, protection will be marginal.

Reference:

R. Paillot. A Systematic Review of Recent Advances in Equine Influenza Vaccination. Vaccines 2014, 2, 797-831. http://www.offlu.net/fileadmin/user_upload/Equine_influenza/Review_EI_vaccines.pdf.

a) between 14 and 90 days before shipment either with a primary course or a booster; or

EU comment

The EU queries whether in respect of the young horses or primo-vaccinates (point a) above), it should be stressed that

- **the primary course should be completed in accordance with the instructions of the manufacturer of the vaccine used for the first shot; and**
- **the booster should be considered valid only if it was a booster to a complete primary course.**

Indeed, it appears that in some cases the second shot of the primary course is given with a different vaccine and the booster may be a third vaccine. In some countries, this is not accepted. Furthermore, we note that the importance of the "same" vaccine is already specifically highlighted for the older horses in point b) below.

b) between 14 and 180 days before shipment, if they are older than four years of age, previously having received at least four doses of the same vaccine at intervals not greater than 180 days.

Information on the *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12 as relevant.

For additional security, countries that are free of EI or undertaking an eradication programme may also request that the domestic equids were tested negative for EIV by an agent identification test for EI described in the *Terrestrial Manual* conducted on samples collected on two occasions at 7 to 14 days and less than 5 days before shipment.

EU comment

The EU suggests deleting the words "For additional security," in the paragraph above. Indeed, they seem discriminatory because we have seen that also vaccinated horses may shed virus, i.e. vaccination is a good remedy but in a completely naïve population the agent identification test is not "additional security" but a well-justified requirement to maintain freedom.

[...]

Annex 24

CHAPTER 14.7.

INFECTION WITH PESTE DES PETITS RUMINANTS VIRUS

EU comment

The EU in general supports the proposed changes to this chapter. A comment is inserted in the text below.

[...]

Article 14.7.3.

~~**PPR free**~~ ~~c~~**Country or zone free from PPR**

A country or *zone* may be considered free from PPR when the relevant provisions of point 2) of Article 1.4.6. and Chapter 1.6. have been complied with, and when within the proposed free country or *zone* for at least the past 24 months:

1) there has been no *case* of *infection* with PPRV;

2) the *Veterinary Authority* has current knowledge of, and authority over, all domestic sheep and goats in the country or *zone*;

3) appropriate *surveillance* has been implemented in accordance with:

   a) Chapter 1.4. where historical freedom can be demonstrated; or

   b) Articles 14.7.27. to 14.7.33. where historical freedom cannot be demonstrated;

4) no *vaccination* against PPR has been carried out;

5) no animals vaccinated against PPR have been introduced since the cessation of *vaccination*.

~~1) The PPR status of a country or *zone* should be determined on the basis of the following criteria, as applicable:~~

~~*a)* PPR is notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field or *laboratory* investigations;~~

~~*b)* an ongoing awareness programme is in place to encourage reporting of all cases suggestive of PPR;~~

~~*c)* systematic *vaccination* against PPR is prohibited;~~

~~*d)* importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter;~~

~~*e)* the *Veterinary Authority* has current knowledge of, and authority over, all domestic sheep and goats in the country or *zone*;~~

~~*f)* appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 14.7.27. to 14.7.33.~~

Annex 24 (contd)

~~2) To qualify for inclusion in the list of PPR free countries or *zones*, a Member Country should either:~~

~~*a)* apply for recognition of historical freedom as described in point 1) of Article 1.4.6.; or~~

~~*b)* apply for recognition of freedom and submit to the OIE:~~

~~*i)* a record of regular and prompt animal disease reporting;~~

~~*ii)* a declaration stating that:~~

~~– there has been no *outbreak* of PPR during the past 24 months;~~

~~– no evidence of PPRV *infection* has been found during the past 24 months;~~

~~– no *vaccination* against PPR has been carried out during the past 24 months;~~

~~– importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter;~~

~~*iii)* supply documented evidence that *surveillance* in accordance with Chapter 1.4. is in operation and that regulatory measures for the prevention and control of PPR have been implemented;~~

~~*iv)* evidence that no animals vaccinated against PPR have been imported since the cessation of *vaccination*.~~

~~The Member Country will be included in the list only after the application and submitted evidence has been accepted by the OIE. Changes in the epidemiological situation or other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.~~

Retention on the list requires ~~annual reconfirmation of point 2) above~~ that information in point 4 *d)* of Article 1.4.6. and points 1) to 3) above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 4 *a)* to 4 *c)* of Article 1.4.6. and points 4) and 5) above should be reported to the OIE.

EU comment

As regards retention on the list, the EU notes that both requirements and reporting obligations are mixed in one single paragraph. For reasons of clarity, it would be preferable to have separate paragraphs with heath status conditions that need to be re-confirmed (e.g. referred to above in Article 14.7.3.) on the one hand, and clear requirements for documented evidence that needs to be sent in as part of a dossier (e.g. on surveillance) on the other.

Furthermore, it is not clear why a reference to both point 4d) of Article 1.4.6. and to point 3) of this article are maintained, as both concern surveillance. This may cause confusion as to what type of surveillance is required for status maintenance.

[...]

Article 14.7.34.

OIE endorsed official control programme for PPR

~~The objective of an OIE endorsed *official control programme* for PPR is for Member Countries to progressively improve the situation in their territories and eventually attain free status for PPR.~~

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for PPR in accordance with Chapter 1.6. when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for PPR to be endorsed by the OIE, the Member Country should provide a detailed *official control programme* for the control and eventual eradication of PPR in the country or *zone*. This document should address and provide documentary evidence on the following:

1. Epidemiology

   a) The detailed epidemiological situation of PPR in the country highlighting the current knowledge and gaps;

   b) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific *zone*;

2. Surveillance and diagnostic capabilities

   a) PPR *surveillance* in place, in accordance with Chapter 1.4. and Articles 14.7.27. to 14.7.33.;

   b) diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;

   c) serosurveillance conducted in susceptible species, including *wildlife* to serve as sentinels for PPRV circulation in the country.

3. Strategies to reach the objectives

   a) Where *vaccination* is practised as a part of the *official control programme* for PPR, provide documentary evidence (such as copies of national legislation, regulations and *Veterinary Authority* directives) that *vaccination* of selected populations is compulsory, and detailed information on *vaccination* campaigns, in particular on:

      i) the strategy that is adopted for the *vaccination* campaign;

      ii) target *populations* for *vaccination*;

      iii) target geographical area for *vaccination*;

      iv) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

      v) technical specification of the vaccines used and description of the vaccine licensing procedures in place;

      vi) proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

      vii) the proposed strategy and work plan including timeline for the transition to the cessation of the use of *vaccination*;

   b) the measures implemented to prevent the introduction of the pathogenic agent, the rapid detection of, and response to, all PPR *outbreaks* in order to reduce *outbreaks* and to eliminate PPRV circulation in domestic sheep and goats in at least one *zone* in the country;

4. defined work plan and timelines of the official control programme;

5. performance indicators for assessing the efficacy of the control measures to be implemented;

6. assessment of the evolution and implementation of the official control programme to demonstrate the effectiveness of the strategies;

7. existence of an emergency preparedness and contingency response plan to be implemented in case of PPR *outbreaks*.

~~1) submit documented evidence on the capacity of its *Veterinary Services* to control PPR; this evidence can be provided by countries following the OIE PVS Pathway;~~

2) submit documentation indicating that the *official control programme* for PPR is applicable to the entire territory (even if it is on a zonal basis);

3) have a record of regular and prompt animal disease reporting in accordance with the requirements in Chapter 1.1.;

4) submit a dossier on the status of PPR in the country describing the following:

   a) the general epidemiology of PPR in the country highlighting the current knowledge and gaps;

   b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all PPR *outbreaks* in order to reduce the incidence of *outbreaks* and to eliminate virus circulation in domestic sheep and goats in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific *zone(s)*;

5) submit a detailed plan of the programme to control and eventually eradicate PPR in the country or *zone* including:

   a) the timeline for the programme;

   b) the performance indicators that will be used to assess the efficacy of the control measures;

6) submit evidence that PPR *surveillance* is in place, taking into account the provisions in Chapter 1.4. and the provisions on *surveillance* in this chapter;

7) have diagnostic capability and procedures in place, including regular submission of samples to a *laboratory*;

8) where *vaccination* is practised as a part of the *official control programme* for PPR, provide evidence (such as copies of legislation) that *vaccination* of sheep and goats in the country or *zone* is compulsory;

9) if applicable, provide detailed information on *vaccination* campaigns, in particular on:

   a) the strategy that is adopted for the *vaccination* campaign;

   b) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

   c) serosurveillance in other susceptible species, including *wildlife* to serve as sentinels for PPRV circulation in the country;

   d) disease *surveillance* in sheep and goat populations;

   e) the proposed timeline for the transition to the cessation of the use of *vaccination* in order to enable demonstration of absence of virus circulation;

10) provide an emergency preparedness and contingency response plan to be implemented in case of PPR *outbreak(s)*.

The Member Country's *official control programme* for PPR will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE.

Retention on the list of endorsed *official control programmes* for PPR 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 the requirements in Chapter 1.1.

Annex 24 (contd)

~~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 PPR that cannot be addressed by the programme.~~